FEDERAL REGISTER

Vol. 89 Wednesday,
No. 65 April 3, 2024

Pages 22879–23496

OFFICE OF THE FEDERAL REGISTER

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Presidential Documents

Title 3—

The President

Proclamation 10714 of March 29, 2024

Arab American Heritage Month, 2024

By the President of the United States of America

A Proclamation

This month, we honor the rich heritage, history, and hopes of the more than 3.5 million Arab Americans across our country who have helped write the American story and move our Nation ever forward embodying the truth that diversity has been and always will be our country's greatest strength.

People with Arab heritage were among the many immigrants who came to our country's shores with a range of cultures, customs, backgrounds, and beliefs, sharing a common courage to start new chapters in an unfamiliar land. As they built their lives, they helped build America—from fighting for our independence in the Continental Army to serving the cause of freedom during World War II to helping build cities and communities across our Nation, often in the face of discrimination and hate.

This legacy of courage, resilience, and service lives on today in Arab Americans across our country. We see it in the brave Arab American service members and public servants, who continue to defend our Nation's security and freedom. We see it in the Arab American engineers, scientists, and medical professionals, who are pioneering new breakthroughs and charting a better future for all. We see it in Arab American business owners and entrepreneurs, who are creating jobs and lifting up communities across the Nation. We see it in Arab American teachers and community leaders, who continue to inspire the next generation. And every day, I see it in the Arab Americans serving throughout my Administration, who are helping us build a stronger, more just Nation.

But as we come together this month to honor these contributions, we must also pause to reflect on the pain being felt by so many in the Arab American community with the war in Gaza. The trauma, death, and destruction in Israel and Gaza have claimed, and continue to claim, far too many innocent lives—including family and friends of Arab Americans across our Nation. I am devastated by the suffering of so many and mourn the lives taken, and I pray for the loved ones left behind and for all the innocent men, women, and children living in dire circumstances.

My Administration is working with partners across the region to respond to the urgent humanitarian crisis, deliver desperately needed aid to Gaza, free the hostages taken during the brutal Hamas terrorist attack on October 7th, and establish an immediate ceasefire that would last at least six weeks, which we would work to build into something more enduring. We are also focused on ensuring that calm is maintained and restored in neighboring states, including Lebanon. We must preserve the space for peace—for a two-state solution with equal measures of security and dignity for both Palestinians and Israelis. We are committed to working with the Arab American community, who remain critical advocates for the Palestinian and Arab people and a just and lasting peace.

This challenge also reminds us of our responsibility as a Nation here at home. Across our country, Arab Americans remain the target of bias and discrimination—including harassment, hate crimes, racist rhetoric, and violent attacks. In recent months, a Palestinian child was killed in his home, a young man was stabbed near a college campus, and a group of students

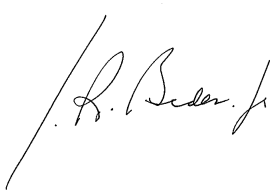
were shot while just walking down the street—tragic reminders that hate never goes away. It only hides. It is up to all of us to give hate no safe harbor.

That is why we are fighting against the rise of all forms of hate, including against Arab Americans. On my first day in office, I rescinded the discriminatory Muslim travel ban that prevented individuals from primarily Middle Eastern and African countries from entering the United States. In 2022, my Administration convened the first United We Stand Summit, which brought together interfaith leaders to counter hate-motivated violence and foster unity. We are also developing our country's first-ever National Strategy to Counter Islamophobia and Related Forms of Bias and Discrimination in the United States, which will identify concrete ways to address the scourge of hate against Muslim, Sikh, South Asian, and Arab American communities. To ensure Arab Americans are fully represented, my Administration finalized the addition of a new Middle Eastern and North African option for the 2030 census and other forms that ask for people's race and ethnicity—a vital step to ensure that Arab Americans are seen, counted, and valued as new policy is being made.

America is the only Nation in the world founded on an idea: that we are all created equal and deserve to be treated equally throughout our lives. We have never fully lived up to that promise, but we have never walked away from it either. This month, we vow that we never will. Together, we recommit to this promise of America by honoring and advancing the dignity, equity, and security of Arab Americans across our Nation.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2024 as Arab American Heritage Month. I call upon all Americans to learn more about the history, culture, and achievements of Arab Americans and to observe this month with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07173

Filed 4–2–24; 8:45 am]

Billing code 3395–F4–P

Presidential Documents

Proclamation 10715 of March 29, 2024

Care Workers Recognition Month, 2024

By the President of the United States of America

A Proclamation

Every day, care workers dedicate themselves to ensuring the people we love are safe and secure. They watch over our children, assist our parents, and support loved ones with disabilities. Their work makes all other work possible. During Care Workers Recognition Month, we honor their tireless efforts; express our gratitude for their unwavering devotion; and commit to ensuring they receive the pay, benefits, and recognition they deserve.

The services care workers provide are not only essential to so many lives—they are crucial for our economy. But for too long, care workers' paychecks have not reflected the value of their demanding and important work. In fact, care workers are among the lowest paid workers in the country. Of the millions of care workers in our Nation, the majority are women of color, deepening racial and gender wage and wealth gaps. Each year, half of the long-term care workforce and nearly 20 percent of the child care workforce end up leaving their jobs, which makes it difficult for the families who depend on care workers to find the stable and secure support they need.

My Administration is committed to getting care workers the resources and respect they deserve. In 2021, we invested over $60 billion from our American Rescue Plan in the care economy. That funding helped keep 225,000 child care centers open during the COVID–19 pandemic, ensuring that the 10 million children they served had a place to go. It also provided increased pay and bonuses and secured better benefits for child care workers, helping hundreds of thousands of mothers with young children enter or re-enter the workforce. Through our expanded earned income tax credit alone, we delivered financial relief to nearly 300,000 child care workers. My Budget includes robust proposals in care infrastructure, including through investments in caregiving for military families and investments in child care to increase accessibility and guarantee affordable, high-quality child care from birth until kindergarten.

In addition, the Executive Order I signed last year includes the most comprehensive set of actions any administration has taken to increase access to high-quality care and support for caregivers. It directs almost every cabinet-level agency to take over 50 actions that provide more peace of mind for families and more dignity for care workers who deserve jobs with good pay and good benefits. For example, the Department of Health and Human Services released a proposed rule that would raise Head Start teacher wages by more than $10,000 on average and strengthen Head Start's ability to recruit and retain staff. Further, I directed the Department of Veterans Affairs to give veterans who need assistance at home more flexibility to pick their own caregivers. The Department of Labor has invested tens of millions of dollars in boosting the quality of care jobs and expanding access to them.

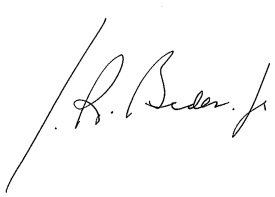
Additionally, agencies are working to improve the quality of home care and nursing home jobs. My Administration is taking steps to get home care workers the pay they deserve by making sure they get a bigger share of Medicaid payments, and to strengthen requirements for nursing homes

so that staff are not stretched thin and residents get the attention they need. My Administration is also promoting apprenticeship programs that put careers as registered and licensed nurses within reach so that we can both add and keep long-term care workers on the job.

Care workers are our Nation's hidden heroes. They support so many of our families across the country, and it is our responsibility to ensure that they are not left behind. This Care Workers Recognition Month, in addition to expressing our gratitude for their selfless dedication to our loved ones and honoring their tremendous value to our society, we also recommit to ensuring that they are rewarded for their extraordinary contributions to America.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2024 as Care Workers Recognition Month. I call upon all Americans to celebrate the contributions of care workers to our Nation with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07174
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10716 of March 29, 2024

Month of the Military Child, 2024

By the President of the United States of America

A Proclamation

This April, we celebrate children of our service members and veterans whose sacrifice and support allow their parents to serve our Nation and protect children everywhere.

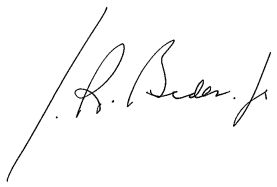
Over the years, the First Lady and I have had the honor of meeting with military and veteran children from every corner of our Nation and witnessing their incredible sense of duty firsthand. These young patriots often pack up their lives every few years, starting new schools and making new friends. From watching our own grandchildren, we also know that military children embody courage and selflessness, remaining brave when their moms or dads are deployed and remaining resilient when celebrating birthdays and holidays with an empty seat at the dinner table. Military and veteran children also take care of loved ones who are wounded, ill, or injured—and far too many grow up with the unbearable pain of losing a parent. It is a solemn reminder that being a military child means sacrificing for our country without ever wearing a uniform.

Our Nation has many obligations, but we have only one truly sacred obligation: to prepare and equip those we send into harm's way and to care for them and their families—especially our military children—while deployed and when they return home. That is why I signed an Executive Order last year that establishes the most comprehensive set of administrative actions in our Nation's history to support the economic security of military and veteran spouses, caregivers, and survivors—including improving access to quality, dependable, and affordable child care. My Administration expanded the Military Parental Leave Program, ensuring that service members have the time they need with their families after a child's birth, adoption, or long-term foster care placement. We are working to guarantee universal pre-kindergarten for military children at Department of Defense schools. We have begun that work by launching a pilot program at a school in Japan. The First Lady's Joining Forces initiative is providing support to military children by improving economic opportunity for military families, making school transitions easier, and expanding resources to promote their families' health and well-being.

Military children embody the very best of America—shouldering the unique challenges military life places on families across our Nation and around the world with tenacity. This month—and every month—we honor their bravery and show our gratitude to the children of our military service members and veterans for their own service to our Nation.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 2024 as the Month of the Military Child. I call upon the people of the United States to honor the children of our service members and veterans with appropriate ceremonies and activities. I also encourage Americans everywhere to find ways to support military-connected children, including by wearing purple during the month of April in honor of their service.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07179
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10717 of March 29, 2024

National Cancer Prevention and Early Detection Month, 2024

By the President of the United States of America

A Proclamation

Cancer has touched nearly every American family. During National Cancer Prevention and Early Detection Month, we honor the enormous courage and strength of the millions of Americans facing the disease today and of the many millions of survivors, whose resilience inspires us all. Together, we will end cancer as we know it and get patients and families the quality care and support that they deserve.

In recent decades, we have made enormous progress toward beating cancer. In addition to new medicines and therapies, we have developed early detection methods and discovered prevention measures that extend and save lives. Studies have shown that over 30 percent of cancers diagnosed today could be prevented through methods like decreasing environmental and toxic exposures to carcinogens and making lifestyle changes like reducing tobacco use and improving nutrition. Still, cancer is the second-leading cause of death in our country.

I came to office determined to change that. Beating cancer is personal to my family, as it is to millions of families across America and around the world. That is why the First Lady and I re-ignited the Cancer Moonshot. The goal is to cut the cancer death rate by at least 50 percent in the next 25 years—starting by preventing the cancers we know we can stop and catching others as early as possible. We are also working to turn more cancers from death sentences into chronic diseases that people can live with and to create more supportive experiences for patients and their families. To help achieve that, I established the Advanced Research Projects Agency for Health, securing $4 billion in bipartisan funding to date to help the scientists, innovators, and public health professionals who are working day and night to improve the prevention, detection, and treatment of cancers and other deadly diseases. We are not just working toward incremental changes—we are looking for quantum leaps forward.

It is important for every American to know that cancer screenings are life-saving—early detection can make all the difference in beating the disease. That is why my Administration is working to ensure that every American can get them. During my first year in office, we expanded coverage under the Affordable Care Act, which requires insurers to pay for cancer screenings and primary care visits. More Americans have insurance than under any President, ensuring that millions of Americans now have health coverage for those services and more. My Administration is also helping millions of families save an average of $800 per year on their health insurance premiums. To increase access to early detection, my Administration has partnered with community health centers to provide screenings closer to folks' homes, and we extended health care coverage for lung cancer screenings. Further, we have closed loopholes so that new stool-based screening tests and follow-up screenings do not lead to surprise costs for patients undergoing colonoscopies. Eliminating these barriers to screenings will save and extend countless lives. To learn your personal risk factors and know which screenings are right for you, please talk to your health care provider, visit cdc.gov/cancerscreening or cancer.gov/screeningtests, or call 1–800–

4–CANCER for more information. We encourage everyone to schedule routine cancer screening appointments.

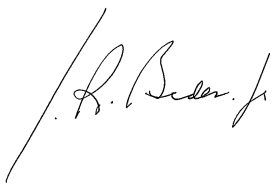
At the same time, healthy life habits—like maintaining a healthy body weight and reducing exposure to tobacco smoke—can prevent certain cancers, so we are working to help all Americans get and stay healthy. Our National Strategy on Hunger, Nutrition, and Health supports expanding incentives to purchase fruits and vegetables with SNAP, ensures more kids have access to free and nutritious school lunches, and expands access to nutrition and obesity counseling. For help with quitting smoking—the leading cause of cancer in America—visit SmokeFree.gov, call 1–800–QUIT–NOW, or text QUITNOW to 333888.

My Administration is working to reduce Americans' exposure to environmental toxins that can lead to cancer. Through our Bipartisan Infrastructure Law, my Administration has invested billions of dollars to clean up toxic sites and help States replace lead pipes and service lines, protecting millions of families from exposure to so-called ''forever chemicals'' and other contaminants that increase people's risk of getting cancer. I was also proud to sign the PACT Act, ensuring that veterans exposed to toxic substances during their military service get the cancer care and benefits that they deserve.

Ending cancer is the kind of big and ambitious goal that America has always embraced. For the patients fighting for a better day, the survivors who give us strength, the caregivers who share their hearts, the lives we have lost, and the lives we can save, let us recommit to this vital work.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim April 2024 as National Cancer Prevention and Early Detection Month. I encourage citizens, government agencies, private businesses, nonprofit organizations, and other interested groups to join in activities that will increase awareness of what Americans can do to prevent, detect, and beat cancer.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07188

Filed 4–2–24; 8:45 am]

Billing code 3395–F4–P

Presidential Documents

Proclamation 10718 of March 29, 2024

National Child Abuse Prevention Month, 2024

By the President of the United States of America

A Proclamation

There is no greater sin than the abuse of power, especially when that abuse is directed at a child. During National Child Abuse Prevention Month, we stand together to prevent abuse and neglect, support brave survivors, and build strong communities and families where every child can grow up happy and safe.

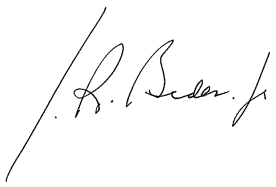
For far too many children across America, the violence, fear, and intimidation associated with physical and emotional abuse define their most formative years. The emotional scars can last a lifetime, making it hard to form healthy relationships, upending their futures, and perpetuating a toxic cycle of abuse. As a United States Senator, I fought to change that by writing and championing the Violence Against Women Act (VAWA), the first law of its kind, which helped secure safety and justice for women and children impacted by domestic violence. Since then, each time we reauthorized VAWA, we have made it stronger—including in 2022, when we increased authorized resources available to children who have been exposed to domestic violence and extended greater jurisdiction to Tribal Courts prosecuting child abuse cases on their own lands.

We are also working to prevent abuse and give survivors the resources they need to heal and thrive. The American Rescue Plan invested $350 million in improving child protective services at the State level and in expanding local child abuse prevention programs. In 2022, I signed a bill that eliminates the Federal statute of limitations for civil claims filed by survivors of child sexual abuse so they can still pursue justice as adults. The Department of Justice is also investing in Children's Advocacy Centers across the country to help law enforcement investigate and prosecute child sexual abuse and exploitation, including acts committed online. The Department of Homeland Security is launching a Government-led campaign to combat the threat of child abuse and exploitation online, which will bring awareness to this growing threat; teach children, parents, caregivers, and educators how to report these crimes; and offer resources to survivors.

Every child in America deserves to grow up safe, supported, and surrounded by love. This month, we remember that we all play a part in making that real. For more information on how to recognize and report child abuse or neglect and to support loving families and safe communities visit childwelfare.gov.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2024 as National Child Abuse Prevention Month. I call upon all Americans to observe this month by joining together as a Nation to promote the safety and well-being of all children and families and to recognize the child welfare professionals and allies who work tirelessly to protect our children. Let us also honor the strength and resilience of survivors of child abuse.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07189
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10719 of March 29, 2024

National Donate Life Month, 2024

By the President of the United States of America

A Proclamation

I often say that we are a good Nation because we are a good people, and during National Donate Life Month, we are reminded of why that is true as we celebrate all the selfless organ donors across our country, who have saved countless lives. We honor the families and friends of donors who have supported their loved ones, and we recognize the professionals devoted to the transplant community. We call upon more Americans to register as organ, eye, tissue, or bone marrow donors and share the gift of life with those in need.

Across the country, organ transplants are being performed at a record pace because of the incredible generosity and courage of organ donors. America's doctors have performed over one million organ transplants to date. Each year, thousands of profoundly compassionate Americans choose to donate their organs, saving the lives of loved ones and people they have never even met.

Despite this progress, there is still so much more to do until every person who needs an organ receives one. More than 100,000 people, including nearly 2,000 children, are currently on the waiting list for an organ transplant—the majority of whom are people of color. With a shortage of organ donors and a high demand for them, 17 Americans die each day while waiting for a transplant.

We can each change that. After someone passes away, their organ donation can save up to 8 people and can improve 75 more lives through eye and tissue donation. What an extraordinary legacy to leave: giving people in need a second chance at life and giving families futures with their loved ones.

My Administration is working to improve the organ donation process and ensure living donors and recipients have access to quality, affordable health care. For the first time in nearly 40 years, we are breaking up the monopoly that has controlled the organ transplant system. A bipartisan law I signed, the Securing the U.S. Organ Procurement and Transplantation Network Act, will transform the organ transplant network by increasing competition in the contracts process. This law allows us to implement an independent board of directors that can strengthen accountability and oversight. In addition, we established the Organ Procurement and Transplantation Network Modernization Initiative, which will bring more transparency to the system and spearhead needed reforms. These actions are critical first steps toward cutting down the wait list for organs.

We have also taken action to extend Medicare coverage of vital drugs for kidney transplant patients and are working to ensure high-quality care for transplants. This year, through my Inflation Reduction Act, out-of-pocket drug costs for seniors on Medicare will be capped at $3,500 a year—even for medications that cost some organ recipients many times that.

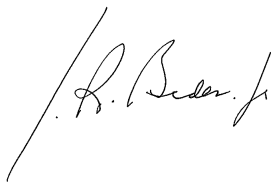
In addition, I worked with the Congress to secure $2.5 billion in bipartisan funding for the Advanced Research Projects Agency for Health (ARPA–H). The scientists, innovators, and public health professionals receiving

ARPA–H funding are working day and night to revolutionize the prevention, detection, and treatment of cancer and other deadly diseases. In time, these breakthroughs could one day reduce the need for organ transplants or eliminate the need for anti-rejection medication. For example, to make it easier and faster for patients to get a transplant, ARPA–H has already invested $26 million into addressing organ transplant shortages through on-demand 3D tissue printing, beginning with a human heart.

Millions of Americans have embraced the American spirit of helping those in need by signing up to be organ donors. Any adult can register, regardless of age or medical history. In many States you can sign up by simply checking a box when you renew your driver's license. I encourage all Americans to learn more about organ, eye, and tissue donation by visiting organdonor.gov or bloodstemcell.hrsa.gov for more information on donating bone marrow. This National Donate Life Month, let us redouble our efforts to save and improve more lives by lending a hand to our fellow Americans in need of life-saving organ transplants.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2024 as National Donate Life Month. I call on every person who can to share the gift of life and hope by becoming an organ, eye, tissue, or bone marrow donor. I also call on this Nation to observe National Pediatric Transplant Week from April 21 through April 27, a week dedicated to ending the pediatric transplant waiting list.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07190
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10720 of March 29, 2024

National Sexual Assault Awareness and Prevention Month, 2024

By the President of the United States of America

A Proclamation

Sexual violence affects every community in this Nation, leaving millions of Americans—our neighbors, friends, colleagues, and loved ones—scarred. For many survivors, healing can take years, and for some, the pain never heals completely. During National Sexual Assault Awareness and Prevention Month, we recommit to standing with survivors, holding perpetrators accountable, and bringing an end to a culture that has allowed sexual assault to occur for far too long.

More than half of all women and nearly one-third of all men in America have experienced sexual violence. The rate of sexual violence is even higher for people of color. Survivors have faced this violence wherever life happens—at work, at school, at home, and online. It can upend people's jobs and contribute to mental health issues like depression, anxiety, and post-traumatic stress disorder. It is an insult to our most basic humanity and everything we stand for as a Nation.

Ending gender-based violence has been the cause of my life. Thirty years ago, as a United States Senator, I wrote and championed the original Violence Against Women Act (VAWA). This law gave us the tools to prevent and prosecute sexual assault, provide support for survivors, and save lives. Every time we have re-authorized it, we have made it stronger. In December 2022, we secured $700 million for VAWA programs—the highest funding level in history—for the next fiscal year. Those funds have helped strengthen the public health response for domestic violence and sexual assault survivors and their children, and expand access to sexual assault medical forensic examinations and culturally specific resources for LGBTQI+ survivors, rural areas, and other underserved and marginalized communities. The reauthorization also established a new offense for Federal law enforcement officers who commit sexual misconduct under color of law and expanded Tribal jurisdiction so that non-Native perpetrators of sexual assault can be prosecuted for crimes they commit on Tribal lands.

My Administration has made ending gender-based violence a top priority in many other ways too. Our American Rescue Plan delivered $1 billion in funding for rape crisis centers, community support organizations, and other sexual violence services nationwide. We released the first-ever National Plan to End Gender-Based Violence, advancing a comprehensive Government-wide approach to preventing and addressing gender-based violence across the country. When we passed the most significant gun law in nearly 30 years, we narrowed the so-called ''boyfriend loophole,'' keeping guns out of the hands of domestic abusers. To combat online harassment and abuse, I worked with Vice President Kamala Harris to launch a Federal task force that has taken concrete steps on prevention, accountability, research, and support for survivors and launched the first 24/7 national helpline for survivors of image-based sexual abuse.

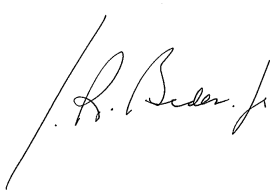
We are also ensuring people are safe from abuse at school and work. I signed an Executive Order that called on the Department of Education to

protect students from discrimination based on sex, including sex-based harassment and sexual violence, and I remain steadfast in my commitment to ensuring all students have an educational environment free from discrimination. I have also signed laws limiting the enforcement of non-disclosure agreements for those who have been sexually assaulted or harassed in the workplace and ending forced arbitration so that survivors can get their day in court. Additionally, I have asked that Federal agencies take action to make leave more accessible for employees seeking safety and recovering from gender-based violence. Furthermore, I have spearheaded historic military justice reforms to better protect survivors in our military and ensure that prosecutorial decisions in cases of gender-based violence are fully independent from the chain of command.

This National Sexual Assault Awareness and Prevention Month, let us each recommit to stepping up and doing our part to intervene in, prevent, and end sexual assault in our communities. Let us redouble our efforts to support and stand with survivors of sexual assault. Let us pledge to work together to create a society that is truly safe, where all Americans can pursue their dreams without fear of assault, abuse, or harassment.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 2024 as National Sexual Assault Awareness and Prevention Month. I urge all Americans to support sexual assault survivors, including when survivors reach out and disclose abuse, and to strengthen our efforts to prevent this abuse in the first place.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07193
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10721 of March 29, 2024

Second Chance Month, 2024

By the President of the United States of America

A Proclamation

America was founded on the promise of new beginnings. During Second Chance Month, we recommit to building a criminal justice system that lives up to those ideals so that people returning to their communities from jail or prison have a fair shot at the American Dream.

Every year, more than 650,000 people are released from State and Federal prisons, some leaving with nothing more than a few dollars and a bus ticket to start their new lives. In total, over 70 million Americans have a criminal history record, which can make it hard to secure a steady job, safe housing, affordable health care, or a good education—all important things to have when trying to build a good life. Studies show that when these needs are met, we do not just empower formerly incarcerated people—we prevent crime and make our communities safer.

That is why, last year, my Administration released a comprehensive strategic plan to improve the criminal justice system and strengthen public safety. It includes over 100 concrete actions that my Administration is taking to boost public safety by improving rehabilitation in jails and prisons, helping people rebuild their lives, and reducing unnecessary interactions with the criminal justice system so police officers can focus on fighting crime.

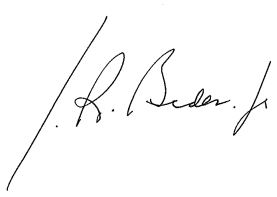
We have also invested nearly $1 billion in job training, addiction recovery, and reentry services across the country, and we have expanded access to Pell Grants so people can earn a college degree while they are incarcerated, starting over with new skills. We are also helping folks find good-paying jobs rebuilding America on projects funded by our historic infrastructure law and expanding opportunities to serve in the Federal Government. We are working to make sure those who have served their time have an equal opportunity to obtain health care, housing, education, and consideration for small business loans. By meeting these needs, we not only empower people to chase their dreams and fuel our economy—we also prevent crime and make our communities safer and stronger.

At the same time, my Administration has taken historic steps to end America's failed approach to marijuana. Incarceration for marijuana possession alone has destroyed too many lives, particularly for Black and brown Americans, who have been arrested, prosecuted, and convicted at higher rates than other racial and ethnic groups. In 2022, I asked the Secretary of Health and Human Services and the Attorney General to start formally reviewing how marijuana is scheduled under Federal law. I have issued categorical pardons for people convicted for simple possession and use under Federal and D.C. law while urging governors to do the same on the State level. It is simple: No one should be in jail or prison for using or possessing marijuana alone. Meanwhile, my Administration has made historic investments to expand access to mental health and substance use services. We have also provided $400 million to prevent juvenile justice involvement and make these systems more responsive to the needs of youth. We have provided over $3 billion in funding for education programs that provide support, services, and interventions, which keep students positively engaged in their schools and communities.

If we pursue this work together, our communities will be safer, stronger, and more just. It will make families and communities whole and help grow our economy, giving everyone a fair chance. I have always believed that our Nation's best days are ahead—and that is true for every single American too. This month, we recommit to fulfilling the fresh promise that every second chance holds.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2024 as Second Chance Month. I call upon government officials, educators, volunteers, and all the people of the United States to observe this month with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07194
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10722 of March 29, 2024

National Public Health Week, 2024

By the President of the United States of America

A Proclamation

During National Public Health Week, we celebrate the life-saving care of public health professionals who work tirelessly to promote our country's health, safety, and well-being. We recognize that the healthier Americans are as individuals, the stronger we are as a Nation.

In the last few years, we have made enormous progress in recovering from the pandemic, vaccinating 230 million Americans and getting kids back in school. None of that would have been possible without the courage and dedication of millions of first responders and social workers, doctors and nurses, and scientists and researchers. Public health professionals have always played an essential role in the life of our Nation—working to boost immunizations, improve safety standards for food and transportation, protect clean air and water, and more. We owe them for carrying us through tough times and making our country healthier and more prosperous long-term. We have to help make their jobs easier by investing in the health of the American people.

I have long said that health care should be a right in this country, not a privilege. That is why my Administration expanded coverage through the Affordable Care Act. Today, more Americans have health care coverage than under any other President, and millions of families are saving an average of $800 per year on insurance premiums. We have also invested $7.6 billion in community health centers so people in rural and underserved areas can get care close to home. After years of trying, we have succeeded in reducing prescription drug costs—for example, capping insulin at $35 per month for seniors on Medicare, down from as much as $400, and finally getting Medicare the authority to negotiate lower drug prices, as the Department of Defense and the Department of Veterans Affairs have long done. Starting next year, no senior on Medicare will have to pay more than $2,000 per year in total out-of-pocket drug costs—not even for expensive cancer medications that cost many times more.

At the same time, we are funding scientific research that will help us make quantum leaps forward in the prevention, detection, and treatment of deadly diseases. I established the Advanced Research Projects Agency for Health, securing $2.5 billion in bipartisan funding for scientists, innovators, and public health professionals making these advances. Further, the First Lady and I reignited the Cancer Moonshot, setting a bold goal to cut the cancer death rate by at least 50 percent over the next 25 years and boost support for people impacted by cancer. We also launched the first-ever White House Initiative on Women's Health Research to close research gaps and maximize our ability to prevent, diagnose, and treat health conditions in women, like cardiovascular disease, Alzheimer's disease, and endometriosis.

I am doing all I can to protect women's fundamental freedom to make their own health care decisions. In the wake of the Supreme Court's decision to overturn the constitutional right to choose, tens of millions of Americans are living under extreme State abortion bans that put women's health and lives at risk and threaten doctors with jail time for providing the health

care their patients need. In response, my Administration has taken steps to safeguard access to emergency medical care, support the ability to travel for reproductive health care, and strengthen privacy protections for patients and health care providers. I will keep pressing the Congress to restore the protections of *Roe* v. *Wade* into Federal law. It is the only way to ensure reproductive freedom for women in every State. At the same time, Vice President Harris is leading the effort to combat the maternal health crisis that is gripping our country, which has been especially devastating to Black and Native women and women in rural communities, where maternal mortality rates are unconscionably high.

We are also making historic investments in improving mental health by putting more counselors in schools and pushing insurers to cover mental health care at the same level as any other care.

We are working hard to ensure that substance use disorder is treated like any other disease by funding the expansion of prevention, harm reduction, treatment, and recovery support services. My Administration removed decades—long administrative barriers to treatment of opioid use disorder and expanded access to opioid overdose reversal medications like naloxone, and we are continuing to advance efforts to address the overdose epidemic and save lives. We are working to end the epidemic of gun violence that has shattered far too many American lives. Two summers ago, I signed the most significant gun safety law in nearly 30 years, funding States' implementation of red flag laws and enhancing background checks for gun buyers under 21. I launched the first-ever White House Office of Gun Violence Prevention. I was also proud to sign the reauthorized Violence Against Women Act, building on the law that I first wrote years ago to expand protections and resources for today's domestic violence survivors.

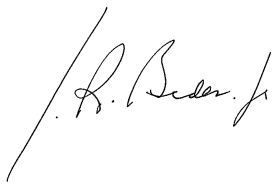
Meanwhile, my Administration is making the largest investment ever in fighting the public health crises caused by climate change. We are working to make communities more resilient to extreme weather and ensuring that 40 percent of our clean energy investments flow to the disadvantaged areas that have borne the brunt of toxic pollution for too long. Through the Bipartisan Infrastructure Law, we are also replacing every poisonous lead pipe in the country so anyone in America can turn on the faucet and drink clean water. We have released a national strategy to end hunger and reduce diet-related diseases, including expanding access to nutrition and obesity counseling, and we are providing millions of students with free, nutritious school meals.

Globally, we are making key investments to combat health challenges like HIV/AIDS, tuberculosis, malaria, cancer, and COVID. With the G20 and other partners, we created the Pandemic Fund to strengthen global pandemic preparedness, prevention, and response. At home, we invested over $7 billion to help State and local public health departments prepare for future crises, and we launched Public Health AmeriCorps to train a strong, diverse public health workforce for tomorrow.

These are vital steps needed to protect the American people. During National Public Health Week, we are reminded how interconnected everyone's health and well-being are and that we are truly all in this together. By continuing to invest in public health, we can help ensure that the lessons of the last 4 years make our Nation stronger for the future.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 1 through April 7, 2024, as National Public Health Week. I call on all citizens, government agencies, private businesses, nonprofit organizations, and other groups to take action to improve the health of our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07195
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10723 of March 29, 2024

César Chávez Day, 2024

By the President of the United States of America

A Proclamation

Today, as we honor César Chávez's life and legacy, we recommit to fulfilling the fundamental vision of La Causa: to give every worker the dignity and respect they deserve and ensure everyone has a fair shot at the American Dream.

César Chávez defined extraordinary moral courage. He was a migrant farm worker who spent long, strenuous hours working in the fields. He and his fellow workers received unlivable wages and labored in unjust working conditions. Even then, a man of unyielding faith and an immovable spirit, Chávez saw every reason to pursue what he knew was the truth of this country: The people who put food on America's tables and sustain our Nation deserve their fair share.

Alongside legendary activist Dolores Huerta, he founded the United Farm Workers. Ever since beginning their work in 1962, this union has led legendary marches, strikes, and boycotts. Chávez himself knocked on doors for years and fasted for weeks on end to bring light to issues facing farm workers. Together, they made historic progress, like earning farm workers the right to collectively bargain and ensuring safe working conditions and better pay. As a leader, Chávez not only empowered tens of thousands of farm workers to make their voices heard, he also inspired an entire generation of Latino leaders to forge a better future for all of us.

I am proud to keep a bust of César Chávez in the Oval Office. It is a daily reminder of our shared commitment to America's workers and our labor unions. My dad used to say that a job is about a lot more than a paycheck—it is about dignity. But if the paycheck is insufficient and the working conditions are subpar, a job can never offer someone the dignity they deserve. That is why since day one of my Administration, I have been working to build an economy that works for everyone—one that grows from the middle out and the bottom up, not the top down. So far, the economy has created nearly 15 million jobs—one of the greatest job creation periods in our Nation's history. Unemployment has been below 4 percent for the longest stretch in 50 years. America's support for unions is higher today than at any time in nearly 60 years. All of this progress is proof that when America's unions do well, we all do well.

I am also proud to be the most pro-worker and pro-union President in American history. Since I took office, the Department of Labor has recovered over $21 million in back pay and damages, ensuring that nearly 26,000 farm workers received the wages they earned. My Administration proposed a new rule last year that would extend overtime pay to as many as 3.6 million workers, ensuring that they are compensated fairly for the hours they spend at work. I also signed into law the Butch Lewis Emergency Pension Plan Relief Act, which protects pensions for millions of union workers—one of the most significant achievements for union workers and retirees in over 50 years. The Department of Labor is also working to protect workers exposed to extreme heat, including conducting targeted inspections in industries with high incidences of heat-related illnesses. They published a rule that strengthens services to migrant and seasonal farm workers by

increasing outreach to farm workers and requiring that outreach field visits involve conversations about farm workers' rights and protections.

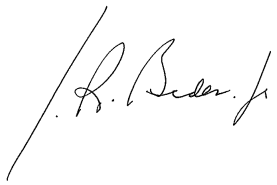
Migrant workers can find helpful resources and more information about their employment-related rights in America at MigrantWorker.gov or Trabajadormigrante.gov. These websites have information about recruitment, working in America, returning home safely, and more.

I know that there is still work to be done to ensure that we are taking care of our workers. We need to finally provide undocumented farm workers a pathway to citizenship. That is why I continue to call on the Congress to pass the Farm Workforce Modernization Act. I also believe every worker in America should have the free and fair choice to join a union or organize and bargain collectively without employer intimidation or coercion. That is why I encouraged the Congress to pass the Protecting the Right to Organize Act. I remain steadfast in my call to ensure paid sick leave for every worker in America and to improve conditions for people who work on farms and ranches and across the food and agricultural industry.

César Chávez once said about the power of La Causa: ''Once social change begins it cannot be reversed. You cannot uneducate the person who has learned to read. You cannot humiliate the person who feels pride. You cannot oppress the people who are not afraid anymore . . . you cannot stamp out a people's cause.'' On this day, we recognize that César Chávez and his fellow farm workers made progress that can never be taken back. They fought for a sacred cause that continues to beat in the hearts of the American people: Every worker—no matter who they are, where they are from, or what they do—deserves dignity and respect.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim March 31, 2024, as César Chávez Day. I call upon all Americans to observe this day as a day of service and learning with appropriate service, community, and education programs to honor César E. Chávez's enduring legacy.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07196

Filed 4–2–24; 8:45 am]

Billing code 3395–F4–P

Presidential Documents

Proclamation 10724 of March 29, 2024

Transgender Day of Visibility, 2024

By the President of the United States of America

A Proclamation

On Transgender Day of Visibility, we honor the extraordinary courage and contributions of transgender Americans and reaffirm our Nation's commitment to forming a more perfect Union—where all people are created equal and treated equally throughout their lives.

I am proud that my Administration has stood for justice from the start, working to ensure that the LGBTQI+ community can live openly, in safety, with dignity and respect. I am proud to have appointed transgender leaders to my Administration and to have ended the ban on transgender Americans serving openly in our military. I am proud to have signed historic Executive Orders that strengthen civil rights protections in housing, employment, health care, education, the justice system, and more. I am proud to have signed the Respect for Marriage Act into law, ensuring that every American can marry the person they love.

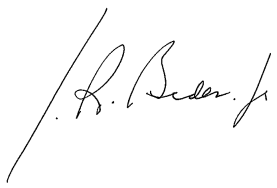
Transgender Americans are part of the fabric of our Nation. Whether serving their communities or in the military, raising families or running businesses, they help America thrive. They deserve, and are entitled to, the same rights and freedoms as every other American, including the most fundamental freedom to be their true selves. But extremists are proposing hundreds of hateful laws that target and terrify transgender kids and their families—silencing teachers; banning books; and even threatening parents, doctors, and nurses with prison for helping parents get care for their children. These bills attack our most basic American values: the freedom to be yourself, the freedom to make your own health care decisions, and even the right to raise your own child. It is no surprise that the bullying and discrimination that transgender Americans face is worsening our Nation's mental health crisis, leading half of transgender youth to consider suicide in the past year. At the same time, an epidemic of violence against transgender women and girls, especially women and girls of color, continues to take too many lives. Let me be clear: All of these attacks are un-American and must end. No one should have to be brave just to be themselves.

At the same time, my Administration is working to stop the bullying and harassment of transgender children and their families. The Department of Justice has taken action to push back against extreme and un-American State laws targeting transgender youth and their families and the Department of Justice is partnering with law enforcement and community groups to combat hate and violence. My Administration is also providing dedicated emergency mental health support through our nationwide suicide and crisis lifeline—any LGBTQI+ young person in need can call ''988'' and press ''3'' to speak with a counselor trained to support them. We are making public services more accessible for transgender Americans, including with more inclusive passports and easier access to Social Security benefits. There is much more to do. I continue to call on the Congress to pass the Equality Act, to codify civil rights protections for all LGBTQI+ Americans.

Today, we send a message to all transgender Americans: You are loved. You are heard. You are understood. You belong. You are America, and my entire Administration and I have your back.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim March 31, 2024, as Transgender Day of Visibility. I call upon all Americans to join us in lifting up the lives and voices of transgender people throughout our Nation and to work toward eliminating violence and discrimination based on gender identity.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of March, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2024–07197
Filed 4–2–24; 8:45 am]
Billing code 3395–F4–P

Rules and Regulations

Federal Register
Vol. 89, No. 65
Wednesday, April 3, 2024

DEPARTMENT OF HOMELAND SECURITY

Immigration and Customs Enforcement

8 CFR Part 214

[DHS Docket No. ICEB–2021–0016]

RIN 1653–AA87

Removal of Obsolete Procedures and Requirements Related to F, J, and M Nonimmigrants

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: On December 12, 2022, the Department of Homeland Security (DHS) issued an interim final rule, which amended regulations to update information that was no longer accurate since the creation of the Student and Exchange Visitor Information System (SEVIS), the Web-based system DHS uses to collect and maintain current and ongoing information on Student and Exchange Visitor Program (SEVP)-certified schools, F–1 and M–1 nonimmigrant students, and J–1 Exchange Visitor Program participants and their sponsors. DHS is now issuing this final rule that introduces no substantive changes from the interim final rule.

DATES: The effective date of this rule is May 3, 2024.

ADDRESSES: Comments and related materials received from the public are available in DHS Docket No. ICEB–2021–0016. For access to the online docket, go to *https://www.regulations.gov* and enter ''DHS Docket No. ICEB–2021–0016'' in the ''Search'' box.

FOR FURTHER INFORMATION CONTACT: Sharon Snyder, Policy and Response Unit Chief, Student and Exchange Visitor Program, U.S. Immigration and Customs Enforcement, 500 12th Street SW, Stop 5600, Washington, DC 20536–5600; or by email at *sevp@ice.dhs.gov* or telephone at 703–603–3400 (this is not a toll-free number). Find program information at *http://www.ice.gov/sevis/*.

SUPPLEMENTARY INFORMATION:

I. Abbreviations

Abbreviation Amplification

CEQ Council on Environmental Quality
CFR Code of Federal Regulations
COVID–19 Coronavirus Disease 2019
DHS Department of Homeland Security
DOJ Department of Justice
DOS Department of State
DSO Designated School Official
EBSVERA Enhanced Border Security and Visa Entry Reform Act of 2002
HSPD–2 Homeland Security Presidential Directive-2
ICE U.S. Immigration and Customs Enforcement
IIRIRA Illegal Immigration Reform and Immigrant Responsibility Act of 1996
INA Immigration and Nationality Act
INS Immigration and Naturalization Service
MD Management Directive
OMB Office of Management and Budget
SEVIS Student and Exchange Visitor Information System
SEVP Student and Exchange Visitor Program
USCIS U.S. Citizenship and Immigration Services

II. Background

A. Purpose of the Regulatory Action

This rule responds to public comments on the interim final rule and finalizes the removal of obsolete procedures and requirements presented in the interim final rule. This final rule introduces no substantive changes and does not raise existing costs. There are no significant changes between the interim final rule and the final rule. In alignment with the Interim Final Rule, the Final Rule places no additional burdens on F, J, and M nonimmigrants, or on sponsoring academic institutions and programs.

B. Legal Authority

Section 102 of the Homeland Security Act of 2002 (Pub. L. 107–296, 116 Stat. 2135), 6 U.S.C. 112, section 103(a)(1) and (3) of the Immigration and Nationality Act (INA), and 8 U.S.C. 1103(a)(1), (3), charge the Secretary with the administration and enforcement of the immigration and naturalization laws of the United States, to include the issuance of regulations. Section 214(a) of the INA, 8 U.S.C. 1184(a), gives the Secretary the authority to prescribe the time and conditions of admission of any noncitizen as a nonimmigrant.

On March 1, 2003, when the responsibilities of the former Immigration and Naturalization Service (INS) transferred from the Department of Justice (DOJ) to DHS pursuant to the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135 (Nov. 25, 2002), SEVP and the SEVIS functions transferred to DHS. Within DHS, U.S. Immigration and Customs Enforcement (ICE) administers SEVP by ensuring that government agencies have essential information related to nonimmigrant students and exchange visitors to preserve national security. For the sake of simplicity in this preamble, in rules promulgated prior to March 1, 2003, any reference to the INS, or ''the Service'' as it was referred to in the past, is now referred to as DHS, and any reference to the Attorney General is now referred to as the Secretary of Homeland Security (the Secretary).

The INA established who may be admitted as F, J, or M nonimmigrants. Specifically, section 101(a)(15)(F) of the INA, 8 U.S.C. 1101(a)(15)(F), established the F classification for nonimmigrants who wish to enter the United States temporarily and solely for the purpose of pursuing a full course of study at an academic or accredited language training school certified by SEVP, as well as for the spouses and minor children of such noncitizens.

Section 101(a)(15)(J) of the INA, 8 U.S.C. 1101(a)(15)(J), established the J classification for nonimmigrants who wish to come to the United States temporarily to participate in exchange visitor programs designated by the Department of State (DOS), as well as for the spouses and minor children of such noncitizens.

Section 101(a)(15)(M) of the INA, 8 U.S.C. 1101(a)(15)(M), established the M classification for nonimmigrants who wish to enter the United States temporarily and solely for the purpose of pursuing a full course of study at an established vocational or other recognized nonacademic institution (other than a language training program) certified by SEVP, as well as for the spouses and minor children of such noncitizens.

SEVP collects information related to nonimmigrant students and exchange visitors under various statutory

authorities. Section 641 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104–208, 110 Stat. 3009–704 (Sep. 30, 1996) (codified as amended at 8 U.S.C. 1372), authorized the creation of a program to collect current and ongoing information from schools and exchange visitor programs regarding nonimmigrant students and exchange visitors during the course of their stay in the United States and stipulated that such information is to be collected electronically, where practicable. Section 641(e) of IIRIRA further directed that this information collection system be self-funded by the nonimmigrant foreign students and exchange visitors. To meet these requirements, DHS promulgated separate rulemakings that established the framework for SEVIS; required mandatory compliance for all schools to use SEVIS for the admission of new F, J, and M nonimmigrant students; [1] and provided for the collection of a fee to be paid by certain nonimmigrants seeking status as F–1, F–3, M–1, or M–3 nonimmigrant students or as J–1 nonimmigrant exchange visitors.[2] The DOS placed similar mandatory SEVIS compliance requirements on DOS-designated Exchange Visitor Program sponsors regarding J nonimmigrants.[3]

SEVP is managed in accordance with Homeland Security Presidential Directive-2 (HSPD–2), Combating Terrorism Through Immigration Policies (Oct. 29, 2001), as amended, and section 502 of the Enhanced Border Security and Visa Entry Reform Act of 2002 Public Law 107–173, 116 Stat. 543, 563 (May 14, 2002) (EBSVERA). HSPD–2 requires the Secretary to conduct periodic, ongoing reviews of institutions certified to accept F nonimmigrants, and to include checks for compliance with recordkeeping and reporting requirements. EBSVERA directs the Secretary to review the compliance with recordkeeping and reporting requirements under 8 U.S.C. 1101(a)(15)(F) and 1372 of all schools approved for attendance by F students within two years of enactment, and every two years thereafter. These additional requirements have also been promulgated in rulemakings.[4]

C. Student and Exchange Visitor Information System

SEVP uses SEVIS to maintain information about:

- SEVP-certified schools;
- F–1 students enrolled in academic programs in the United States (and their F–2 dependents);
- M–1 students enrolled in vocational programs in the United States (and their M–2 dependents);
- DOS-designated Exchange Visitor Program sponsors; and
- J–1 Exchange Visitor Program participants (and their J–2 dependents).

SEVIS provides authorized users access to reliable information on F, J, and M nonimmigrants and their dependents. Schools use SEVIS to petition SEVP for certification, which allows the school to offer programs of study to nonimmigrant students. Designated school officials (DSOs) of SEVP-certified schools use SEVIS to:

- Update school information and apply for recertification of the school for the continued ability to issue the Form I–20, Certificate of Eligibility for Nonimmigrant Student Status or successor form, to nonimmigrant students and their dependents;
- Issue the Form I–20 or successor form to specific individuals to obtain F or M status while enrolled at the school;
- Fulfill the school's reporting responsibility regarding student addresses, courses of study, enrollment, employment, and compliance with the terms of student status; and
- Transfer student SEVIS records to other institutions.

Exchange Visitor programs use SEVIS to petition DOS for designation as a sponsor so they can offer educational and cultural exchange programs to exchange visitors. Responsible officers of designated Exchange Visitor programs use SEVIS to:

- Update sponsor information and apply for re-designation every two years;
- Issue the Form DS–2019, Certificate of Eligibility for Exchange Visitor (J–1) Status, to specific individuals to obtain J status;
- Fulfill the sponsor's reporting responsibility regarding exchange visitor addresses, sites of activity, program participation, employment, and compliance with the terms of the J status; and
- Transfer the exchange visitor SEVIS records to other institutions.

Noncitizens must apply to an SEVP-certified school and be accepted for enrollment as a student. SEVP-certified schools enter the prospective student's information into SEVIS and issue a Form I–20 or successor form. The prospective student then presents that endorsed form when applying for an F or M visa with DOS abroad. Similarly, a noncitizen must apply to a DOS-designated Exchange Visitor program and be accepted for enrollment as a basis for applying for a J exchange visitor visa. The Exchange Visitor program enters the prospective exchange visitor's information into SEVIS and issues a Form DS–2019. The prospective exchange visitor then submits that endorsed form when applying for a J visa with DOS abroad.

At the time of admission into the United States, U.S. Customs and Border Protection inspection officers will enter information into DHS systems related to the F, J, or M nonimmigrant's admission. These systems interface with SEVIS to provide SEVP and DOS with entry information about nonimmigrant students and exchange visitors.

After admission and during the nonimmigrant student or exchange visitor's stay in the United States, SEVP-certified schools and Exchange Visitor programs are required to update information about approved F, J, and M nonimmigrants. SEVIS allows schools and Exchange Visitor programs to transmit required information electronically about F, J, and M nonimmigrants throughout the nonimmigrant student or exchange visitor's stay in the United States.

SEVIS enables DHS and DOS to monitor and ensure proper recordkeeping and reporting by SEVP-certified schools and Exchange Visitor programs. Further, SEVIS provides a mechanism for nonimmigrant student and exchange visitor status violators to be identified so that appropriate action may be taken (*i.e.,* denial of admission, denial of benefits, or removal from the United States). Prior to the creation of SEVIS in January 2003, enrollment of nonimmigrant students was an entirely manual and paper-based process, which meant that schools maintained their own paper records about nonimmigrant students that were only produced upon request.

D. Interim Final Rule

On December 12, 2022, DHS published an interim final rule which removed obsolete procedures and

[1] Retention and Reporting of Information for F, J, and M Nonimmigrants; Student and Exchange Visitor Information System (SEVIS), 67 FR 76256 (Dec. 11, 2002).

[2] Authorizing Collection of the Fee Levied on F, J, and M Nonimmigrant Classifications Under Public Law 104–208; SEVIS, 69 FR 39814 (July 1, 2004).

[3] Exchange Visitor Program: SEVIS Regulations, 67 FR 76307 (Dec. 12, 2002).

[4] Allowing Eligible Schools to Apply for Preliminary Enrollment in the Student and Exchange Visitor Information System (SEVIS), 67 FR 44344 (July 1, 2002); Requiring Certification of all Service Approved Schools for Enrollment in the Student and Exchange Visitor Information System (SEVIS), 67 FR 60107 (Sept. 25, 2002); Adjusting Program Fees and Establishing Procedures for Out-of-Cycle Review and Recertification of Schools Certified by the Student and Exchange Visitor Program to Enroll F and/or M Nonimmigrant Students, 73 FR 55683 (Sept. 26, 2008).

requirements in 8 CFR 214.1, 214.2, 214.3, 214.4, 214.12, and 214.13 governing F, J, and M nonimmigrants that no longer apply since the implementation of SEVIS in 2003. The rule also removed language requiring original signatures on Form I–17 or successor form and clarified the regulatory language that implies the requirement for original signatures on Form I–20 or successor form, and made technical changes to correct typographical errors, update references, and reflect the transfer of responsibilities to DHS from DOJ.[5] See *Removal of Obsolete Procedures and Requirements Related to F, J, and M Nonimmigrants,* 87 FR 75891 (Dec. 12, 2022) (2022 Interim Final Rule), amended by; *Removal of Obsolete Procedures and Requirements Related to F, J, and M Nonimmigrants; Correcting Amendments,* 88 FR 53761 (Aug. 11, 2023) (correction to 2022 Interim Final Rule). DHS received four comments on the 2022 Interim Final Rule. DHS considered all public comments before issuing this final rule. DHS is finalizing these changes to eliminate confusion and provide clarity to the public. A discussion of the public comments and responses follows later in this preamble.

E. Regulatory Changes From Interim Final Rule to Final Rule

The interim final rule made general wording, capitalization, and style changes. Some examples of these changes include, replacing numeric symbols under 10 with the corresponding word; inserting indefinite articles where appropriate; and replacing phrases such as ''not pursuing'' with ''no longer pursuing.'' Additionally, the interim final rule removed references to ''approval'' and its derivatives and replaced them with ''certify'' and its derivatives to mean authorization for schools to enroll foreign students.[6] Further, the interim final rule updated terminology to reflect the transfer of certain functions and responsibilities of the former INS to DHS. Technical amendments of this nature apply throughout the amended sections. As discussed in the III. Discussion of Public Comments on the Interim Final Rule section below of this final rule, DHS has considered the input provided by commenters in response to the interim final rule. The majority of commenters supported the proposed changes, and DHS is finalizing the changes in the interim final rule, with some non-significant modifications. This final rule amends 8 CFR 214 to clarify who can provide medical evidence, removes and reserves obsolete language related to transfers, and adopts some of the commenters' suggestions.

III. Discussion of Public Comments on the Interim Final Rule

A. Summary of Public Comments

In response to the interim final rule, DHS received four public comments from stakeholders, including two institutions of higher education, an association of international educators, and a member of the public. DHS reviewed all the comments and addresses them in this final rule.

Three of the four commenters expressed support for the interim final rule. Two commenters thanked DHS and SEVP for their continued engagement and willingness to modernize. Another commenter said that they welcomed the opportunity to review (the interim final rule) because it helps clarify and streamline the workflow, ''which benefits our international students and scholars as well.'' One commenter suggested clarifying one of the changes, and the other three offered suggestions for additional regulatory changes. All of the comments were reviewed and considered, but some of the suggestions were out of scope for this final rule and adopting them would require notice and comment; for that reason, those out-of-scope comments were not adopted in this final rule. However, DHS may consider those suggestions when contemplating future enhancements to SEVP and SEVIS.

B. Comments Expressing General Support

Comment: Some commenters described how the interim final rule helps to clarify, streamline, and modernize processes.

Response: DHS appreciates this observation and believes that this rulemaking places no additional burden on F, J, and M nonimmigrants, or on sponsoring academic institutions and programs. Further, DHS observes that eliminating original signatures on the Form I–17 or successor form will further streamline processes because it eliminates the requirement for DSOs to obtain original signatures.

C. Comments Expressing Opposition

DHS received no comments expressing opposition to the interim final rule.

D. Comments Providing Additional Suggestions

Comment: One commenter suggested that DHS clarify the language about who may provide the medical documentation that a DSO must see before authorizing a reduced course load for a nonimmigrant student. The commenter specifically suggests removing ''psychiatrist'' from the approved provider list. The commenter states that because a psychiatrist is a medical doctor there is no need to parse psychiatrists out from other medical doctors.

Response: DHS agrees with the commenter that medical doctor includes psychiatrist and that the wording about who may provide the medical documentation could be clarified further; therefore, DHS is adopting this suggestion by amending the regulatory text to read: ''In order to authorize a reduced course load based upon a medical condition, the student must provide medical documentation from a licensed medical doctor, a licensed doctor of osteopathy, a licensed psychologist, or a licensed clinical psychologist to the DSO to substantiate the illness or medical condition.''

Comment: Some commenters suggested that DHS expand the list of medical providers qualified to provide the medical documentation that a DSO must see before authorizing a reduced course load. For instance, they stated that ''these days, many U.S. citizens are likelier to be seen by a nurse practitioner. . ., or a social worker or mental health counselor.''

Response: DHS acknowledges that many health care services can be delivered by a variety of providers, such as the ones suggested by commenters. However, the scope and purpose of this interim final rule and final rule are not to add more medical professionals to the list of accepted medical providers, (*see* 8 CFR 214.2(f)(6)(iii)(B)), but to clarify the language of the regulation to indicate that a licensed psychologist or psychiatrist could provide the evidence for the student's mental health diagnoses; Expanding the list of medical providers is a significant change that would require public review and comment and is outside the scope of this rulemaking. Therefore, DHS cannot adopt this suggestion at this time, but may consider this suggestion in the event of a future rulemaking.

Comment: Two commenters suggested that DHS should eliminate obsolete wording about transfer procedures.

Response: DHS agrees with this suggestion because the transfer procedures outlined in 8 CFR

[5] Pursuant to the Homeland Security Act of 2002.

[6] SEVP previously used both ''certified'' and ''approved'' interchangeably. To eliminate confusion, SEVP now uses only ''certify'' and its derivatives.

214.2(f)(8)(iii) no longer apply since the implementation of SEVIS. DSOs no longer note ''transfer completed on (date)'' on a student's Form I–20 (or successor form), return the Form I–20 (or successor form) to the student, and send a copy elsewhere. Therefore, DHS is removing and reserving that paragraph.

Comment: One commenter suggested DHS make additional changes to remove other obsolete procedures and requirements, including:

- ''Item (2) of Table 2 to Paragraph (f), the paragraph contents of 8 CFR 214.2(f), should be revised by changing '(2) I–20 ID' to '(2) Student maintenance of Form I–20 or successor form.'
- ''Remove 8 CFR 214.2(f)(8)(iii), a pre-SEVIS provision.''
- ''Remove 8 CFR 214.2(f)(9)(ii)(F)(2), a pre-SEVIS provision.''
- ''In 8 CFR 214.2(f)(9)(i), remove the three asterisks (* * *) that appear between the third and fourth sentences.''
- ''In 8 CFR 214.2(m)(l)(i)(B), remove the word ''SEVIS'' that precedes the term 'Form 1–20.' ''
- ''In 8 CFR 214.2(j)(l)(i), the term 'SEVIS Form DS–2019' appears four times. The word 'SEVIS' should be removed in those instances.''
- ''In 8 CFR 214.2(j)(l)(vii), the term 'SEVIS Form DS–2019' appears one time. The word 'SEVIS' should be removed in that instance.''
- ''To retain parity with the F and M regulations, DHS should consider using the term 'Form DS–2019 or successor form' wherever the term 'Form DS–2019' appears in 8 CFR 214.1.''

Response: DHS appreciates these suggestions for additional changes and has made some of the suggested corrections already (see ICEB–2021–0016, Correcting amendments, published August 9, 2023). DHS will adopt the suggestions to amend paragraphs 8 CFR 214.2(f) and (m) related to the Form I–20 and pre-SEVIS provisions. However, 8 CFR 214.2(j) falls under the authority of DOS, so DHS cannot adopt the suggestions related to the Form DS–2019.

E. Comments Out of Scope

Comment: One commenter suggested that to meet the student demand for online, hybrid, and in-person courses, and to give schools the ability to offer instruction using these preferred learning styles, DHS should eliminate or reduce the physical presence requirement for nonimmigrant students.

Response: DHS acknowledges that hybrid and online instruction methods are becoming increasingly common. However, changing the regulatory requirement for nonimmigrant students to take no more than the equivalent of one online or distance education course [7] is a significant change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: Some commenters suggested DHS should allow additional reduced course load authorizations beyond what is currently allowed.

Response: Changing regulations to allow nonimmigrant students to engage in less than a full course of study [8] with more frequency than is currently allowed under 8 CFR 214.2(f)(6)(iii) is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: One commenter suggested that DHS should allow DSOs to make exceptions for nonimmigrant students who have not applied for an extension of their program of study.

Response: Allowing DSOs to grant exceptions to nonimmigrant students who did not apply for an extension until after the program end date noted on the Form I–20 or successor form is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: Some commenters suggested that DHS should clarify the meaning of ''initial'' in 8 CFR 214.2(f)(6)(iii)(A), which states, ''The DSO may authorize a reduced course load on account of a student's initial difficulty with the English language or reading requirements, unfamiliarity with U.S. teaching methods, or improper course level placement,'' noting ''it would be helpful to clarify which reasons can (or cannot) be used.'' In addition, commenters suggested expanding when the list of reasons may be used to include times beyond the initial period.

Response: DHS interprets the term ''initial'' as it is used in 8 CFR 214.2(f)(6)(iii)(A) to refer to a new student at the beginning of their studies in the United States. Expanding when the reasons to drop below a full course of study for academic reasons may be used is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: One commenter suggested that DHS allow practical training to be authorized once per educational level instead of only allowing an additional 12 months of practical training when a student changes to a higher educational level.

Response: DHS appreciates that practical training is useful to students. However, changing practical training requirements is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: One commenter suggested that DHS should allow for ''continued authorization of a medical reduced course load beyond 12 months for chronic and/or serious conditions.'' The commenter stated that the current policy is discriminatory to students with disabilities.

Response: DHS appreciates that nonimmigrant students with health challenges may require additional time to complete a course of study and is considering how to better address this reality. However, changing the requirements for how long a DSO may authorize a reduced course load (or, if necessary, no course load) due to a chronic or serious illness or a disability is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: One commenter suggested that DHS remove the requirement that an optional practical training application must be filed with USCIS within a certain number of days from the date when the DSO recommends it in SEVIS.

Response: Changing practical training requirements is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: Some commenters suggested that DHS eliminate the requirement for a travel endorsement signature on the Form I–20 for students returning to the United States from a temporary absence of five months or less.

Response: Eliminating the requirement for returning students to present a properly endorsed Form I–20

[7] Only one class or three credits per session, term, semester, trimester, or quarter may be counted toward the full course of study requirement if the class is taken online or through distance education and does not require the student's physical attendance for classes, examination, or other purposes integral to completion of the class. If the F–1 student's course of study is in a language training program, no online or distance education classes may be considered to count toward the student's full course of study requirement.

[8] A full course of study is described in 8 CFR 214.2(f)(6).

(or successor form) is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

Comment: One commenter suggested that DHS clarify what the term ''continues'' means in 8 CFR 214.2(f)(5)(ii) and that DHS clarify that the transfer from one educational level to another can be downward as well as upward.

Response: DHS interprets the term ''continues'' as it is used in 8 CFR 214.2(f)(5)(ii) to mean that a student is maintaining status when they continue to be enrolled, even when transferring from one educational level to another. The term as used here underscores the importance of continued enrollment to maintain status. Adding a description of what ''continues'' means within the context of 8 CFR 214.2(f)(5)(ii) is a significant regulatory change that would require public review and comment and is outside the scope of this rule; therefore, DHS cannot adopt this suggestion at this time.

V. Statutory and Regulatory Requirements

DHS developed this final rule after considering numerous statutes and Executive orders related to rulemaking. The below sections summarize the analyses based on a number of these statutes or Executive orders.

A. Executive Orders 12866 and 13563

Executive Orders 12866 (Regulatory Planning and Review) as amended by Executive Order 14094 (Modernizing Regulatory Review), and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is deemed to be necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This final rule has not been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, this final rule has not been reviewed by the Office of Management and Budget (OMB).

This final rule removes unnecessary procedures and requirements in 8 CFR 214.1, 214.2, 214.3, 214.4, 214.12, and 214.13 that govern F, J, and M nonimmigrants. These changes are necessary to improve clarity and remove obsolete or unnecessary information that no longer applies since the implementation of SEVIS. This final rule introduces no substantive changes; does not raise existing costs; and places no additional burden on F, J, and M nonimmigrants or their sponsoring academic institutions and programs.

Summary of the Analysis

DHS estimates that this final rule will have no costs and will result in quantifiable cost savings and additional unquantifiable benefits. As shown in Table 1, DHS estimates this final rule will have a 10-year annualized monetized cost savings of $27,568 in 2022 dollars (for both 3 and 7 percent discount rates) and unquantified benefits with regard to convenience, time savings, and improvements to the environment from reduced paper use. Table 1 summarizes the findings of this regulatory impact analysis (RIA).

TABLE 1—OMB CIRCULAR A–4 ACCOUNTING STATEMENT

[In millions 2022 dollars]

Category	Impact	Source
Benefits		
Annualized Monetized Benefits ($ Mil):		
(3%)	$0.03	RIA.
(7%)	$0.03	RIA.
Annualized Quantified, but Unmonetized, Benefits.		
Unquantified Benefits	Convenience and time savings in signature collection Reduced paper use.	RIA.
Costs		
Annualized Monetized Costs ($ Mil):		
(3%)	No Cost	RIA.
(7%)	No Cost	RIA.
Annualized Quantified, but Unmonetized, Costs	No Cost	RIA.
Qualitative (Un-quantified) Costs	No Cost	RIA.
Transfers		
Annualized Monetized Transfers. From Whom to Whom.		
Other Analyses		
Effects on State, Local, and/or Tribal Governments	No Impact	FR.
Effects on Small Business	No Impact	FR.
Effects on Wages.		
Effects on Growth.		

Baseline

This section details the regulatory baseline for this final rule. Table 2 below provides a summary of the anticipated changes to baseline conditions.

TABLE 2—BASELINE ANALYSIS

Provision	Description of change	Affected population	Cost impact to affected population	Benefit impact to affected population
Original Signatures for Form I–17.	Removing original signature requirement to allow for greater freedom in adopting electronic signature and transmission of documents.	SEVP-certified schools.	None	Cost savings for schools in reducing the time needed for school officials to physically sign forms for electronic filing.
All Other Technical Revisions.	Changing the wording in the rule to promote clarity and consistency, remove obsolete language, and codify procedures and practices.	School officials, students, and others who need to understand and follow the requirements of the rule, including legal practitioners and school administrators.	None	The benefit of the rule's greater clarity, accuracy, and currency and the promotion of an overall better understanding of the rule.

The baseline is the state of the world prior to the Coronavirus Disease 2019 (COVID–19) pandemic, in which all signatures on Form I–17 documents were required to be original, rather than electronic. It also includes all of the previous wording in SEVP regulations that would remain unchanged if this final rule does not take effect.

Background and Purpose

SEVP certifies qualifying schools and grants them access to SEVIS. DSOs at these SEVP-certified schools are their primary respondents in terms of reporting data. DSOs collect and enter the required information in SEVIS. That data is used to populate a school's Form I–17 and a student's Form I–20. DSOs carry nearly all of their school's reporting burden.

This final rule removes obsolete procedures and requirements and clarifies regulatory language associated with SEVP. The only quantifiable economic impact is from DHS allowing electronic signatures to replace original signatures on Form I–17 documents, which DSOs must prepare and send electronically to ICE. This change has been in place since 2020, as a result of the COVID–19 allowances that DHS implemented. However, prior to those allowances, DSOs were required to prepare their own paper copies of the Form I–17 documents, with the original signatures of each DSO who was required to sign the form, as well as that of the president, owner, or head of the school. Furthermore, many of those original signatures on any given Form I–17 document had to be made on the same piece of paper (on any pages in the document having space for more than one signature), thus requiring that piece of paper to be physically delivered to each individual who needed to sign their name on the same page. These individuals may be located in different buildings on the same campus, or even on different campuses for schools with more than one campus location. Consequently, the signing of the Form I–17 often required the transport of the same paper document among individuals in different locations and required coordination among them and other school officials to complete the process.

To prevent circulation of paper documents during the pandemic, DHS allowed DSOs to use electronic signature software to sign the Form I–17, rather than requiring original signatures among the various school officials. DSOs can also generate completed Form I–17 documents electronically, without needing to scan the signed paper documents before sending them electronically to ICE. In this final rule, DHS is allowing these cost savings and conveniences to continue permanently after the pandemic is sufficiently mitigated and the COVID–19-related allowances are no longer in effect.

The other changes proposed in this final rule are changes in wording that have largely become obsolete and irrelevant, such as references to ''INS'' or references to procedures that are no longer implemented. These revisions will improve the clarity, accuracy, and currency of the regulations for school officials, students and others who need to read and understand them.

Analytical Considerations

DHS divided the analysis into two general categories: (1) the effects of DHS allowing Form I–17 documents to be signed and transmitted electronically after the COVID–19-related allowances no longer apply; and (2) the effects of revisions in language, references, and stated procedures to improve the accuracy and clarity of SEVP-related regulations and to codify practices that have already been adopted. Of these two areas of the analysis, DHS determined that only the first (involving electronic signing and transmission of the Form I–17) is amenable to quantitative analysis and to the estimation of benefits and costs. DHS determined that the second area (textual changes to improve the accuracy, clarity, and understanding of the regulations) is not amenable to quantitative measures. DHS made this determination based on the many ambiguities that would exist in any efforts to define and measure such concepts as ''clarity,'' or to define and measure the extent to which individuals

would benefit from such improvements in clarity (such as in time savings or levels of comprehension). Nevertheless, DHS determined that qualitative descriptions of this second area would be sufficient to justify the changes.

DHS identified one effect of this final rule, with regard to electronic signatures for the Form I–17, that could provide an additional benefit. As stated, one of the advantages of electronic signatures is that paper documents no longer need to be physically transported to each person who signs the form. DHS allowance of electronic signatures avoids resources being spent by the school to transport these documents from one place to another for the required school officials to sign them. It also avoids resources being spent to place the documents in envelopes and address them and then for other individuals to open the envelopes and sign the documents.

However, DHS is unable to quantify this potential cost savings. DHS does not have data on how many people on average need to sign the form and how far away they are from each other (such as whether they have offices adjacent to each other or they are at campuses in different cities). Adding to the uncertainty would be whether the transport of these documents occurred along with other documents between the offices, so that no separate delivery was required to transport them individually. The burden of these original signatures would depend on whether school employees needed to take extra time to transport the documents separately from other documents delivered via intra-campus mail. DHS also does not have data on the time needed to produce electronic signatures, which would then need to be subtracted from the time needed to sign the paper documents for DHS to estimate the cost savings of electronic signatures. For example, if the mechanisms for officials to electronically sign documents are easily accomplished on their computers, it might not take very long to sign. However, if officials must follow complicated procedures on their computer to provide those electronic signatures, then it might take more time to sign.

Time Horizon for the Analysis

DHS estimates the economic effects of this final rule will be sustained indefinitely. ICE used a 10-year timeframe (from 2023 through 2032) to outline, quantify, and monetize the costs and benefits of this final rule, and to demonstrate its net effects.

Affected Population

This final rule affects two types of entities: (1) SEVP-certified schools (and the DSOs who work for those SEVP-certified schools), and (2) any individuals and organizations that might benefit from improvements in the way the regulations are written, including offices within DHS that interact with the affected SEVP-certified schools, and various U.S.-based and international organizations that may assist or represent F and M nonimmigrant students. In 2022, SEVP-certified schools submitted in SEVIS a total of 8,535 distinct Form I–17 documents to ICE.

Costs of the Rule

DHS determined that there are no costs associated with this final rule. When considering the cost of this final rule, DHS determined that there are no costs for SEVP-certified schools to develop information-technology capabilities to electronically sign and transmit documents. DHS assumes that SEVP-certified schools already have the necessary information technology capabilities in place to electronically sign and transmit the Form I–17 documents.

Cost Savings

DHS estimated the cost savings to SEVP-certified schools if paper copies and original signatures are no longer needed for the Form I–17 documents in accordance with this final rule. Table 3 displays these cost savings, estimated at $27,568 per year, in 2022 dollars. This cost savings estimate is based on 8,535 Form I–17 documents submitted to ICE in 2022. Without this final rule in place, DSOs would have to provide their original signatures on the Form I–17, as they did before the COVID–19 pandemic. DSOs would then need to scan these documents and send an electronic copy of them to ICE. DHS estimated that each document would require approximately 3 minutes of labor to be scanned. As shown in Table 3, this results in total labor costs of $19,033. DHS estimated the average number of pages per Form I–17 document to be 10 pages, which, at an estimated cost of $0.10 per page for paper and printing, contributes to an additional cost savings of $8,535.

TABLE 3—COST SAVINGS FROM ORIGINAL SIGNATURES NOT REQUIRED FOR FORM I–17

[In 2022 dollars]

Factor in the analysis	Measures	Costs savings
A. Number of Forms I–17 Scanned in 2022	8,535	
B. Number of Minutes to Scan Each Document	3	
C. Hourly Labor Rate for DSO[9]	$44.68	
D. Estimated Labor Cost Per Document Scanned [(B/60) × C]	$2.23	
E. Total Labor Costs (A × D)		$19,033
F. Estimated Pages Per Scan	10	
G. Estimated Cost Per Page (for Paper and Printing)	$0.10	
H. Estimated Paper Costs Per Mailing (H × I)	$1.00	
I. Total Paper Costs (A × H)		8,535
Total Cost Savings for Not Preparing and Scanning the Forms I–17 (E+I)		27,568

[9] Total DSO compensation of $44.68 is based on the mean hourly national wage estimates for Educational, Guidance, and Career Counselors and Advisors multiplied by the benefits-to-wage multiplier for civilian workers, calculated as $30.87 * 1.45. The benefits-to-wage multiplier represents the employee wages and benefits costs paid by employers, as calculated by BLS for civilian workers, and is calculated as follows: ($43.93 Total Employee Compensation per hour)/($30.35 Wages and Salaries per hour) = 1.44744 = 1.45 (rounded). See U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics: 21–1012 Educational, Guidance, and Career Counselors and Advisors, May 2022, *https://www.bls.gov/oes/2022/may/oes211012.htm*; and U.S. Bureau of Labor Statistics, Economic News Release, Employer Cost for Employee Compensation (September 2023), Table 1, Employer Costs for Employee Compensation by ownership (dated December 15, 2023), *https://www.bls.gov/news.release/archives/ecec_12152023.htm*. Last accessed January 30, 2024.

Table 4 summarizes the impact of this final rule over the 10-year period, starting in 2023. The 10-year discounted cost-savings of this final rule in 2022 dollars would range from $193,626 to $235,161 (with 7 percent and 3 percent discount rates, respectively).

TABLE 4—TOTAL ESTIMATED COST SAVINGS

[In 2022 dollars]

Year	Undiscounted	Discounted at 3%	Discounted at 7%
1	$27,568	$26,765	$25,765
2	27,568	25,986	24,079
3	27,568	25,229	22,504
4	27,568	24,494	21,032
5	27,568	23,780	19,656
6	27,568	23,088	18,370
7	27,568	22,415	17,168
8	27,568	21,762	16,045
9	27,568	21,129	14,995
10	27,568	20,513	14,014
Total	275,681	235,161	193,626
Annualized	.....	27,568	27,568

Qualitative Cost Savings

As previously described, the qualitative benefits of this final rule include benefits to those who may need to understand and follow the regulations, including school officials and organizations that assist or represent F and M students. Specifically, the technical revisions increase clarity, accuracy, and currency, and promote a better understanding of the regulation.

Analysis of Alternatives

Because this final rule does not pose any costs to the public or to the government, DHS is not able to find any alternative that could have any lower costs. In principle, even when the costs of a new rule are zero, an alternative rule could still be preferable if that rule could offer higher benefits, and thus higher net benefits. However, this too would not be possible in this case, because the benefits of any comparable rule could only be in the same form as the benefits of this final rule—those benefits being cost savings (for SEVP-certified schools). For any alternative to offer greater benefits, it would need to reduce the costs that SEVP-certified schools incur in processing and delivering Form I–17 documents. Because this final rule already allows for electronic signatures and submission of the forms by email, there are no less-expensive alternatives to preparing and distributing the forms.

DHS considered the no-action alternative for this final rule. Table 5 summarizes the effects of this alternative. The no-action alternative would result in continued costs to SEVP-certified schools for original signatures and would maintain obsolete language. As a result, DHS rejected this alternative.

TABLE 5—SUMMARY OF ALTERNATIVES

Action	Benefits	Costs
Take No-Action	None	1. Annual costs to SEVP-certified schools of $27,568 due to the preparation and scanning of Form I–17 documents (reverting to the pre-COVID signature requirement). 2. Cost associated with the greater difficulty imposed on school officials, students, and others who need to understand and follow requirements governing F and M non-immigrant students due to the obsolescence of certain language in the current regulatory text.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. However, a regulatory flexibility analysis is not required when a rule is exempt from notice-and-comment rulemaking; therefore, since this action is exempt under the Administrative Procedure Act, it is not subject to the regulatory flexibility analysis requirements. *See* 5 U.S.C. 604(a).

C. Small Business Regulatory Enforcement Fairness Act of 1996

This is not a major rule, as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This final rule will not result in an annual effect on the United States economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. Executive Order 13132: Federalism

This final rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

E. Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (in 1995 dollars) or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

F. Congressional Review Act

This final rule is not a major rule as defined by 5 U.S.C. 804, also known as the ''Congressional Review Act,'' as enacted in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, 110 Stat. 847, 868 *et seq.* This final rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. *See* 5 U.S.C. 804(2). The rule will be submitted to Congress and GAO consistent with the Congressional Review Act's requirements no later than its effective date.

G. Executive Order 12988 Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

H. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, Public Law 104–13, all departments are required to submit to OMB, for review and approval, any reporting requirements inherent in a rule. This final rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act.

I. National Environmental Policy Act

DHS Management Directive 023–01 Rev. 01 and Instruction Manual 023–01–001–01 Rev. 01 establishes the policy and procedures that DHS and its Components use to comply with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4375, and the Council on Environmental Quality (CEQ) regulations for implementing NEPA, 40 CFR parts 1500 through 1508.

The CEQ regulations enable Federal agencies to establish categories of actions that do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment or Environmental Impact Statement. 40 CFR 1508.4. The DHS Categorical Exclusions are listed in IM 023–01–001–01 Rev. 01, Appendix A, Table 1.

For an action to be categorically excluded, the action must satisfy each of the following three conditions:

1. The entire action clearly fits within one or more of the Categorical Exclusions;

2. The action is not a piece of a larger action; and

3. No extraordinary circumstances exist that create the potential for a significant environmental effect. IM 023–01–001–01 Rev. 01 section V(B)(2)(a)–(c).

If the action does not clearly meet all three conditions, DHS or the Component prepares an Environmental Assessment or Environmental Impact Statement, according to CEQ requirements, MD 023–01, and IM 023–01–001–01 Rev. 01.

DHS has analyzed this action under MD 023–01 Rev. 01 and IM 023–01–001–01 Rev.01. DHS has made a determination that this rulemaking action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This action clearly fits within the Categorical Exclusion found in IM 023–01–001–01 Rev. 01, Appendix A, Table 1, number A3(d): ''Promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, advisory circulars, and other guidance documents of the following nature: (d) Those that interpret or amend an existing regulation without changing its environmental effect.'' This final rule is not part of a larger action and presents no extraordinary circumstances creating the potential for significant environmental effects. Therefore, a more detailed NEPA review is not necessary. DHS seeks any comments or information that may lead to the discovery of any significant environmental effects from this final rule.

J. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

DHS reviewed this final rule and has determined that under Executive Order 13175, *Consultation and Coordination with Indian Tribal Governments,* it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

DHS reviewed this final rule and has determined that it will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, *Governmental Actions and Interference with Constitutionally Protected Property Rights.*

L. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

DHS reviewed this final rule and has determined that it does not create an environmental risk to health or risk to safety that might disproportionately affect children.

M. National Technology Transfer and Advancement Act

DHS reviewed this final rule and determined that it does not use technical standards.

N. Family Assessment

DHS has determined that this action would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

List of Subjects in 8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

Amendments to the Regulations

DHS amends part 214 of chapter I, of title 8 of the Code of Federal Regulations as follows:

PART 214—NONIMMIGRANT CLASSES

■ 1. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1357, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2;

Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

■ 2. Amend § 214.2 as follows:
■ a. In Table 2 to Paragraph (f)—Paragraph Contents, item (2), remove ''I–20 ID'' and add in its place ''Form I–20 or successor form''.
■ b. Paragraph (f)(6)(iii)(B) is revised.
■ c. Paragraph (f)(8)(iii) is removed and reserved.
■ d. Paragraph (f)(9)(ii)(F)(2) is removed and reserved.
■ e. In paragraph (m)(l)(i)(B), remove ''SEVIS Form I–20'' and add in its place ''Form 1–20''.
■ f. The introductory text of paragraph (m)(9)(vi) is revised.

The revisions read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(f) * * *

(6) * * *

(iii) * * *

(B) Medical conditions. The DSO may authorize a reduced course load (or, if necessary, no course load) due to a student's temporary illness or medical condition for a period of time not to exceed an aggregate of 12 months while the student is pursuing a course of study at a particular program level. In order to authorize a reduced course load based upon a medical condition, the student must provide medical documentation from a licensed medical doctor, a licensed doctor of osteopathy, a licensed psychologist, or a licensed clinical psychologist to the DSO to substantiate the illness or medical condition. The student must provide current medical documentation and the DSO must reauthorize the drop below full course of study each new term, session, or semester. A student previously authorized to drop below a full course of study due to illness or medical condition for an aggregate of 12 months may not be authorized by a DSO to reduce their course load on subsequent occasions while pursuing a course of study at the same program level. A student may be authorized to reduce course load for a reason of illness or medical condition on more than one occasion while pursuing a course of study, so long as the aggregate period of that authorization does not exceed 12 months.

* * * * *

(m) * * *

(9) * * *

(vi) *Reduced course load.* The designated school official may authorize an M–1 student to engage in less than a full course of study only where the student has been compelled by illness or a medical condition that has been documented by a licensed medical doctor, a licensed doctor of osteopathy, a licensed psychologist, or a licensed clinical psychologist to interrupt or reduce their course of study. A DSO may not authorize a reduced course load for more than an aggregate of 5 months per course of study. An M–1 student previously authorized to drop below a full course of study due to illness or medical condition for an aggregate of 5 months, may not be authorized by the DSO to reduce their course load on subsequent occasions during their particular course of study.

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2024–06657 Filed 4–2–24; 8:45 am]

BILLING CODE 9111–CB–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2022–0073]

Regulatory Guide: Guidance for a Technology-Inclusive Content of Application Methodology To Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a new Regulatory Guide (RG) 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.'' This new RG provides guidance to assist interested parties and prospective applicants in the development of content for major portions of their safety analysis reports required in applications for permits, licenses, certifications, and approvals by the NRC to ensure that applications for non-light water reactor (non-LWR) facility designs using the Licensing Modernization Project (LMP) process meet the minimum requirements for construction permit, operating license, combined license, or design certification applications.

DATES: RG 1.253, Revision 0, is available on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0073 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0073. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

RG 1.253 and the regulatory analysis may be found in ADAMS under Accession Nos. ML23269A222 and ML22076A002, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Anders Gilbertson, Office of Nuclear Reactor Regulation, telephone: 301–415–1541, email: *Anders.Gilbertson@nrc.gov* and Ramon Gascot Lozada, Office of Nuclear Regulatory Research, telephone: 301–415–2004, email: *Ramon.GascotLozada@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC staff is issuing a new guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe

methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits, certifications, approvals, and licenses.

RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' provides guidance to assist interested parties and prospective applicants in the development of content for major portions of their safety analysis reports required in applications for permits, licenses, certifications, and approvals by the NRC to ensure that applications for non-LWR facility designs using the LMP process meet the minimum requirements for construction permit, operating license, combined license, or design certification applications.

II. Additional Information

RG 1.253 was issued as a draft regulatory guide (DG) with a temporary identification of DG–1404 (ADAMS Accession No. ML22076A003).

The NRC published DG–1404, Revision 0 in the **Federal Register** on May 25, 2023 (88 FR 33846), for a 45-day public comment period. Subsequently, the comment period was extended by 30-days as noted in the **Federal Register** June 28, 2023 (88 FR 41862). The public comment period closed on August 10, 2023. On September 8, 2023, the NRC published a request for public comment on Revision 1 to DG–1404 in the **Federal Register** (88 FR 61989). Revision 1 to DG–1404 provided additional guidance for the scope, level of detail, elements and plant representation for a probabilistic risk assessment supporting an LMP-based construction permit application. The public comment period for Revision 1 to DG–1404 closed on October 10, 2023. Public comments on DG–1404 Revision 0 and Revision 1, and the staff responses to the public comments are available in ADAMS under Accession No. ML23269A223.

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development of major portions of safety analysis report content for these non-LWR applications. The guidance describes the development of major portions of the safety analysis report using the industry-developed guidance contained in Nuclear Energy Institute (NEI) 21–07, Revision 1, ''Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18–04 Methodology,'' (ADAMS Accession No. ML22060A190). The guidance will facilitate the development of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.''

The NRC staff notes it is developing a rule to amend parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-Al66). This RG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this RG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking previously mentioned in this document, or if the Commission issues a final 10 CFR part 53 rule.

The TICAP is an industry led guidance activity focused on the scope and depth of information to include in the portions of a safety analysis report that address the implementation of the LMP methodology described in NEI 18–04, Revision 1, and endorsed by the NRC in Regulatory Guide 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS also recommended specific changes to DG–1404. As set forth in its letter dated March 18, 2024, (ADAMS No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff revised RG 1.253 to address specific ACRS recommendations.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

The table in this rulemaking provides the document description, ADAMS accession number, and, if appropriate, the docket identification number on supporting documents associated with the document that is the subject of this **Federal Register** document.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.''.	ML23269A222	NRC–2022–0073
Regulatory Analysis for DG–1404	ML22076A002	NRC–2022–0073
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology Inclusive Advanced Reactor Applications—Roadmap.' ''.	ML23277A139	NRC–2022–0074

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information.' ''.	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste.' ''.	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose.' ''.	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations.' ''.	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program.' ''.	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs.' ''.	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications.' ''.	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations).' ''.	ML23277A147	NRC–2022–0082
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance.	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''.	ML24024A025	NRC–2022–0074

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

RG 1.253, Revision 0, does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in RG 1.253, applicants and licensees would not be required to comply with the positions set forth in RG 1.253.

V. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2024–07022 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2020–BT–STD–0015]

RIN 1904–AE87

Energy Conservation Program: Clarifying Amendments to the Error Correction Rule

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (''DOE'' or ''the Department'') is amending its procedures for providing public input on possible corrections of errors contained in the regulatory text of energy conservation standard final rules. In this final rule, DOE modifies certain aspects of these procedures to clarify and reflect the Department's intent regarding the error correction process that it previously created. The procedures as amended in this final rule do not in any way restrict, limit, diminish, or eliminate the Secretary's discretion to determine whether to establish or amend an energy conservation standard, or to determine the appropriate level at which to amend or establish any energy conservation standard.

DATES: The effective date of this rule is April 3, 2024.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available. The docket web page can be found at *www.regulations.gov/docket?D=EERE-2020-BT-STD-0015.* The docket web page explains how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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I. Summary of Final Rule

This procedural rule amends DOE's procedures for providing the public with an opportunity to request the correction of a possible error identified in the regulatory text of a final rule that would establish new or amended energy conservation standards prior to the rule's publication in the **Federal Register**.[1] *See* 10 CFR 430.5. On October 9, 2020, DOE issued a notice of proposed rulemaking (''NOPR''), proposing various amendments to 10 CFR 430.5.[2] 85 FR 64071. This final rule adopts some of the NOPR proposals. Specifically, the amendments contained within this final rule clarify that the Secretary was not, and is not, under a mandatory duty to post final energy conservation standard rules online for error-correction purposes, but to do so was, and is, a discretionary and voluntary act.

When DOE elects to post online an energy conservation standard final rule prior to its submission and publication in the **Federal Register**—or what is referred to as the pre-publication final rule for the purposes of this final rule discussion—DOE shall follow the procedures set forth in the error correction process found in 10 CFR 430.5. Additionally, this final rule amends language in 10 CFR 430.5 to clarify that, if DOE posts a rule for error-correction purposes, DOE will continue to strive to provide a 45-day review period for error correction, but it is within DOE's discretion to provide a shorter or longer period.

As for other amendments proposed in the NOPR, DOE is retaining certain of the current regulatory requirements in 10 CFR 430.5. Specifically, DOE is retaining the current definitions, as well as the requirement for DOE to submit for publication in the **Federal Register** a pre-publication final rule that has been posted in accordance with the error correction process. *See* 10 CFR 430.5(b) and (f). DOE is also retaining the language in 10 CFR 430.5(a), except to clarify that the error correction process is an optional and voluntary process. Furthermore, DOE is retaining the current requirements in 10 CFR 430.5(g) and (h).

The adopted amendments are summarized in Table I.1 and compared to the proposed amendments, as well as the requirements prior to the amendments.

TABLE I.1—LIST OF REVISIONS IN THIS DOCUMENT

Section	Current DOE requirement	Proposed revisions from the October 2020 NOPR	Amended requirements
§ 430.5(a) *Scope and purpose.*	Describes the procedures through which DOE will consider submissions regarding potential Errors for those rulemakings establishing or amending energy conservation standards under EPCA.	Rename section and separate into two subsections; and clarify there is no affirmative obligation on the Secretary to provide the public with an opportunity for error correction review.	Retain current regulatory language found in § 430.5(a), except for adding ''optional'' before ''procedure'' and ''may'' before ''accept and consider'' to clarify the error correction process is a procedure that may be voluntarily implemented by the Secretary.
§ 430.5(b) *Definitions*	Defines ''Act,'' ''Error,'' ''Rule,'' and ''Secretary''.	Revise definition of ''Error'' and replace the term ''Rule'' with the term ''Pre-publication draft''.	Retain current definitions found in § 430.5(b).
§ 430.5(c) *Posting of rules*	Describes the beginning of the error correction process.	Revise section title; clarify that the posting of a pre-publication final rule for error correction review is within the Secretary's discretion and if posted, it would be available for a period of 45 days, but the review period may be shortened or lengthened at the Secretary's discretion; remove any implication that the Secretary will publish a rule that has undergone error correction review; and revise the disclaimer notice language to be consistent with other proposed amendments.	Adopt the proposal to clarify that the posting of a pre-publication final rule for error correction review is within the Secretary's discretion in § 430.5(c)(1) and if posted, it would be available for a period of 45 days, but the review period may be shortened or lengthened at the Secretary's discretion in § 430.5(c)(2). Retain current disclaimer notice text in § 430.5(c)(3).
§ 430.5(d) *Request for Correction.*	Explains how to submit a request to DOE to correct an Error and describes what a request must contain.	Update to include the term ''Pre-publication draft;'' clarify that the Secretary is not obligated to take action on an error correction request; and clarify that the ECR would be limited to identifying Errors in the regulatory text of a pre-publication final rule.	Adopt proposed amendments to § 430.5(d), with the exception of replacing ''pre-publication draft'' with ''rule.''
§ 430.5(e) *Correction of rules.*	Describes the courses of action DOE may undertake if it believes an identified error needs to be corrected.	Revise to impose no requirement for publication in the **Federal Register** upon completion of the error correction process and to clarify DOE's authority to determine the appropriate remedy for an identified error.	Retain current regulatory language in § 430.5(e).
§ 430.5(f) *Publication in the **Federal Register**.*	Describes how DOE will eventually publish a final rule in the **Federal Register**.	Revise to prevent the inference that publication in the **Federal Register** is the only outcome available at the conclusion of the error correction process.	Retain current regulatory language in § 430.5(f), with the exception of two clarifying amendments and two minor non-substantive edits.
§ 430.5(g) *Alteration of standards.*	Explains that DOE may change a standard that has been posted but not yet published in the **Federal Register**.	Remove as unnecessary in light of amendments proposed for the remaining sections of 10 CFR 430.5.	Retain current regulatory language in § 430.5(g).

[1] DOE typically posts pre-publication versions energy conservation test procedures and standards rulemaking documents on a publicly accessible website. However, the posting of those rulemaking documents is separate from the error correction process outlined in 10 CFR 430.5.

[2] Although DOE took notice and comment on the NOPR, agency rules of procedure and practice, such as the one described in this document, are not subject to the requirement to provide prior notice and an opportunity for public comment pursuant to authority at 5 U.S.C. 553(b)(A). See section III of this document for additional discussion.

TABLE I.1—LIST OF REVISIONS IN THIS DOCUMENT—Continued

Section	Current DOE requirement	Proposed revisions from the October 2020 NOPR	Amended requirements
§ 430.5(h) *Judicial review*	Explains the timing related to a potential petition for review that may be filed pursuant to 42 U.S.C. 6306.	Renumbered to § 430.5(g) and included new text to reaffirm that pre-publication final rules are not final rules or prescribed rules within the meaning of EPCA.	Retain current regulatory language in § 430.5(h).

While this final rule contains amendments to the error correction process—the process will be applied to identify errors in pre-publication final rules that might be difficult to remedy due to EPCA's anti-backsliding provision (42 U.S.C. 6295(o)(1))—these modifications do not impair DOE's ability to meet its statutorily prescribed deadlines for either establishing or amending energy conservation standards. Instead, these modifications focus solely on DOE's intent to allow the public to identify possible technical and objective errors in certain pre-publication final rules. DOE will use the error correction process only to seek input on the narrow question of whether an error has occurred in the regulatory text of a pre-publication final rule document.

The remainder of this final rule discusses comments received in response to the NOPR, as well as DOE's responses and the amendments adopted in this final rule.

II. General Discussion

The NOPR included a summary detailing how DOE intended to amend specific sections of the ECR to better align with the rule's intended purpose. DOE received seven comments in response to the NOPR (*see* Table II.1) voicing various levels of support and opposition.

TABLE II.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE NOPR, 85 FR 64071

Commenter(s)	Abbreviation	Comment No. in the docket	Commenter type
A. O. Smith Corporation	A.O. Smith	8	Manufacturer.
Air-Conditioning, Heating, and Refrigeration Institute, the Association of Home Appliance Manufacturers, and the National Electrical Manufacturers Association.	Joint Industry Commenters	3	Manufacturers.
American Public Gas Association and Spire Inc	APGA/Spire	5	Utility Associations.
GE Appliances	GEA	7	Manufacturer.
Joseph Richardson	Richardson	2	Individual.
Lennox International Inc	Lennox	4	Manufacturer.
Natural Resources Defense Council and Appliance Standards Awareness Project.	NRDC/ASAP	6	Energy Efficiency Advocates.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[3]

A. General Comments

Commenters generally expressed support of DOE's proposal to clarify the application of the error correction process, but they also harbored reservations regarding certain aspects of DOE's proposals. For example, APGA/Spire supported the Department's proposed amendments to clarify that the rule does not establish a non-discretionary duty to publish pre-publication final rules in the **Federal Register** after undergoing error correction review. (APGA/Spire, No. 05, at p. 2) However, those commenters disagreed with the proposal's attempt to clarify the extent of DOE's discretion with respect to the posting of documents for review. (APGA/Spire, No. 05, at p. 2) Similarly, the Joint Industry Commenters, while supportive of DOE's efforts to better reflect the Department's intent behind the rule, noted their collective concerns that the proposal would curtail DOE's ability to cure errors and limit public certainty regarding the error correction process. (Joint Industry Commenters, No. 03, at p. 1) These commenters stated that the ECR does not impose non-discretionary mandates superseding DOE's inherent discretion to make policy determinations but, in their view, the ECR is separate from DOE's policy discretion and the proposal's attempt at clarifying its discretion instead created uncertainty. (Joint Industry Commenters, No. 03, at pp. 1–2)

Lennox agreed with the NOPR's proposed amendment to clarify that the ECR does not create a nondiscretionary duty to publish pre-publication final rules at the end of the review process. (Lennox, No. 4 at p. 5 (referencing 85 FR 64072)) But Lennox asserted that the entire error correction process should not be made voluntary. (Lennox, No. 4 at p. 5) GEA supported the comments submitted by the Joint Industry Commenters and added that a rule containing an error making a material difference to that rule should be corrected and that having a consistent, transparent, and predictable error correction process would benefit all parties. (GEA, No. 7 at p. 2)

A.O. Smith supported the idea of narrowly tailoring the error correction process to correct clerical errors without reopening portions of the rulemaking process, but it expressed it opposition to the proposed amendments contained within the NOPR and questioned the legality of the rulemaking in light of the Ninth Circuit's opinion.[4] (A.O. Smith, No. 08 at p. 1)

Separately, one individual commenter supported the rule in its entirety and explained that the proposal offered a good way for the Department to ''remain as transparent as possible with the public'' and maintain a relationship that allowed for public involvement in the rulemaking process. This commenter supported the existence of a method to correct and amend documents to more

[3] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking for amending the error correction process. (Docket No. EERE–2017–BT–STD–0015, which is maintained at *www.regulations.gov/#!docketDetail;D=EERE-2017-BT-STD-0015*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

[4] See *Natural Resources Defense Council* v. *Perry*,940 F.3d 1072 (9th Cir. 2019).

accurately report data relevant to DOE activities and projects. (Richardson, No. 02 at p. 1)

In the NOPR, DOE clarified that the Secretary was not, and is not, under a mandatory duty to post pre-publication final rules online, but to do so was, and is, a discretionary and voluntary act. DOE is not compelled by statute to offer such a procedural step. Therefore, DOE proposed amending 10 CFR 430.5(c) to account for the Secretary's discretion to post energy conservation standard final rules for error correction review. 85 FR 64071, 64073. As discussed further in the Section-by-Section Analysis, DOE is adopting this proposal to amend 10 CFR 430.5(c) in this final rule.

Furthermore, DOE initially proposed to clarify that the ECR does not create a non-discretionary duty to publish in the **Federal Register** a pre-publication final rule that has been posted in accordance with the error correction process. 85 FR 64071, 64074. However, DOE has determined it will retain the language currently found in 10 CFR 430.5(f). DOE notes that while the ECR provides a means by which interested parties may notify DOE of potential errors found in the regulatory text of a pre-publication final rule document that has been posted for public viewing, it is not a means for raising issues relating to the determinations and conclusions made by the Secretary in an energy conservation standard rulemaking. The posting of an energy conservation standards final rule signals the end of DOE's substantive analysis and decision-making regarding the applicable standards. Therefore, upon conclusion of the error correction process, DOE will submit a final rule, correcting any identified errors, to the **Federal Register** for publication in accordance with the requirements in 10 CFR 430.5(f). DOE's decision not to amend 10 CFR 430.5(f) at this time also recognizes the narrow scope and purpose of the error correction process, which DOE notes is separate from the Department's policy-making discretion.

B. Comments Concerning EPCA's Anti-Backsliding Provision

Some commenters asserted that the NOPR mistakenly relied on EPCA's anti-backsliding provision, 42 U.S.C. 6295(o)(1), to justify the amendments proposed. The Joint Industry Commenters argued that DOE fundamentally misunderstands the anti-backsliding rule, which causes the premise behind the error correction process to be faulty. If there is an error in the analysis provided for an energy conservation standard, these commenters argue that the standard is not justified under EPCA's required economic and technical justifications. In their view, this would mean that the anti-backsliding provision cannot legally be used to maintain the standard. (Joint Industry Commenters, No. 03 at p. 6) They urged DOE to determine that it is authorized to correct errors in its analysis at any point if the errors lead to an energy conservation standard that is not justified under EPCA. While this would ultimately make the error correction process unnecessary, it would result, according to the commenters, in a better reading of EPCA—*i.e.,* that the anti-backsliding provision does not limit DOE from correcting standards that were not actually justified in the first place. (Joint Industry Commenters, No. 03 at pp. 6–7) GEA also noted that EPCA's anti-backsliding provision does not prevent error correction and that any concern regarding a reduction in efficiency requirements through error correction is outweighed by the importance of maintaining the overall integrity of the energy conservation program. (GEA, No. 07 at p. 2)

Under EPCA, DOE may not prescribe any amended standard that either (1) increases the maximum allowable energy use (or water use in the case of certain types of water products and equipment) or (2) decreases the minimum require energy efficiency of a covered product or covered equipment. (42 U.S.C. 6295(o)(1)) Although DOE agrees with commenters that retaining flexibility to correct any errors is important for integrity of the energy conservation program, industry commenters' reading of EPCA's anti-backsliding provision is inconsistent with *Abraham's* reading of that provision. *See NRDC* v. *Abraham,* 355 F.3d 179, 196 (2d Cir. 2004) (noting that ''publication [of an energy conservation standard] must be read as the triggering event for the operation of section 325(o)(1).''). In light of *Abraham,* proceeding in the manner suggested by these commenters presents the risk that a reviewing court would invalidate an attempt by DOE to correct an error after publication of a final rule if the result of that correction was a standard with a greater maximum allowable energy use or decreased required energy efficiency as compared to the final rule that contained the error. Regardless of the reading that should be ascribed to the anti-backsliding provision, DOE concludes that the adoption of the ECR process (as revised by this rule) will be helpful in minimizing the risk that DOE may inadvertently adopt a final rule containing an objective error.

Further, DOE's efforts to address errors as part of the ECR's process are necessarily limited to addressing errors that affect the amended standards' regulatory text prior to the publication of a final rule amending the energy conservation standards for a covered product or covered equipment. To the extent that an error appears outside of the posted regulatory text of a draft pre-publication document, such as in a supporting rulemaking document it authored (*e.g.,* technical support document), DOE may, under its own discretion, make corrections to those documents, but these types of issues will be handled on an individual basis as appropriate outside of the ECR process.

C. Other Comments

DOE also received comments on other topics. NRDC/ASAP noted that nothing in the proposal conferred to DOE the authority to delay a rule or impact a standard the Department must select other than by providing an opportunity for DOE to correct any inadvertent mistakes. They suggested DOE add language to the ECR to explicitly state that the rule does not disturb or modify any of DOE's statutory obligations. (NRDC/ASAP, No. 06 at p. 1) They further suggested that DOE clarify in the final rule regarding the timeline and general procedures for error correction, including specifying when a rule would be made available for review, the duration of the review period, and whether the Department envisioned initiating a second error correction process for a pre-publication draft document. (NRDC/ASAP, No. 06 at p. 2)

A.O. Smith claimed that the proposal would have significant impacts on manufacturers because it would allow for the rulemaking process to be ''reopened in perpetuity'' by not limiting the Secretary's authority, would allow for the introduction of new data, additional analyses, and would create the potential for a revised final decision to result if an error is identified. (A.O. Smith, No. 08 at p. 2) Alternatively, A.O. Smith supported the original 2016 ECR, which ensured any request ''must identify the claimed error, explain how the record demonstrates the regulatory text to be erroneous, and state what the corrected version should be.'' (A.O. Smith, No. 08 at p. 2)

The ECR does not permit DOE to ignore EPCA's statutory deadlines or other applicable deadlines when finalizing a rulemaking action, and it is within DOE's authority to re-evaluate the document within the applicable deadline for that rulemaking. Nothing in the ECR authorizes DOE to circumvent

statutory or other applicable deadlines. Additionally, when an energy conservation standards final rule is posted for error correction review, its posting signals the end of DOE's substantive analysis and decision-making regarding the applicable standards, thus eliminating any concern that the rulemaking would be reopened in perpetuity. Accordingly, the ECR remains limited to identifying errors relating to the standards regulatory text in a pre-publication draft.

D. Section-by-Section Analysis of Comments

Section 430.5(a)

In the NOPR, DOE proposed to amend 10 CFR 430.5(a) by renaming the section and separating the section into two separate subsections that address the purpose and scope of the regulations in this section. The proposed subsections described (1) the procedures through which the Department may accept and consider public input for review of a pre-publication final rule document's regulatory text, and (2) the scope of the procedure that would be available. 85 FR 64071, 64072–64073.

DOE received comments opposing its proposal to clarify that the error correction process was strictly a voluntary activity on the part of the Department and did not create a legal obligation to offer the public an additional review period for energy conservation standards beyond that which is already provided under EPCA and other applicable provisions of the Administrative Procedure Act.

The Joint Industry Commenters disagreed with this aspect of the proposal. They argued that the ECR's review process should not be a discretionary activity and must provide stakeholders with a process to ensure no errors in the analysis exist before publishing a rule that would create an unjustified standard. (Joint Industry Commenters, No. 03 at p. 2) APGA/Spire similarly suggested that DOE strike the word ''voluntary'' from § 430.5(a)(1) as proposed because there are no mandatory submissions for the public at large, making it redundant to characterize such submissions as ''voluntary.'' (APGA/Spire, No. 05 at p. 2) GEA asserted that the proposal lacked justification for leaving the implementation of the ECR review process solely to DOE's discretion. (GEA, No. 07 at p. 2) Lennox opposed characterizing the ECR review as voluntary because it would limit the rule and undermine the critical protections provided to industry and stakeholders from inaccurate rules being made final. (Lennox, No. 04 at p. 4, 1) In its view, the ECR should be mandatory for all energy conservation standards as it would help avoid litigation costs resulting from efforts to correct erroneous rules. Lennox added that requiring all energy conservation standard rulemakings to undergo the error correction process would enable DOE to avoid errors that would disrupt the supply chain and avoid the risk of consumers being harmed through mislabeled equipment. (Lennox, No. 04 at p. 2) In addition to there being a clear need for error correction review to ensure that all energy conservation standards are technologically feasible and economically justified under 42 U.S.C. 6295(o)(2), Lennox argued that making the error correction process voluntary would destroy public confidence in that process. (Lennox, No. 04 at pp. 3–4)

GEA challenged DOE's decision to limit the scope of the error correction process to final rules and argued DOE should determine that it is authorized to correct errors in its analysis at any time if the error would result in a standard not justified under EPCA. GEA suggested that DOE make the error correction process mandatory for all energy conservation standard rulemakings. In its view, doing so would provide consistency, transparency, and predictability to the rulemaking process, which decreases uncertainty and the regulatory burden. (GEA, No. 07 at p. 2)

NRDC/ASAP supported DOE's proposal to make the review process discretionary and asserted that some circumstances may require waiving the normal process, making a shorter review period or no review period justified. They encouraged DOE to include in the final rule a clarification that some products may warrant shorter review periods. (NRDC/ASAP, No. 06 at 2)

DOE's proposal also noted that it would continue to exclude energy conservation standards set through the issuance of a direct final rule pursuant to section 325(p)(4) of EPCA (42 U.S.C. 6295(p)(4)). 85 FR 64071, 64073. The Joint Industry Commenters and Lennox supported this approach because, in their view, EPCA (through section 325(p)(4)) already provided the necessary opportunity for review and comment prior to the finalization of such rules. (Joint Industry Commenters, No. 03 at p. 2; and Lennox, No. 04 at p. 4)

EPCA mandates certain procedures that DOE must follow in its rulemakings. *See* 42 U.S.C. 6295(p). Beyond the procedures mandated in EPCA, the Secretary is under no statutory obligation to provide the public with an additional opportunity to submit error correction requests on any document. DOE has considered the approach of turning this process into a mandatory one for all energy conservation standard rulemakings, as suggested by these commenters, but notes that doing so would be both impractical and unnecessary. DOE notes that the public has many opportunities to review and provide input on EPCA rulemakings already during the robust rulemaking process as provided by EPCA and other applicable provisions of the Administrative Procedure Act. Additionally, DOE recognizes that situations may arise, such as complying with a judicial decree, that would necessitate shortening or waiving of the error correction process. DOE reminds commenters that opening an energy conservation standard rulemaking to error correction review is only to confirm that no errors exist in the regulatory text prior to anticipated publication; it is not intended for parties to argue the findings and conclusions of the rulemaking. The voluntary nature of the ECR provides the Secretary the flexibility to subject specific rulemakings to one last review and not unnecessarily elongate the rulemaking process for energy conservation standard rulemakings.

DOE's proposal to amend 10 CFR 430.5(a) was intended to describe an error correction process that is an optional and voluntary, specifically on the part of DOE. However, given DOE's decision in this final rule to retain the current regulatory requirements found in 10 CFR 430.5(f), which prescribe the steps DOE will take to publish a final rule upon conclusion of the error correction process, DOE no longer believes it is necessary at this time to extensively revise the text in 10 CFR 430.5(a), except to clarify DOE is under no legal obligation to offer the public this additional error correction process from the outset. Accordingly, DOE is retaining the current regulatory provisions contained in 10 CFR 430.5(a), with the exception of adding the term ''optional'' before ''procedure'' and ''may'' before ''accept and consider'' to clarify it is within the Secretary's discretion to allow for an error correction review of a final energy conservation standard rule.

Section 430.5(b)

DOE proposed amending the definition of ''Error'' found in 10 CFR 430.5(b) to more narrowly define it as meaning an objective mistake in the regulatory text of a pre-publication final rule document that may result in the

establishment or amendment of an energy conservation standard. DOE also proposed replacing the term ''Rule'' with the term ''Pre-publication draft.'' 85 FR 64071, 64077.

The Joint Industry Commenters opposed narrowing the definition of ''Error'' and argued that substantial errors can occur outside of the regulatory text and its erroneous results will not be explicit or disclosed in the regulatory text. They argued that the review should be extended to include errors that may exist in the Technical Support Document as well as the preamble to a final rule as these errors could also result in arbitrary and capricious standards. (Joint Industry Commenters, No. 03 at pp. 2–3)

It is DOE's current practice to post a pre-publication copy of a rulemaking document online, prior to the rule's publication in the **Federal Register**, for the public to access. This action is separate and distinct from the error correction process. Given that DOE uses the term ''pre-publication'' when posting and disseminating these documents, DOE believes it may create potential confusion for DOE to adopt the proposed definition for ''pre-publication draft'' in this final rule. Additionally, the use of the term ''draft'' may also suggest that the final rule document is open to further deliberations and policy considerations. Accordingly, DOE is not adopting its proposal to amend 10 CFR 430.5(b), and is retaining the current definitions found in 10 CFR 430.5(b) in this final rule.

However, DOE's decision to not amend 10 CFR 430.5(b) does not diminish the intent of the ECR, which is to minimize the potential risk of finalizing and publishing the regulatory text of an energy conservation standard with an apparent error that establishes a level that was not intended by DOE. With the utilization of the ECR, DOE is seeking to avoid the need for any subsequent rulemaking, correcting that error, that might violate the anti-backsliding provision of 42 U.S.C. 6295(o)(1). Therefore, by addressing concerns with the draft regulatory text of an energy conservation standard before that text is finalized, DOE can significantly reduce the risk of litigation over an unintended error. This same difficulty does not exist for an error identified in the preamble text or Technical Support Document published in support of an energy conservation standard. For that, DOE can issue a correction to remedy such a mistake. And in the event an error appears in a Technical Support Document for a given rule, if DOE agrees that error impacts the resulting standard that DOE intended to adopt (as reflected in a posted draft document), then DOE retains the authority to make the appropriate correction in that posted draft document.

Section 430.5(c)

The NOPR proposed revising 10 CFR 430.5(c) to clarify that the Secretary was not, and is not, under a mandatory duty to post pre-publication final rules online for error correction review, but to do so was, and is, a discretionary and voluntary act. If the Secretary chooses to post a final rule online for error correction review, the document would be available for 45 days, but the Secretary in his or her discretion may shorten or lengthen that time period. DOE also proposed revising 10 CFR 430.5(c) to clarify that the ECR does not impose a deadline by which the Secretary must determine whether to establish or amend an energy conservation standard, or when the Secretary must submit a final rule for publication in the **Federal Register**. DOE further proposed revising the text in the disclaimer notice, which is posted along with a final rule made available for error correction review, to explain that the Department may conduct additional review of the regulatory test prior to finalizing a potential energy conservation standard to ensure that the text is consistent with the Secretary's intent and with data and analysis available at the time of posting. 85 FR 64071, 64073.

APGA/Spire objected to this aspect of the proposal, arguing that every final rule should be posted routinely since DOE would have complete discretion on what to do with any comment received under paragraph (e). (APGA/Spire, No. 05 at p. 2) The Joint Industry Commenters objected to the proposal's failure to obligate DOE to post pre-publication draft final energy conservation standard rules. In their view, it is critical that the public be given the opportunity to review these types of documents for errors that could result in a standard that is not, in fact, technically or economically justified. (Joint Industry Commenters, No. 03 at p. 3) They added that the Secretary should not retain the discretion to determine whether to post pre-publication drafts because any rulemaking that may impact an energy conservation standard should be subject to error correction review. (Joint Industry Commenters, No. 03 at p. 4) These commenters also supported posting a pre-publication draft for the proposed continuation of the 45-day review period, but disagreed with the proposal's inclusion to provide the Secretary the discretion to adjust the length of the review period. They suggested there should be a set period of time that the rule is posted and the Secretary may extend that time period if needed, but that this time period cannot be limited to less than the 45-day window on a whim. (Joint Industry Commenters, No. 03 at p. 3)

Lennox also objected to a shortening of the 45-day review period because energy conservation standard rulemakings are complex and that modifying the ECR to permit a shorter review period would ''gut'' the ECR process by allowing the Secretary to unilaterally provide inadequate time for a meaningful review. (Lennox, No. 04 at p. 4) Other commenters suggested that DOE include a firm minimum time limit for error correction requests to be considered, such as 30 days. (NRDC, et al., No. 06 at p. 1)

Furthermore, Joint Industry Commenters and Lennox were supportive of DOE's proposal to retain discretion on whether a pre-publication draft that has undergone error correction review is submitted for publication as a final rule. (Joint Industry Commenters, No. 03 at p. 4; Lennox, No. 04, at p. 1) The Joint Industry Commenters agreed with DOE's clarification to remove any inference of an implied timeline for the Secretary's decision to publish a potential rule that was subject to the error correction process and that the Secretary should retain discretion to determine the degree to which the document may or may not be amended. (Joint Industry Commenters, No. 03 at p. 4) These commenters agreed with DOE that the error correction process should not obligate the Secretary to publish a document simply because that document has completed the error correction process. They asserted that DOE has broad authority to execute its statutory obligations and that the ECR's scope is limited only to the opportunity for stakeholders to comment on errors and DOE's obligation to consider those comments. (Joint Industry Commenters, No. 03 at p. 4)

The Joint Industry Commenters also supported DOE's proposed revision to the disclaimer in § 430.5(c)(3) that DOE may conduct additional review of the regulatory text prior to finalizing a standard to ensure that the text itself is consistent with the Secretary's intent and relevant data and analysis available at the time of posting. They also supported DOE's proposed revision emphasizing that it is ''within the 'Secretary's discretion to determine the appropriate remedy'' for an error identified during the error correction process. (Joint Industry Commenters, No. 03 at p. 4)

As previously noted, EPCA already specifies the procedures DOE is mandated to follow in an energy conservation standard rulemaking. The error correction process is an extra step that DOE is choosing to adopt as a tool to help DOE avoid promulgating a final energy conservation standard rule with an apparent error. It is DOE's judgment that not all energy conservation standard rulemakings will need to undergo a 45-day review period. For example, there may be instances where an unanticipated legal obligation may arise, or a statutory deadline may be approaching, that may necessitate a modification to a 45-day review period. While DOE will continue to strive to provide a 45-day review period, retaining flexibility to account for case-by-case circumstances would enable DOE to continue offering the public this additional review opportunity while accounting for those circumstances where a 45-day review period is not warranted or feasible. Upon posting of a pre-publication draft, the public will be notified of the length of the review period for that specific energy conservation standard final rule.

Moreover, posting a pre-publication final rule for review under this process is an additional step in the already comprehensive review process the Department follows when developing a standard in accordance with EPCA's requirements. Providing this step—which itself is a discretionary act by DOE—offers the public with a final opportunity, not required under EPCA, to help DOE in verifying that no errors in the regulatory text went unnoticed and unaddressed. Although DOE anticipates that this step would be routinely provided, it may not be necessary to do so for every energy conservation standard rulemaking and requiring it in those instances where it would be unnecessary or impractical to do so would unnecessarily restrict DOE's flexibility to carry out its statutory obligations under EPCA or other legal obligations in an efficient manner. Rigidly applying a mandatory minimum review period requirement not only ignores the potential for conflicts with preexisting statutory deadlines but also assumes that all energy conservation standard rulemakings are the same. Not every energy conservation standard rulemaking will require this additional review period and to mandate one may unnecessarily lengthen the rulemaking process.

With these considerations in mind, DOE is adopting its proposal to amend 10 CFR 430.5(c) to clarify that the Secretary was not, and is not, under a mandatory duty to post pre-publication final rules online for error correction review, but to do so was, and is, a discretionary and voluntary act. DOE is also adopting its proposal to amend 10 CFR 430.5(c) to note that it will ordinarily post the pre-publication final rule online for a period of 45 calendar days, but noting that the period for review may be shortened or lengthened to best serve the needs of that rulemaking in accordance with DOE's statutory or other legal obligations.

While DOE is adopting the aforementioned proposals in this final rule, DOE is not adopting the remaining revisions proposed in the NOPR for 10 CFR 430.5(c)(2). Those revisions concerned the submittal of rules for publication and DOE's authority to amend standards prior to publication. DOE's decision to not adopt those proposed revisions is due to repetitive nature of some of the language, as well as the decision to retain the current requirements in 10 CFR 430.5(f) and (g). Section 430.5(c) as adopted in this final rule already expresses that the Secretary is not obligated to post pre-publication final rules on a publicly accessible website for public review. Adopting the proposed revision that it would be in the Secretary's discretion both before and after posting of a pre-publication final rule to determine whether to establish or amend an energy conservation standard would conflict with DOE's decision to retain the current requirements in 10 CFR 430.5(f) and (g). Therefore, to maintain the current numbering in 10 CFR 430.5(c), DOE has made slight clarifying amendments to revise and renumber the proposed regulatory text that DOE is adopting in this final rule.

Furthermore, due to DOE's decision to retain the current definitions in 10 CFR 430.5(b), DOE is retaining the current disclaimer notice text found in 10 CFR 430.5(c)(3).

Section 430.5(d)

In the NOPR, DOE explained how the public could submit a request for error correction, what errors will be reviewed, and identified the evidence the Department would accept in considering such a request under 10 CFR 430.5(d). Specifically, DOE proposed to clarify that the Secretary would not be obligated to take an action, and would have the discretion to choose whether to correct an error properly identified and determined to be consequential. The proposal also explained that the review would be limited to identifying Errors in the regulatory text and not be expanded to include issues related to the policy decision itself; policy decisions would continue to remain strictly within the discretion of the Secretary. 85 FR 64071, 64073.

The Joint Industry Commenters opposed DOE's proposal for 10 CFR 430.5(d) and argued that the Secretary lacks the discretion to not amend a consequential or inconsequential error properly identified. While the commenters agreed that it is within the Secretary's discretion in deciding not to act when an inconsequential error is identified, they asserted that in those instances where an error is uncorrected, DOE should explain its reasons for doing so. (Joint Industry Commenters, No. 03 at p. 4) When deciding not to act on a consequential error, the Joint Industry Commenters argued that the Secretary should explain why no action is being taken. (Joint Industry Commenters, No. 03 at pp. 4–5) The Joint Industry Commenters reiterated that DOE should not limit error review to the regulatory text and should consider addressing errors in the technical support document and the preamble if the error substantially affects the resulting standard in the regulatory text. (Joint Industry Commenters, No. 03 at p. 5) The Joint Industry Commenters also argue that the evidence used to substantiate the error should not be limited to the existing rulemaking record—any evidence that may substantiate an error should be permitted, including evidence that is not part of the existing record. (Joint Industry Commenters, No. 03 at p. 5)

Determining whether a purported error in a pre-publication final rule is, actually, an error, and, if so, whether such error is consequential or inconsequential—along with the decision on how to handle that error—resides solely within the Secretary's discretion under 10 CFR 430.5(d)(1). The Secretary is also under no obligation to consider a request that does not comply with 10 CFR 430.5(d). As a practical matter, DOE likely would consider an inconsequential error as one not meriting a response, while a consequential error likely would be addressed in the form of a correction to the relevant regulatory text.

While some commenters suggested that DOE accept evidence not previously included in the record, DOE again emphasizes that the error correction process is the final step immediately prior to when DOE submits a document to the **Federal Register** for publication. At this stage, all of the information pertaining to the substance of the rulemaking should have already been submitted to DOE for its consideration. If DOE were to permit the

submission of additional information at this late juncture for consideration, the risk of parties withholding valuable and useful information for DOE to consider until the error correction process would be considerably higher, resulting in a process that would adversely impact the rulemaking process by delaying finality to the rulemaking. Moreover, DOE wishes to ensure that parties provide as much information as possible during the relevant and appropriate stages of a given rulemaking—that is, during any pre-NOPR stages, which DOE typically offers, as well as in response to a designated comment period for a NOPR or supplemental NOPR. Commenters have these multiple opportunities to bring data or information to the Department's attention during the rulemaking process. Accordingly, DOE is declining to adopt the approach suggested by the commenters and will continue to restrict consideration of available data and evidence to information that is already part of the relevant rulemaking record.

Section 430.5(e)

In the NOPR, DOE explained that this section would continue to describe the course of action that the Department may take in the event that a request for correction has appropriately identified an error. DOE proposed new text explaining the Secretary's authority to determine the appropriate remedy for an error identified and the Secretary's discretion to initiate additional review of the regulatory text so that it mirrors the Secretary's intent. 85 FR 64071, 64074

In response to the NOPR, Joint Industry Commenters recommended that DOE respond to every error correction request submitted even if the Secretary decides not to act under 10 CFR 430.5(e). In their view, the requester should be notified that its request for review was received, considered, and provided a rationale for why the Department decided not to act upon the request. (Joint Industry Commenters, No. 03 at pp. 5–6)

The Joint Industry Commenters further concurred with DOE's proposal to clarify that the ECR does not establish any obligation on the Secretary to publish a pre-publication draft document upon completion of the error correction process. Joint Industry Commenters acknowledged timing for publication remains within the Department's discretion, which are separate and apart from the error correction process. (Joint Industry Commenters, No. 03 at p. 5)

In light of DOE's decision to not amend the regulatory requirements currently found in 10 CFR 430.5(f), as discussed in more detail below, DOE will be retaining the regulatory text currently found in § 430.5(e). In DOE's view, the ECR process is designed solely as an additional review period to address errors that may be contained in the regulatory text of a draft pre-publication document. In those cases where DOE agrees that a properly submitted error correction request identified an error in the posted text and that error requires correcting, DOE's response will come in the form of DOE's correction of that error. If DOE concludes that any request for error-correction is not valid, and if it has identified no errors on its own, DOE will proceed to submit the rule for publication in the **Federal Register** in the same form it was previously posted. By doing so, the Department will effectively be rejecting any error-correction requests it has received, and will ordinarily not respond directly to a requester or provide additional notice regarding the request.

Compelling DOE to individually address each error correction request submitted in instances where no change is merited is not an appropriate use of DOE's limited resources. Moreover, in DOE's experience, many of the error correction requests that DOE receives are transmitted at the end of the error correction process and often do not identify what this rule defines as ''Errors.'' Therefore, at this time, DOE declines to implement any requirements that it affirmatively address every error correction request received. DOE will, however, docket all properly submitted error correction requests in the appropriate docket to ensure that the public is aware of any properly submitted requests that were received.

DOE notes that commenters continue to remain free to submit input to the relevant docket throughout the duration of the rulemaking to help inform DOE regarding any aspects of that rulemaking.

Section 430.5(f)

In the NOPR, DOE proposed revising 10 CFR 430.5(f) to prevent the inference that publication in **Federal Register** is the only outcome available at the conclusion of the error correction process. 85 FR 64071, 64074. While some commenters asserted that the Secretary is not obligated to submit a pre-publication final rule for publication in the **Federal Register** at the end of the review process and that it remains within the Secretary's discretion to determine what happens once the review period concludes (*see* Joint Industry Commenters, No. 03 at p. 5–6; Lennox, No. 04 at 5; NRDC/ASAP, No. 06 at p. 1), one commenter opposed DOE's proposal and questioned the legality of the rulemaking considering a decision from the United States Court of Appeals for the Ninth Circuit. *Natural Resources Defense Council* v. *Perry,* 940 F.3d 1072 (9th Cir. 2019) (A.O. Smith, No. 8 at p. 1) Additionally, others argued that DOE is obligated to provide a publicly available statement detailing how any properly received requests were handled. (Lennox, No. 04 at p. 4) Commenters stated that if DOE is unable to fix an error identified, then DOE must provide a consistent process to help ensure energy conservation standards are supported by error-free analysis that is justified under EPCA. (Joint Industry Commenters, No. 03 at p. 6)

At this time, DOE is retaining the current regulatory text found in 10 CFR 430.5(f), notwithstanding two clarifications and two minor non-substantive changes to reflect updated cross-references to amended 10 CFR 430.5(c). As explained in the NOPR, the Ninth Circuit held that 10 CFR 430.5(f) created a non-discretionary duty to submit draft rules (*i.e.,* a pre-publication draft) for publication in the **Federal Register** within 30 days of the close of the error correction submission period. Although DOE declines to adopt its proposal to amended 10 CFR 430.5(f) as discussed in the NOPR, DOE continues to maintain that the error correction process is intended to correct errors, as defined in 10 CFR 430.5(b), and is separate from DOE's policy-making discretion.

In this final rule, DOE provides two clarifying amendments to the current regulatory text found in 10 CFR 430.5(f). Specifically, DOE amends 10 CFR 430.5(f)(2) to remove the term ''in due course.'' The use of the term ''in due course'' in 10 CFR 430.5(f)(2) could imply that a final rule for which DOE does not receive any properly filed error correction requests and determines that no corrections are necessary, is subject to a different or longer time frame for submission for publication in the **Federal Register** than a final rule for which DOE has received one or more properly filed requests and determines that no corrections are necessary (*see* 10 CFR 430.5(f)(1). This is not the case. In either scenario, DOE expects that the rule will be submitted for publication in the **Federal Register** within the 30 days allotted for rules that actually require correction prior to submittal in 10 CFR 430.5(f)(3). DOE also amends 10 CFR 430.5(f)(3) to add ''or discovers an Error on the Secretary's own initiative.'' This amendment addresses the scenario of when the Secretary discovers an Error

on his or her own initiative and determines a correction is necessary—a scenario that had only been addressed in 10 CFR 430.5(e), but has not been explicitly included as a scenario in 10 CFR 430.5(f).

DOE will continue to consider the impact of the Ninth Circuit decision on 10 CFR 430.5(f), as well as any impact a proposed change to § 430.5(f) would have on stakeholders in providing certainty and transparency during the error correction process. Should DOE desire to amend the language in paragraph (f) of this section, DOE will consider and follow the appropriate rulemaking procedures for making such amendments. The decision to maintain the current language in § 430.5(f) does not in any way restrict, limit, diminish, or eliminate the Secretary's discretion to determine whether to establish or amend an energy conservation standard, or to determine the appropriate level at which to amend or establish any energy conservation standard.

Section 430.5(g) and (h)

DOE proposed renumbering 10 CFR 430.5(g) and (h) and including new text to reaffirm that a pre-publication document is not a final rule within the meaning of EPCA. 85 FR 64071, 64073. DOE received comments supporting its proposed modification to 10 CFR 430.5(g). The Joint Industry Commenters supported the reaffirmation that the publication of such drafts did not finalize the substance of the rule or signal an end to the rulemaking process. (Joint Industry Commenters, No. 03 at p. 6)

While DOE acknowledges the comments it received in support of this proposal, DOE has decided to retain the current regulations at 10 CFR 430.5(g) and (h). Since DOE's proposal for 10 CFR 430.5(g) was simply intended to reorganize and reaffirm the language currently found in 10 CFR 430.5(g) and (h), DOE believes retaining the current requirements would not be inconsistent with the intent and purpose of its proposal. Therefore, DOE is retaining the current regulations at 10 CFR 430.5(g) and (h) in this final rule.

III. Procedural Issues and Regulatory Review

A. Administrative Procedure Act

Agency rules of procedure and practice, such as the one described in this document, are not subject to the requirement to provide prior notice and an opportunity for public comment pursuant to authority at 5 U.S.C. 553(b)(A). DOE notes that a rule of this nature is also not a substantive rule subject to a 30-day delay in effective date pursuant to 5 U.S.C. 553(d). Nonetheless, DOE voluntarily offered an opportunity to the public to make comments on the changes set forth in this final rule.

B. Review Under Executive Orders 12866, 13563, and 14094 [5]

This regulatory action is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, this action was not subject to review under that Executive order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB).

The revisions contained in this regulatory action are designed to clarify DOE's process with respect to its error correction process for addressing errors identified in the regulatory text of a draft pre-publication document of a potential rule that would establish or amend the energy conservation standards of a regulated product or equipment. These revisions clarify the manner in which DOE will implement this error correction process and affirms the agency's retention of its discretion with respect to the handling of these pre-publication documents and any comments received regarding potential errors contained in the relevant regulatory text. These revisions would not impose any regulatory costs or burdens on stakeholders, nor would they in any way limit public participation in DOE's rulemaking process.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') and a final regulatory flexibility analysis (''FRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The proposed rule was not subject to the requirement to provide prior notice and an opportunity for public comment, therefore, this final rule is not subject to the analytical requirements of the Regulatory Flexibility Act.

[5] Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review,'' 76 FR 3821 (Jan. 21, 2011) and E.O. 14094, ''Modernizing Regulatory Review,'' 88 FR 21879 (April 11, 2023),

D. Review Under the Paperwork Reduction Act

This final rule does not contain a collection of information for purposes of the Paperwork Reduction Act.

E. Review Under the National Environmental Policy Act of 1969

DOE has determined that this final rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this rule is strictly procedural and is covered by the Categorical Exclusion in 10 CFR part 1021, subpart D, paragraph A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

F. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process that it will follow in the development of such regulations. 65 FR 13735. DOE has examined this final rule and has determined that it will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products and equipment that would be subject to this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

G. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of

new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *www.energy.gov/gc/office-general-counsel.* DOE examined this final rule according to UMRA and its statement of policy and determined that the final rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 18, 1988), that this regulation will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This final rule is not a significant energy action because the ability to correct regulations will not, in itself, have a significant adverse effect on the supply, distribution, or use of energy. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule before its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

IV. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on March 25, 2024, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been

authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 26, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE amends part 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Revise and republish § 430.5 to read as follows:

§ 430.5 Error correction procedures for energy conservation standards rules.

(a) *Scope and purpose.* The regulations in this section describe an optional procedure through which the Department of Energy may accept and consider submissions regarding possible Errors in its rules under the Energy Policy and Conservation Act, as amended (42 U.S.C. 6291–6317). This section applies to rules establishing or amending energy conservation standards under the Act, except that this section does not apply to direct final rules issued pursuant to section 325(p)(4) of the Act (42 U.S.C. 6295(p)(4)).

(b) *Definitions.*

Act means the Energy Policy and Conservation Act of 1975, as amended (42 U.S.C. 6291–6317).

Error means an aspect of the regulatory text of a rule that is inconsistent with what the Secretary intended regarding the rule at the time of posting. Examples of possible mistakes that might give rise to Errors include:

(i) A typographical mistake that causes the regulatory text to differ from how the preamble to the rule describes the rule;

(ii) A calculation mistake that causes the numerical value of an energy conservation standard to differ from what technical support documents would justify; or

(iii) A numbering mistake that causes a cross-reference to lead to the wrong text.

Rule means a rule establishing or amending an energy conservation standard under the Act.

Secretary means the Secretary of Energy or an official with delegated authority to perform a function of the Secretary of Energy under this section.

(c) *Posting of rules.* (1) It is within in the sole discretion of the Secretary to make a rule available to the public to review for Errors in the document's regulatory text.

(2) If a rule is made available for review, the Secretary ordinarily will keep the document posted for a period of 45 calendar days, but the Secretary in his or her discretion (while remaining consistent with his or her statutory obligations under EPCA and other legal obligations when promulgating an energy conservation standard) may shorten or lengthen the time period during which the rule document is posted.

(3) Any rule document posted pursuant to paragraph (c)(1) of this section shall bear the following disclaimer: *Notice:* The text of this rule is subject to correction based on the identification of errors as defined in 10 CFR 430.5 before publication in the **Federal Register**. Readers are requested to notify the United States Department of Energy, by email at [EMAIL ADDRESS PROVIDED IN POSTED NOTICE], of any typographical or other errors, as described in such regulations, by no later than midnight on [DATE SPECIFIED IN THE POSTING OF THE DOCUMENT ON THE DEPARTMENT'S WEBSITE], in order that DOE may make any necessary corrections in the regulatory text submitted to the Office of the Federal Register for publication.

(d) *Request for error-correction review.* (1) A person identifying an Error subject to this section may request that the Secretary review a potential Error. Such a request must ordinarily be submitted within 45 calendar days of the posting of the rule pursuant to paragraph (c)(1) of this section. The Secretary in his or her discretion may shorten or lengthen the time period during which such requests may be submitted.

(2)(i) A request under this section must identify a potential Error with particularity. The request must specify the regulatory text claimed to be erroneous. The request must also provide text that the requester contends would be a correct substitute. If a requester is unable to identify a correct substitute, the requester may submit a request that states that the requester is unable to determine what text would be correct and explains why the requester is unable to do so. The request must also substantiate the claimed Error by citing evidence from the existing record of the rulemaking, demonstrating that the regulatory text of the rule is inconsistent with what the Secretary intended the text to be.

(ii) A person's disagreement with any policy choices or discretionary decisions that are contained in the rule will not constitute a valid basis for a request under this section. All policy and discretionary decisions with regard to whether to establish or amend any conservation standard and, if so, the appropriate level at which to amend or establish that standard, remain within the sole discretion of the Secretary without regard to the procedures established in this section.

(3) The evidence to substantiate a request (or evidence of the Error itself) must be in the record of the rulemaking at the time of posting the rule, which may include an accompanying preamble. The Secretary will not consider new evidence submitted in connection with an error-correction request.

(4) A request under this section must be filed in electronic format by email to the address that the disclaimer to the rule designates for error-correction requests. Should filing by email not be feasible, the requester should contact the program point of contact designated in the rule order to ascertain an appropriate alternative means of filing an error-correction request.

(5) A request that does not comply with the requirements of this section will not be considered.

(e) *Correction of rules.* The Secretary may respond to a request for correction under paragraph (d) of this section or address an Error discovered on the Secretary's own initiative by submitting to the Office of the Federal Register either a corrected rule or the rule as previously posted.

(f) *Publication in the* ***Federal Register****.* (1) If, after receiving one or more properly filed requests for correction, the Secretary decides not to undertake any corrections, the Secretary will submit the rule for publication to the Office of the Federal Register as it was posted pursuant to paragraph (c)(1) of this section.

(2) If the Secretary receives no properly filed requests after posting a rule and identifies no Errors on the Secretary's own initiative, the Secretary will submit the rule, as it was posted pursuant to paragraph (c)(1) of this section, to the Office of the Federal Register for publication. This will occur after the period prescribed pursuant to paragraph (c)(2) of this section has elapsed.

(3) If the Secretary receives a properly filed request after posting a rule pursuant to paragraph (c)(1) of this section and determines that a correction is necessary, or discovers an Error on the Secretary's own initiative, the Secretary will, absent extenuating circumstances, submit a corrected rule for publication in the **Federal Register** within 30 days after the period prescribed by paragraph (c)(2) of this section has elapsed.

(4) Consistent with the Act, compliance with an energy conservation standard will be required upon the specified compliance date as published in the relevant rule in the **Federal Register**.

(5) Consistent with the Administrative Procedure Act, and other applicable law, the Secretary will ordinarily designate an effective date for a rule under this section that is no less than 30 days after the publication of the rule in the **Federal Register**.

(6) When the Secretary submits a rule for publication, the Secretary will make publicly available a written statement indicating how any properly filed requests for correction were handled.

(g) *Alteration of standards.* Until an energy conservation standard has been published in the **Federal Register**, the Secretary may correct such standard, consistent with the Administrative Procedure Act.

(h) *Judicial review.* For determining the prematurity, timeliness, or lateness of a petition for judicial review pursuant to section 336(b) of the Act (42 U.S.C. 6306), a rule is considered ''prescribed'' on the date when the rule is published in the **Federal Register**.

[FR Doc. 2024–06690 Filed 4–2–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1046; Project Identifier AD–2023–00253–T; Amendment 39–22700; AD 2024–05–09]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 757–200, –200CB, and –300 series airplanes. This AD was prompted by a report of a crack at fuselage station (STA) 1640 frame web common to the lower hinge intercostal tee clip center hole of the upper fastener row. This AD requires a maintenance records check for existing repairs at STA 1640, repetitive ultrasonic (UT) inspections for cracking of the frame web, and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 8, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 8, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1046; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Boulevard, MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website: *myboeingfleet.com.*
- You may view this material that is incorporated by reference at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–1046.

FOR FURTHER INFORMATION CONTACT: Wayne Ha, Aviation Safety Engineer, Continued Operational Safety Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: 562–627–5238; email: *wayne.ha@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 757–200, –200CB, and –300 series airplanes. The NPRM published in the **Federal Register** on June 1, 2023 (88 FR 35783). The NPRM was prompted by a report of a crack at fuselage STA 1640 frame web common to the lower hinge intercostal tee clip center hole of the upper fastener row. In the NPRM, the FAA proposed to require a maintenance records check for existing repairs at STA 1640, repetitive UT inspections for cracking of the frame web, and applicable on-condition actions. The FAA is issuing this AD to address possible undetected cracking in the STA 1640 frame web common to the lower hinge intercostal tee clip center hole of the upper fastener row. Such cracking, if not addressed, could result in the inability of a principal structural element to sustain limit loads which could adversely affect the structural integrity of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Air Line Pilots Association, International, who supported the NPRM without change.

The FAA received additional comments from seven commenters, including Aviation Partners Boeing (APB), Boeing, Delta Air Lines (DAL), European Air Transport GmbH (DHL), FedEx Express, United Airlines (UAL), and VT Mobile Aerospace Engineering, Inc. (VT MAE). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Correct the Location of the Unsafe Condition

Boeing requested that the location of the cracking be corrected from ''inboard and center holes'' to ''center hole'' of the upper fastener row in the Summary and Background of the NPRM, and paragraph (e) of the proposed AD. Boeing said that cracking was found only in the center hole.

The FAA agrees. The correction has been made in the specified sections of this AD.

Request To Change Inspection Requirement for Certain Converted Airplanes

VT MAE proposed that no additional inspection be required other than the inspection specified in VT MAE 15-Pallet Maintenance Planning Data (MPD) Supplement 757SF–MPD–01 for airplanes converted per VT MAE Supplemental Type Certificate (STC) ST04242AT. VT MAE asserted that Boeing has performed analysis of the modified airplanes, including the new STA 1640 frame, which is inspected as part of the VT MAE MPD Supplement 757SF–MPD–01.

The FAA disagrees with the commenter's request because sufficient

data was not submitted to substantiate that the inspections specified in VT MAE MPD Supplement 757SF–MPD–01 would provide an acceptable level of safety. Under the provisions of paragraph (i) of this AD, however, the FAA will consider requests for approval of alternative actions and compliance times if sufficient data are submitted to substantiate that the change would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

Request To Clarify a Certain Exception

DAL requested that paragraph (h)(3) of the proposed AD be amended or revised to clarify whether aircraft configured with STC ST01518SE but without winglets require the specified reduction in applicable compliance times and repeat intervals. DAL stated that this approved configuration was not clearly addressed in the proposed AD.

The FAA agrees to clarify. Because a longer compliance time for the identified configuration (STC ST01518SE without winglets) has not been evaluated, all configurations with the STC ST01518SE modification must be included in the requirement. The FAA has revised paragraph (h)(3) of this AD to specify that airplanes modified in accordance APB STC ST01518SE, with or without blended or scimitar blended winglets installed, have the reduced compliance time. However, as specified in paragraph (i) of this AD, the FAA will consider requests for approval of alternative actions and compliance times if sufficient data are submitted to substantiate that the change would provide an acceptable level of safety.

Request To Clarify What Prompted the NPRM

Boeing requested that the Background section of the NPRM be revised to clarify the sequence of events and the associated service documents that led to detection of the cracking that prompted the NPRM. Boeing asserted that the NPRM indicated that the crack was found as a result of inspections required by AD 2020–20–10, Amendment 39–21266 (85 FR 63002, October 6, 2020) (AD 2020–20–10), but the crack was actually found as a result of inspections required by AD 2018–06–07, Amendment 39–19227 (83 FR 13398, March 29, 2018) (AD 2018–06–07).

The FAA agrees that the AD number reference in the Background section of the NPRM described by Boeing should have been AD 2018–06–07 (which was superseded by AD 2020–20–10). However, since that portion of the Background section does not reappear in the final rule, no change to the final rule is necessary.

Request To Extend Compliance Time

APB, DAL, and DHL proposed that APB Service Bulletin AP757–53–005 be incorporated into the final rule. APB, DAL, DHL, and UAL suggested that paragraph (h)(3) of the proposed AD be revised to extend the required time for compliance. APB explained that APB Service Bulletin AP757–53–005 is currently in approval review by an independent DER (Designated Engineering Representative) for submittal to the FAA, and this service information proposes less restrictive compliance times than specified by paragraphs (g) and (h)(3) of the proposed AD. DHL added that halving the compliance time for the initial inspection is more burdensome than halving the time for repetitive inspections, which can still be accomplished during base maintenance events. DAL and UAL added that the reduced initial inspection time would mean that the inspection could not occur during a regularly scheduled check, resulting in extended unscheduled ground time and increased costs for operators.

The FAA does not agree. Waiting for the review and approval of APB Service Bulletin AP757–53–005 would delay the rulemaking process. The urgency of the unsafe condition warrants issuing this AD as proposed because it adequately addresses the unsafe condition. Until APB completes its evaluation of airplanes with APB STC ST01518SE installed to determine an appropriate compliance time for the inspection, the conservative factor of 2 will apply to these airplanes. Under the provisions of paragraph (i) of this AD, however, the FAA will consider requests for approval of alternative compliance times if sufficient data are submitted to substantiate that the change would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

Request for Clarification on Credit for Certain Airplanes

UAL requested clarification on the NPRM as it does not give operators credit for airplanes on which the required inspection in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, was already accomplished prior to release of the pending AD. UAL said they intend to start inspection as soon as possible, and not having any allowance for credit prior to AD release may drive some of UAL's Model 757 fleet into another round of the required inspection sooner than the required repetitive inspection time limit.

The FAA provides the following clarification. Paragraph (f) of this AD states that operators must comply with the requirements of the AD unless those actions have already been done, which negates the need to add the requested credit. Any repetitive actions must be done within the compliance times required by this AD. This AD has not been changed regarding this request.

Request To Exclude Certain Airplanes From AD Requirements

VT MAE requested that no inspection be required for aircraft converted per ST03952AT that have a long inner chord strap at the STA 1640 fuselage frame. VT MAE and FedEx Express requested that no inspection be required for aircraft converted per VT MAE STC ST03562AT that have a long inner chord strap at the STA 1640 fuselage frame. The commenters asserted that the modified STA 1640 frame is identical to that of Boeing 757–200 special freighter airplanes, which are not included in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022. The commenters claimed that Boeing and the FAA stated that these special freighter-configured airplanes were not subject to cracking at the lower hinge intercostal tee clip. The commenters stated that the stresses in the inner chord are higher, and AD 2020–20–10 and Boeing Alert Service Bulletin 757–53A0108, Revision 1, dated July 17, 2019, would be able to detect the web cracks sooner.

The FAA agrees with the proposed change. For aircraft converted per VT MAE STC ST03562AT and ST03952AT that have a long inner chord strap at the STA 1640 fuselage frame, the modified STA 1640 frame is identical to that of Boeing 757–200 special freighter airplanes. Paragraph (h)(4) of this AD has been added to provide an exception stating that the actions of paragraph (g) of this AD are not required for Group 1 airplanes that have been converted from passenger to freighter configuration using VT MAE STC ST03562AT or ST03952AT that have a long inner chord strap at the STA 1640 fuselage frame.

Request for Alternative Required Actions for Certain Airplanes

VT MAE and FedEx Express requested the use of Group 4 inspections/methods/compliance times, given in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, for the airplane having registration number N935FD, which was converted per VT MAE STC

ST03562AT. The commenters noted that this airplane has a short inner chord strap at the STA 1640 fuselage frame, and that the modified STA 1640 frame is identical to the STA 1640 frame found on Boeing 757–200 special freighter airplanes, which are identified as Group 4 in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

The FAA agrees that the modified STA 1640 frame is identical to the STA 1640 frame found on Boeing 757–200 special freighter airplanes, identified as Group 4 in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022. The FAA has added paragraph (h)(5) of this AD to specify that airplanes modified in this manner should accomplish the actions for Group 4 airplanes at the applicable times for Group 4 airplanes, as specified in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

Limited ODA Approvals

APB stated that Boeing does not have a delegation to approve repairs in areas affected by the scimitar blended winglet configuration of STC ST01518SE. APB also commented that approval by The Boeing Company Organization Designation Authorization (ODA), as specified in paragraph (i)(3) of the proposed AD, may not be given for an alternative method of compliance (AMOC) for repairs in those areas, but such approval must be obtained as specified in paragraph (i)(1) of this AD.

The FAA acknowledges and concurs with APB's assertions. However, no change to the AD is necessary. Paragraph (h)(2) of this AD states that AMOC approval be obtained using a method approved in accordance with the procedures specified in ''paragraph (i)'' of this AD, and does not limit approvals to the provisions of paragraph (i)(1) or (3) of this AD. Therefore, AMOC approval in accordance with paragraph (i)(1) or (3) of this AD would be provided based on whether the actions needing an AMOC apply to the APB design or the Boeing design.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022. This service information specifies procedures for a maintenance records check of the left- and right-side STA 1640 frame web between S–9 and S–20 for existing repairs; repetitive UT inspections of the frame web for any cracks; and applicable on-condition actions. On-condition actions include repair.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 309 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Maintenance records check	1 work-hour × $85 per hour = $85.	$0	$85	$26,265.
UT inspection	39 work-hours × $85 per hour = $3,315 per inspection cycle.	$0	$3,315 per inspection cycle	$1,024,335 per inspection cycle.

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–05–09 The Boeing Company: Amendment 39–22700; Docket No.

FAA–2023–1046; Project Identifier AD–2023–00253–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 8, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 757–200, –200CB, and –300 series airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

(d) Subject

Air Transport Association (ATA) of America Code: 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report of a crack at fuselage station (STA) 1640 frame web common to the lower hinge intercostal tee clip center hole of the upper fastener row. This condition, if not addressed, could result in the inability of a principal structural element to sustain limit loads, which could adversely affect the structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 757–53A0121, dated September 28, 2022, which is referred to in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

(h) Exceptions to Service Information Specifications

(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, use the phrase ''the original issue date of Requirements Bulletin 757–53A0121 RB,'' this AD requires replacing those words with ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair, or doing the alternative inspections and applicable on-condition actions using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(3) For airplanes modified in accordance with Aviation Partners Boeing (APB) Supplemental Type Certificate (STC) ST01518SE, with or without blended or scimitar blended winglets installed: This AD requires dividing the applicable compliance times and repeat intervals specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, by a factor of two.

(4) For Group 1 airplanes identified in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, that have been converted from passenger to freighter configuration using VT MAE STC ST03562AT or ST03952AT and that have a long inner chord strap part number 146N8711–65 at the STA 1640 fuselage frame: The actions specified in paragraph (g) of this AD are not required.

(5) For Group 3 airplanes identified in Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, that have been converted from passenger to freighter configuration using VT MAE STC ST03562AT: Do all applicable actions for Group 4, as identified in, and in accordance with, Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022, at the applicable times for Group 4 as specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-SACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Wayne Ha, Aviation Safety Engineer, Continued Operational Safety Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: 562–627–5238; email: *wayne.ha@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(3) of this AD.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin 757–53A0121 RB, dated September 28, 2022.

(ii) [Reserved]

(3) For material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Boulevard, MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website: *myboeingfleet.com.*

(4) You may view this material that is incorporated by reference at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or *emailfr.inspection@nara.gov.*

Issued on March 4, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–06995 Filed 4–2–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1986; Project Identifier AD–2022–00015–T; Amendment 39–22693; AD 2024–05–03]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 767 airplanes. This AD was prompted by a report of cracks on the forward entry door and forward service door cutout aft lower corner fuselage skin and bear strap. This AD requires repetitive inspections for cracking at the affected area, and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 8, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 8, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1986; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view service information that is incorporated by reference at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1986.

FOR FURTHER INFORMATION CONTACT:

Joseph Hodgin, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3962; email: *Joseph.J.Hodgin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 767 airplanes. The NPRM published in the **Federal Register** on October 5, 2023 (88 FR 69107). The NPRM was prompted by a report of cracks on the forward entry door and forward service door cutout aft lower corner fuselage skin and bear strap. In the NPRM, the FAA proposed to require repetitive inspections for cracking at the affected area, and applicable on-condition actions. The FAA is issuing this AD to address undetected fatigue cracks which, if not addressed, could result in a principal structural element's loss of limit load capability, adversely affecting the airplane's structural integrity.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters who supported the NPRM without change.

The FAA received additional comments from five commenters, including ABX Air, All Nippon Airways, Boeing, United Airlines, and UPS. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Clarification of Exemption From Alternative Methods of Compliance (AMOC)

ABX Air requested clarification as to whether repairs performed using approval via Form 8110–3 are exempt from needing an AMOC for this AD, similar to repairs made using approval via Form 8100–9 repairs. The commenter provided no justification for the request.

Repairs performed using Form 8110–3 are not exempt from requiring an AMOC for this AD. As specified in paragraph (l)(3) of this AD, only those repairs, modifications, or alterations required by this AD are exempt from an FAA approved-AMOC if those AMOCs are approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. All other repairs, including those approved on Form 8110–3, will require an AMOC approved in accordance with paragraph (l) of this AD. This is necessary to ensure the repairs maintain an adequate level of safety.

Request for Inclusion of B767–300BCF SRM as an Acceptable Method of Compliance

All Nippon Airways requested that the proposed rule be modified to include B767–300BCF SRM Repair 1 as an acceptable method of compliance. It was not listed as a method of compliance whereas 767–200, –300, –300F, and –400 SRMs were in Tables 1 and 2(a). The commenter requested this change because All Nippon Airways owns 767–300BCF aircraft.

The FAA agrees with this change because the repairs and repeat instructions are the same for B767–300BCF as the B767–300 SRM. The FAA has revised paragraph (h) of this AD to include exceptions for repairs performed in accordance with B767–300BCF SRM 53–10–01 Repair 1.

Request for Repetitive Inspections To Be Outlined if No Crack Is Found

Boeing requested that the AD include repetitive inspections for Model 767–2C if no crack is found. This change is requested to maintain the safety of the fleet since paragraph (i) of this AD should include all follow-on actions for the condition of no crack found.

The FAA agrees with adding the repetitive inspections to account for all follow-on actions for no crack found to maintain the safety of the fleet. Paragraph (i) of this AD is revised to include the repetitive inspections.

Boeing also requested that paragraph (j) of this AD be changed to reference the Airworthiness Limitations (AWL) document associated with the Compliance Time Definitions for Model 767–2C airplanes. The commenter is concerned with the redefining compliance times already defined within the AWL, which could create a conflict with the rule that would require a rule revision if the definitions in the AWL were to be redefined.

The FAA disagrees. The FAA's intent is for the compliance time terms used in paragraph (j) of this AD to be the same terms already defined in the Model 767–2C Airworthiness Limitations document. Including the compliance time definitions for Model 767–2C in paragraph (j) of this AD ensures that those definitions are followed, notwithstanding any future changes to the definitions in the AWL. If the compliance time definitions in the AWL are changed in the future, the FAA will consider revising this Airworthiness Directive at that time. In any event, an operator may request approval to use later revised compliance time definitions as an alternative method of compliance (under the provisions of paragraph (l) of this AD).

Request for Change To State That a Ref/C/SRM Repair Terminates the Need for Repetitive Inspections

United Airlines requested the AD be amended to state that repetitive inspections associated with Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023 conditions 3, 4, 7, and 8 (Ref/B) are not required in areas covered by 53–10–01 Repair 1 of the applicable Model 767 SRM (Ref/C/SRM) if done after the initial inspections required by Ref/B/RB. This change is requested because the commenter believes that the installation of a Ref/C/SRM repair after the initial Ref/B/RB inspection should provide at least an equivalent level of safety with the unsafe condition this AD is addressing. The FAA disagrees with

revising the AD to state that a Ref/C/SRM repair terminates the need for repetitive inspections associated with RB conditions 3, 4, 7, and 8. In the RB Section 5 Accomplishment Instruction Tables 1 and 2, there is note (c) which states that accomplishment of 53–10–01 Repair 1 of the applicable Model 767 SRM is terminating action for the inspections at this location only. The FAA has determined that note (c) sufficiently outlines that performing repair 1 is the terminating action for the inspections at that location and no further clarification is necessary.

Request Change to Paragraphs (g) and (j) of This AD for Clarity

UPS requested amending paragraph (g) of this AD to state ''For Model 767–200, –300, –300F, or –400ER series airplanes, as identified in Section (c) Applicability of the AD'' to avoid confusion on where applicability is established in the AD.

UPS also requested revising paragraph (j) of this AD to state ''Compliance Time Definitions for Model 767–2C'' instead of ''Compliance Time Definitions'' to avoid confusion.

The FAA disagrees with changing paragraph (g) of this AD language because paragraph (c) of this AD specifies the applicability of the AD and therefore the airplane models affected by paragraph (g) of this AD. For clarification, airplanes not identified in paragraph (c) of this AD are not affected by any paragraph of this AD. The FAA agrees with revising paragraph (j) of this AD to state ''Compliance Time Definitions for Model 767–2C'' for clarity.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 767–3A0301 RB, Revision 2, dated May 24, 2023. This service information specifies procedures for repetitive inspections (external detailed, internal detailed, and open hole high frequency eddy current) for cracking at the forward entry door and forward service door cutout aft lower corner fuselage skin and bear strap area. This service information also specifies procedures for on-condition actions, including crack repair.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 682 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	Up to 8 work-hours × $85 per hour = Up to $680 per inspection cycle.	$0	Up to $680 per inspection cycle.	Up to $463,760 per inspection cycle.

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions (*i.e.,* possible crack repair) specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–05–03 The Boeing Company: Amendment 39–22693; Docket No. FAA–2023–1986; Project Identifier AD–2022–00015–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 8, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1) and (2) of this AD.

(1) Model 767–200, –300, –300F, and –400ER series airplanes, as identified in Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023.

(2) Model 767–2C series airplanes, line numbers 1065, 1066, 1067, 1069, 1091, 1092, 1098, 1100, 1102, 1104, 1107, 1109, 1111, 1113, 1114, 1116, 1117, 1119, 1120, 1122, 1124, 1126, 1128, 1129, 1131, 1132, 1134, 1135, 1137, 1139, 1143, 1145, 1147, 1149, 1151, 1154, 1156, 1158, 1160, 1162, 1164, 1166, 1168, 1170, 1172, 1174, 1176, 1178, 1181, 1184, 1188, 1192, 1196, 1200, 1202, 1205, 1207, 1210, 1213, 1216, 1219, 1223, 1226, 1230, 1234, 1236, 1238, 1241, 1243, 1246, 1248, 1250, 1252, 1254, 1257, 1259, 1261, 1264, 1267, 1269, 1271, and 1273.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report of cracks found on the forward entry door and forward service door cutout aft lower corner fuselage skin and bear strap. The FAA is issuing this AD to address undetected fatigue cracks. The unsafe condition, if not addressed, could result in a principal structural element losing its limit load capability, adversely affecting the airplane's structural integrity.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions: Model 767–200, –300, –300F, and –400ER

For Model 767–200, –300, –300F, –400ER series airplanes: Except as specified by paragraph (h) of this AD, at the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 767–53A0301, Revision 2, dated May 24, 2023, which is referred to in Boeing Alert Requirements Bulletin 767–53A0301, Revision 2, dated May 24, 2023.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Requirements Bulletin 767–53A0301 RB, dated May 24, 2023, compliance time columns in Tables 1 and 2, paragraph E (Compliance), use the phrase ''the Original Issue date of Requirements Bulletin 767–53A0301 RB,'' this AD requires using the effective date of this AD.

(2) Where Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023, specifies contacting Boeing for repair instructions: This AD requires doing the repair before further flight using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(3) Where Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023, refers to ''767–200 SRM 53–10–01 Repair 1, 767–300 SRM 53–10–01 Repair 1, 767–300F SRM 53–10–01 Repair 1 or 767–400 SRM 53–10–01 Repair 1,'' this AD requires replacing that text with ''767–200 SRM 53–10–01 Repair 1, 767–300 SRM 53–10–01 Repair 1, 767–300F SRM 53–10–01 Repair 1, 767–400 SRM 53–10–01 Repair 1, or B767–300BCF SRM 53–10–01 Repair 1, as applicable.''

(4) Where Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023, refers to ''767–200 SRM 53–10–01 Repair 1, 767–300 SRM 53–10–01 Repair 1, or 767–400 SRM 53–10–01 Repair 1,'' this AD requires replacing that text with ''767–200 SRM 53–10–01 Repair 1, 767–300 SRM 53–10–01 Repair 1, 767–400 SRM 53–10–01 Repair 1, or B767–300BCF SRM 53–10–01 Repair 1, as applicable.''

(i) Required Actions: Model 767–2C

At the later of the times specified in paragraphs (i)(1) and (2) of this AD: Perform inspections (external detailed, internal detailed, and open hole high frequency eddy current, as applicable), including repetitive inspections as applicable, for cracking at the forward entry door and forward service door cutout aft lower corner fuselage skin and bear strap area, and repair any cracks found, in accordance with a method and at the times specified, as approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA.

Note 2 to paragraph (i): Guidance on doing the required actions can be found in Boeing Alert Requirements Bulletin 767–53A0303 RB, Revision 1, dated June 29, 2023; and Boeing Alert Requirements Bulletin 767–53A0308, Revision 1, dated June 21, 2023.

(1) Before 15,000 cumulative flight cycles or 30,000 cumulative total accumulated cycles, whichever occurs first. These terms are defined in paragraph (j) of this AD.

(2) Within 2,250 flight cycles, 4,500 total accumulated cycles, or 24 months after the effective date of this AD, whichever occurs first.

(j) Compliance Time Definitions for Model 767–2C

The definitions in paragraphs (j)(1) through (5) of this AD apply to this AD.

(1) A ''flight cycle'' is an operation by an aircraft that is initially stopped on the ground, departs in flight, attains a maximum above ground level (AGL) altitude greater than 5,000 feet relative to the runway, lands on a runway, and stops on the ground. A flight cycle may include one or more touch-and-go cycles.

(2) A ''touch-and-go cycle'' is an operation by an aircraft that lands and departs on a runway without stopping or exiting the runway and is immediately followed by a short flight with a maximum AGL altitude of 5,000 feet relative to the runway.

(3) ''Total accumulated cycles'' is the sum of the accumulated number of flight cycles, accumulated missed approaches, and the accumulated number of touch-and-go cycles.

(4) A ''missed approach'' (or go-around) is an aircraft landing approach that is discontinued and proceeded by a climb-out for any reason without landing gear touching the runway and is either immediately preceded by or immediately followed by a short flight with a maximum AGL altitude of 5,000 feet relative to the runway. Any flight operation not meeting this definition is considered a flight cycle.

(5) ''Cumulative'' cycles are total cycles since new.

(k) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 767–53A0301 RB, dated April 21, 2021, or Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 1, dated April 11, 2022.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(m) Related Information

(1) For more information about this AD, contact Joseph Hodgin, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3962; email: *Joseph.J.Hodgin@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the address specified in paragraph (n)(3) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin 767–53A0301 RB, Revision 2, dated May 24, 2023.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

(4) You may view service information that is incorporated by reference at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on February 29, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–06993 Filed 4–2–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1897; Project Identifier MCAI–2023–00921–T; Amendment 39–22692; AD 2024–05–02]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A320–214, A320–216, A320–251N, A320–271N, and A321–253NX airplanes. This AD was prompted by a quality review of the forward cargo door frame-to-fuselage skin panel assembly identified several fastener holes that deviated from the manufacturing requirements. This AD requires a geometrical check of the diameter of certain fastener holes for deviations, and if any deviation is found, repetitive special detailed inspections of the affected area for discrepancies and, depending on findings, accomplishment of applicable corrective actions, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 8, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 8, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1897; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1897.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3667; email: *timothy.p.dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A320–214, A320–216, A320–251N, A320–271N, and A321–253NX airplanes. The NPRM published in the **Federal Register** on October 5, 2023 (88 FR 69110). The NPRM was prompted by AD 2023–0153, dated July 26, 2023 (EASA AD 2023–0153) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states a quality review of the forward cargo door frame-to-fuselage skin panel assembly identified several drillings as deviating from manufacturing requirements, creating oversized fastener holes, which could lead to cracking. This condition, if not addressed, could lead to reduced structural integrity of the fuselage.

In the NPRM, the FAA proposed to require repetitive special detailed inspections of the affected area for discrepancies and, depending on findings, accomplishment of applicable corrective actions, as specified in EASA AD 2023–0153. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1897.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters. Air Line Pilots Association, International (ALPA) and an individual who both supported the NPRM without change.

Additional Changes Made to This AD

Since the NPRM was published, EASA AD 2023–0153 was superseded by EASA AD 2023–0179, dated October 11, 2023 (EASA AD 2023–0179). Since EASA AD 2023–0153 was issued, it has been determined that, depending on inspection findings, no repetitive inspection may be required. EASA AD 2023–0179 also clarified that the initial inspection is a geometrical check of the diameter of certain fastener holes for deviations. The FAA has updated this final rule accordingly by replacing EASA AD 2023–0153 with EASA AD 2023–0179 in all affected paragraphs and added a ''Credit for Previous Actions'' paragraph to retain the requirements of EASA AD 2023–0153, however the concession identified in EASA AD 2023–0153 was removed in EASA AD 2023–0179.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0179 specifies procedures for a geometrical check of the diameter of certain fastener holes for deviations, and if any deviation is found, repetitive special detailed inspections of the affected area for discrepancies and, depending on findings, accomplishment of applicable corrective action. The special detailed inspection consists of a rototest inspection for cracking of the forward cargo door frame to fuselage skin panel, and if no cracking is found, checking the fastener hole diameters. Corrective actions include installing oversized fasteners if the fastener hole diameter is less than or equal to the specified nominal diameter, contacting the manufacturer for repair instructions if the fastener hole diameter is greater than the specified nominal diameter, and repairing any cracking by contacting the manufacturer for repair instructions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the section.

Costs of Compliance

The FAA estimates that this AD affects 8 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
42.5 work-hours × $85 per hour = $3,613	$100	$3,713	$29,704

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–05–02 Airbus SAS: Amendment 39–22692; Docket No. FAA–2023–1897; Project Identifier MCAI–2023–00921–T.

(a) Effective Date

This airworthiness directive (AD) is effective May 8, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A320–214, A320–216, A320–251N, A320–271N, and A321–253NX airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2023–0179, dated October 11, 2023 (EASA AD 2023–0179).

(d) Subject

Air Transport Association (ATA) of America Code: 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a quality review of the forward cargo door frame-to-fuselage skin panel assembly identified several drillings as deviating from manufacturing requirements, creating oversized fastener holes. The FAA is issuing this AD to address oversized fastener holes and cracking. The unsafe condition, if not detected and corrected, could result in reduced structural integrity of the fuselage.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0179.

(h) Exceptions to EASA AD 2023–0179

(1) Where EASA AD 2023–0179 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (4) of EASA AD 2023–0179 specifies ''If, during any SDI as required by paragraph (3) of this AD, any crack is detected, before next flight, contact Airbus for approved repair instructions and, within the compliance time identified therein, accomplish those instructions accordingly,'' this AD requires replacing those words with ''If, during any SDI as required by paragraph (3) of this AD, any cracking is found, before next flight, repair the cracking using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.''

(3) Where paragraph (8) of EASA AD 2023–0179 specifies the repair be done in

accordance with ''approved Airbus repair instructions,'' for this AD the repair must have been done using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Where paragraph (6) of EASA AD 2023–0179 specifies to ''oversize that fastener hole and install a new oversize fastener and new rivet,'' this AD requires replacing those words with ''before next flight, oversize that fastener hole and install a new oversize fastener and new rivet.''

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0179.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using EASA AD 2023–0153, dated July 26, 2023.

(j) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0179 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(k) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address in paragraph (l) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraphs (j) and (k)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3667; email: *timothy.p.dowling@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0179, dated October 11, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0179, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on February 29, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–06996 Filed 4–2–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 115 and 125

[Docket No. FR–6355–F–02]

RIN 2529–AB07

Expanding the Fair Housing Testing Pool for FHIP and FHAP Funded Entities

AGENCY: Office of Fair Housing and Equal Opportunity, HUD.

ACTION: Final rule.

SUMMARY: Through this final rule, HUD eliminates the restrictions for Fair Housing Initiatives Program (FHIP) grantees and for Fair Housing Assistance Program (FHAP) agencies that currently bar FHIP and FHAP funded entities from using HUD funds to deploy fair housing testers with prior felony convictions or convictions of crimes involving fraud or perjury. The final rule ensures that FHIP and FHAP funded entities are able to fully investigate criminal background screening policies that are potentially discriminatory under federal civil rights laws by using a diverse group of testers with actual criminal convictions. This final rule also improves inclusivity in HUD programs for people with criminal convictions, consistent with President Joseph R. Biden's March 31, 2022 Proclamation on Second Chance Month and Secretary Marcia Fudge's April 12, 2022 Memorandum, ''Eliminating Barriers That May Unnecessarily Prevent Individuals with Criminal Histories from Participating in HUD Programs,'' and is based on a HUD determination that no valid interest is served by categorically barring FHIP and FHAP funded entities from using testers with such convictions.

DATES: *Effective date:* This final rule is effective May 3, 2024.

FOR FURTHER INFORMATION CONTACT: Aztec Jacobs, Director, Office of Programs, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 7th Street SW, Room 5250, Washington, DC 20410–8000, telephone number 202–402–7861 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of the Civil Rights Act of 1968, as amended (Fair Housing Act or Act), prohibits discrimination in the sale, rental, or financing of dwellings and in other housing-related activities because of race, color, religion, sex (including sexual orientation and gender identity), disability, familial status, or national origin.[1] Section 817 of the Fair Housing Act provides that the Secretary may reimburse State and local fair housing enforcement agencies that assist the Secretary in enforcing the Act.[2]

Although Section 817 was part of the original 1968 Act, it was not until 1980, through an annual appropriations act (Pub. L. 96–103), that Congress

[1] 42 U.S.C. 3601–3619, 3631.

[2] 42 U.S.C. 3616.

authorized funding for it, establishing the Fair Housing Assistance Program (FHAP). In requesting funding for the FHAP, the Carter administration cited limitations that localities had in processing fair housing complaints.[3]

While the FHAP funds State and local governmental agencies to assist in enforcement of the Fair Housing Act, the Fair Housing Initiative Program (FHIP) was established in 1987 to fund private non-profits to do the same. Section 561 of the Housing and Community Development Act of 1987 (Section 561) established the FHIP as a temporary program, which Congress made permanent in 1992 through the Housing and Community Development Act of 1992.[4] In combination, the FHAP and FHIP strengthen HUD's enforcement of the Fair Housing Act and further fair housing.

Among other things, the FHAP and FHIP fund testing activities designed to enhance enforcement of the Fair Housing Act. Testing refers to the use of an individual or individuals who, without a bona fide intent to rent or purchase a house, apartment, or other dwelling, pose as a prospective renter or purchaser for the purpose of gathering information that may indicate whether a housing provider is complying with fair housing laws. Both FHIP and FHAP funded entities can use testing as a tool to investigate potential violations of the Fair Housing Act.

Section 561 specifically required HUD, during the demonstration period for the FHIP, to ''establish guidelines for testing activities funded under the private enforcement initiative of the fair housing initiatives program'' and noted that the purpose of the guidelines was ''to ensure that investigations in support of fair housing enforcement efforts [. . .] shall develop credible and objective evidence of discriminatory housing practices.'' [5] The Housing and Community Development Act of 1992 eliminated testing guidelines as a permanent requirement for the FHIP.[6]

Current Regulatory Landscape

HUD regulations currently forbid FHIP and FHAP funded entities from using federal funds for fair housing testing that involves testers with prior felony convictions or convictions of crimes involving fraud or perjury.[7]

For FHIP funded entities, this restriction dates back to the 1988 proposed regulations for the demonstration period that, among many other requirements, prohibited testers under the FHIP from having ''prior felony convictions or convictions of crimes involving fraud or perjury.'' [8] HUD did not explicitly explain why it proposed this specific restriction, nor did HUD receive comments related to this specific restriction. The regulations for the demonstration period were finalized in 1989 at 24 CFR part 125, and contained a section titled ''Guidelines for private enforcement testing'' (previously codified at § 125.405). The guidelines contained numerous prescriptive requirements about how eligible testing was to be designed and conducted (*e.g.,* allowing testing only in response to a ''bona fide allegation''), including the requirement for a ''formal recruitment process designed to obtain a pool of credible and objective persons to serve as testers,'' followed by a restriction on testers having felony convictions or convictions of crimes involving fraud or perjury.[9]

In 1994, HUD proposed eliminating the testing guidelines, noting that Congress specifically limited the testing guidelines requirement to the demonstration period and did not include this requirement in its permanent authorization of the FHIP. However, HUD proposed keeping the restriction on hiring testers with ''prior felony convictions or convictions of crimes involving fraud or perjury'' and keeping a requirement that testers receive training or be experienced in testing procedures and techniques.[10] HUD did not provide an explanation for why it chose to retain the restriction regarding convictions in the proposed rule, nor in the 1995 final rule.[11] The language—''The following requirements apply to testing activities funded under the FHIP: Testers must not have prior felony convictions or convictions of crimes involving fraud or perjury''—has not changed since 1995.[12]

HUD did not address the criminal backgrounds of FHAP testers in its regulations until 2005.[13] While HUD established the eligibility criteria for participants in the FHAP in a 1980 interim rule and issued subsequent rules for the FHAP in 1982, 1988, and 1989, none of these addressed fair housing testing in any way.[14] The proposed rule in 2005 proposed a tester conviction restriction identical to that contained in the FHIP regulations. As with the FHIP rulemaking, there were no public comments on this restriction, and it was codified in 2007 in a final rule.[15]

The Proposed Rule

On October 31, 2023, HUD issued a Notice of Proposed Rulemaking, which proposed to amend its regulations by eliminating the tester restrictions that restrict FHIP and FHAP funded entities from using fair housing testers with prior felony convictions or convictions of crimes involving fraud or perjury (the proposed rule).[16] The proposed rule was a response to an April 12, 2022 directive from Secretary Marcia Fudge to HUD to ''review our programs and put forth changes that ensure that our funding recipients are as inclusive as possible of individuals with criminal histories.'' [17]

In the proposed rule, HUD explained that it presumably first enacted the restrictions on testers' criminal convictions and then continued them in subsequent rulemakings because of the idea that certain criminal convictions would undermine a tester's credibility in testifying in court to what the tester witnessed under Rule 609 of the Federal Rules of Evidence (FRE), which provides that certain criminal convictions may be admitted to attack witness's ''character for truthfulness.'' [18]

However, HUD explained that it viewed a categorical bar on anyone with a felony conviction, or conviction involving fraud or perjury to be

[3] *See* The Fair Housing Act: HUD Oversight, Programs, and Activities, Congressional Research Service R44557 (April 7, 2021) and U.S. Department of Housing and Urban Development, *FY1980 Budget Justifications,* p. Q–2 and Pub. L. 96–103) *available at sgp.fas.org/crs/misc/R44557.pdf.*

[4] Public Law 102–550, October 28, 1992, 106 Stat. 3672.

[5] Public Law 100–242, February 5, 1988, 101 Stat. 1943.

[6] As explained in the 1994 proposed rule, ''the passage of section 905 establishes FHIP as a permanent program, and with the expiration of the demonstration period, the requirement for testing guidelines is removed.'' 59 FR 44596 (Aug. 29, 1994).

[7] 24 CFR 125.107(a); 24 CFR 115.311(b).

[8] 53 FR 25581.

[9] 54 FR 6492, 6501.

[10] 59 FR 44596, 44604.

[11] 60 FR 58452, 58453.

[12] 60 FR 58452, 58453.

[13] *See* 45 FR 31880 (May 14, 1980); 47 FR 8991 (March 3, 1982); 53 FR 34668 (Sept. 7, 1988); 54 FR 20094 (May 9, 1989); 61 FR 7674 (Feb. 28, 1996); 61 FR 41282 (Aug. 7, 1996) (containing no conviction restrictions on testers) *compare to* 70 FR 28748 (May 18, 2005) (containing the conviction restrictions on testers at issue in this final rule).

[14] 45 FR 31880; 47 FR 8991; 53 FR 34668; 54 FR 20094.

[15] 72 FR 19070 (Apr. 16, 2007), currently codified at 24 CFR 115.311(b).

[16] 88 FR 74381.

[17] ''Eliminating Barriers That May Unnecessarily Prevent Individuals with Criminal Histories from Participating in HUD Programs'' *available at https://www.hud.gov/sites/dfiles/Main/documents/Memo_on_Criminal_Records.pdf.*

[18] FRE 609(a). Also, twenty-four states have local rules of evidence with substantially similar provisions to FRE 609. 6 Weinstein's Federal Evidence Article VI (2021).

overbroad, outdated, and unnecessary. First, such a broad and categorical bar includes a broader range of convictions than does FRE 609. Second, even for those convictions covered by FRE 609, HUD saw no reason to categorically bar those who conduct testing using FHIP or FHAP funds from employing testers with such convictions. Those entities may reasonably conclude that the prospect of admissibility under FRE 609 in litigation is of little consequence, especially because audio and video recording is often used in testing, which means that the recordings—more than the testers' testimony—are often the most important evidence. HUD pointed out that FRE 609 itself is not always applied even where a conviction comes under its potential application. Further, other requirements in these regulations will continue to apply to testers to help ensure that testers are objective, credible, and well qualified, regardless of their criminal backgrounds. For example, testers still must be trained in testing procedures and techniques.[19] Testers cannot have an economic interest in the outcome of the test;[20] be a relative or acquaintance of any party in the case;[21] have had a recent employment history or other affiliation with the person or organization to be tested;[22] or be a competitor (or licensed competitor) of the person or organization to be tested.[23]

HUD also noted that it had been contacted by fair housing organizations urging reform of conviction restrictions because they prevent fair housing centers from testing for certain types of criminal background-based discrimination by preventing them from employing testers with felonies to test the entire application process. HUD recognized that many FHIP and FHAP funded entities now have an affirmative need to hire testers with criminal histories, who in cases that are of great priority to HUD may actually be better positioned to help those entities uncover discrimination. HUD explained that when the restrictions on testers' criminal convictions were first promulgated as a demonstration regulation in 1989, landlords were unlikely to conduct criminal background checks on prospective applicants.[24] Since then, landlords have increasingly implemented policies and practices to screen applicants based on their criminal convictions.[25]

In 2016, HUD issued a memo explaining how these admissions policies and practices may be discriminatory under the Fair Housing Act.[26] One way landlords may discriminate is by using a criminal records policy as a cover (or pretext) for intentional discrimination because of a protected class. For example, a landlord may tell Black applicants that they are being rejected because of their criminal record but accept white applicants with the same or similar record. The real reason for the rejection is the person's race, even though the landlord is saying the reason is the person's criminal record. Another example of how a landlord may violate the Fair Housing Act is if a landlord has a criminal records policy that disproportionately excludes people of a certain protected class, and that policy is not necessary to achieve a substantial, legitimate, nondiscriminatory interest, or if there is a less discriminatory policy that can achieve that interest.[27] Testers with actual criminal records ranging from misdemeanor to felony convictions are in certain circumstances the best suited to obtain evidence of what modern-day criminal record screening practices are and whether these policies are being applied in a discriminatory way because of a protected characteristic. HUD explained how testers *without* bona fide criminal records are limited to investigating discrimination that occurs pre-application. Only testers with real criminal records will be able to submit an application to obtain evidence of what the policy is in practice at the admission stage and whether the policy is being applied (after the application is submitted) in a discriminatory manner.[28]

Finally, HUD pointed out that HUD's current regulation disproportionately excludes people of color from opportunities to work for FHIP and FHAP funded entities, even as it serves questionable value in ensuring credible evidence in view of the other safeguards that apply to fair housing testing.

This Final Rule

After reviewing and considering public comments on this Rule, HUD finalizes its proposal to remove the conviction restrictions for testers in the FHIP and FHAP regulations.

HUD notes that in addition to the reasons expressed in the proposed rule, summarized above, and echoed by many public comments summarized below, HUD received several public comments from local fair housing organizations regarding the difficulties they have had due to the conviction restrictions recruiting testers of color to conduct race and national origin-based testing. Further, commenters highlighted the catch-22 organizations are put in regarding compliance with these HUD restrictions and compliance with anti-discrimination employment restrictions and/or civil-rights based values. Finally, several commenters noted that removing this restriction is necessary for HUD to be consistent in terms of its own commitment to equity and civil rights. HUD believes these are important

[19] 24 CFR 115.311(c); 24 CFR 125.107(b).

[20] 24 CFR 115.311(d)(1); 24 CFR 125.107(c)(1).

[21] 24 CFR 115.311(d)(2); 24 CFR 125.107(c)(2).

[22] 24 CFR 115.311(d)(3) (prohibiting any such affiliation within five years of the testing); 24 CFR 125.107(c)(3) (prohibiting any such affiliation within one year of the testing).

[23] 24 CFR 115.311(d)(4); 24 CFR 125.107(c)(4) (specifying such ''licensed'' competitors are barred from conducting testing).

[24] *See* David Thatcher, Law & Social Inquiry Volume 33, Issue 1, 12, Winter 2008 (explaining the upward trend since the 1990s in criminal background checks, including that no ''how to'' landlord books reviewed in a literature review prior to 1990 suggested conducting criminal background checks on tenants whereas all ''how to'' books suggested such checks as of the article's publication in 2008).

[25] *See, e.g., id.* at 12 (describing a 2005 survey of large landlords which revealed that 80 percent screened prospective tenants for criminal histories).

[26] *See* Office of General Counsel Guidance on Application of Fair Housing Act Standards to the Use of Criminal Records by Providers of Housing and Real Estate-Related Transactions (April 4, 2016) (''While having a criminal record is not a protected characteristic under the Fair Housing Act, criminal history-based restrictions on housing opportunities violate the Act if, without justification, their burden falls more often on renters or other housing market participants of one race or national origin over another (*i.e.,* discriminatory effects liability). Additionally, intentional discrimination in violation of the Act occurs if a housing provider treats individuals with comparable criminal history differently because of their race, national origin or other protected characteristic (*i.e.,* disparate treatment liability).'')

[27] *See id.* (explaining that achieving resident safety and/or protecting property may be substantial and legitimate interests, assuming they are the actual reasons for the policy, but that a housing provider must be able to prove through reliable evidence that its policy or practice of making housing decisions based on criminal history actually assists in protecting resident safety and/or property).

[28] *See, e.g.,* Implementation of the Office of General Counsel's Guidance on Application of Fair Housing Act Standards to the Use of Criminal Records by Providers of Housing and Real Estate-Related Transactions (June 10, 2022) Memorandum directed to FHIP and FHAP funded entities, highlighting the different ways in which criminal records policies may violate the Act, and explaining that a landlord may have a policy in writing that differs from a policy in practice, and that fully ''[i]dentify[ing] all policies, including written and unwritten policies or practices'' is an important first step in investigating the potential discriminatory effects of a policy) *available at https://www.hud.gov/sites/dfiles/FHEO/documents/Implementation%20of%20OGC%20Guidance%20on%20Application%20of%20FHA%20Standards%20to%20the%20Use%20of%20Criminal%20Records%20-%20June%2010%202022.pdf.* Without having testers that go through the entire application process, it is difficult to find out whether there is a difference between what a tester is told the policy is and what the policy is in practice.

additional reasons to finalize the proposed rule and to remove the restrictions on testers with felony convictions and convictions involving fraud and perjury.

II. Public Comments and HUD's Response to Public Comments

HUD received 192 comments from FHIP and FHAP funded entities, advocacy and re-entry organizations, appraisers, testers, persons with criminal convictions, and other individuals. This public comments section includes a summary of the public comments that HUD received in response to the proposed rule.

A. General Support for the Proposed Rule

Several commenters expressed their general support for HUD's proposal to eliminate the agency's restrictions on the use of fair housing testers with prior felony convictions or certain other convictions by FHIP and FHAP funded entities. Commenters writing in support of the rule emphasized the value of or necessity for testing, generally. One commenter said that ''testers play a vital role and necessity in assisting to eradicate housing discrimination in America.''

Comments Criticizing the Current Regulation

Some commenters noted that HUD's current restrictions are ''antiquated'' and ''outdated.'' One of these commenters also described the current restrictions as ''overbroad'' and ''unnecessary.'' Another questioned their policy justification. Two commenters said the current restrictions never should have been on the books in the first place.

Some commenters said the current restrictions amount to a discriminatory ''blanket ban'' on persons with criminal histories.

Other commenters said the current restrictions constitute employment discrimination. Some commenters noted that the restrictions are inconsistent with Equal Employment Opportunity Commission guidance on the use of criminal records in employment decisions. One commenter said complying with the current regulation causes them to face potential liability for employment discrimination. One commenter noted that the proposed changes would also allow FHIP and FHAP funded entities to abide by state and local laws which prohibit employment discrimination based on criminal legal system interaction.

One commenter said the current regulation is inconsistently applied and frequently misunderstood with some grant technical monitors enforcing the regulation while others do not, and several FHIP staff across the country have misunderstood the regulation to only bar testers with felonies related to fraud or perjury.

Consistent Anti-Discrimination Message From HUD

Commenters said the proposed rule would make it easier for housing organizations to uncover housing discrimination, and therefore further the current Administration's goal of advancing core values of equity, civil rights, racial justice, and equal opportunity.

Several commenters said that there is a contradiction between HUD forbidding housing providers from discriminating against tenants on the one hand, but on the other hand engaging in discrimination by forcing FHIP and FHAP funded entities to discriminate in employment. One commenter said HUD's ''blanket ban'' on testers with criminal convictions negates HUD's stated commitment to breaking down barriers for criminal justice system involved persons. One commenter said the existing regulation tells justice-impacted communities that fair housing organizations are ''hypocrites'' for indulging in the very discrimination those organizations work to combat. One commenter said it is hypocritical to test for discrimination on the basis of criminal record while barring those who have served their sentences from testing. Another commenter said revoking the current restrictions would meaningfully aid in HUD's commitment to make reentry into the workforce more accessible for persons with a prior felony conviction. This commenter cited prior HUD statements that align with the proposed rule, which note that criminal history is not a good predictor of housing success, and that denying housing to prospective tenants could violate the Fair Housing Act. Some commenters said eliminating the current restrictions would reinforce rather than contradict HUD's own guidance. These commenters said the proposed rule was essential to ensure a consistent anti-discrimination message from HUD and its grantees.

Advancing Equity

Several commenters supported the proposed rule, noting that it aligns with their organizational missions. Commenters supported the proposed rule because it would help to make HUD programs more fair and inclusive.

Commenters indicated specific populations that this rule would help, including those who are being discriminated against by housing authorities and employers, domestic violence survivors, people with disabilities who have felony convictions, and those needing a place to live. One commenter said the proposed rule takes a step to deter the criminal justice system's oppression and discrimination against people of color.

Several commenters said employment-based criminal history restrictions discriminate against Black people and minorities. Other commenters also pointed out that the current regulation disproportionately affects certain groups which have been unfairly impacted by mass incarceration and biases in the criminal justice system, including Black and Latino individuals and other racial minorities, and these people are the exact demographic of people who are needed to be fair housing testers. Some of these commenters said that excluding individuals with convictions from serving as fair housing testers undermines efforts to address the inequalities in housing by perpetuating inequalities in employment– a double negative impact. One commenter noted that the proposed changes are a step towards rectifying centuries of policies and practices that have created worse housing and employment outcomes for underserved groups.

HUD Response: HUD thanks these commenters for their comments and notes that this final rule mirrors the proposed rule.

B. General Opposition to the Proposed Rule

Commenters opposing the proposed rule cited various potential disadvantages as outweighing values such as inclusion, equity, or anti-racism. One commenter said those values are not worth making testing worse, and potentially dangerous.

Some commenters opposed the proposed rule, expressing disapproval of fair housing testing in appraisal transactions. One commenter said that national rules outlined in USPAP (the Uniform Standards of Professional Appraisal Practice) already forbid appraisers from utilizing any kind of bias when preparing a report or opinion of value. Another commenter said that ''[i]f a property is accurately evaluated, it is a non-biased issue. The property speaks for itself'' and noted that those controlling testing are not knowledgeable about the appraisal process.

One commenter expressed disapproval of the proposed rule , stating that HUD Secretary Marcia

Fudge has ''commented publicly and on the record with her own racial bias without substantiating evidence or proof.'' Another commenter said the proposed rule was an ''egregious idea,'' and that HUD should instead be promoting safe and affordable housing.

One commenter noted that ''there are plenty of people who do not have criminal records that are from diverse populations and socio-economic backgrounds that can assist with this job.''

Another commenter said the proposed rule hides information from the screening decision process, and that if an applicant has prior felony convictions or convictions of crimes involving fraud or perjury, then it should be known.

HUD Response: HUD thanks the commenters for their comments.

HUD respectfully disagrees that there are enough candidates of diverse backgrounds to fill the job of testers. HUD notes that it received several comments from organizations that conduct fair housing testing that say that they find it either difficult or impossible to recruit a diverse set of fair housing testers under the current regulation. Based on those comments, this problem seems to be particularly heightened in rural communities. Commenters also note that persons with criminal convictions are needed to effectively test for certain kinds of discrimination (*i.e.,* using criminal convictions as a pretext for discrimination based on race), because only these people can complete the application process to effectively uncover this kind of discrimination.

HUD notes that this rulemaking does not hide any information from the tester screening process. Instead, the final rule *permits* FHIP and FHAP funded entities who hire testers to screen for felony convictions or crimes involving fraud or perjury and allows them to have discretion to reject such applicants based on such convictions.

HUD disagrees with the commenter that this rule could make testing potentially dangerous. HUD also believes this rule supports access to safe and affordable housing free from discrimination.

HUD notes that this rule is not related to the necessity of testing generally or in any particular industry such as the appraisal industry. It also does not change who controls testing or their knowledge of the appraisal process. Under this rule, testing remains an available option for FHIP and FHAP funded entities to utilize to enforce the Fair Housing Act in all covered housing transactions. This rule only changes who can qualify as a tester funded through FHIP and FHAP funds. HUD further notes that the fact that appraisers are legally prohibited from discriminating does not mean that they actually refrain from discriminating under the Fair Housing Act. Therefore, testing is still a potentially relevant tool.

C. Potential Impacts on Fair Housing Testing

Negative Impacts

Two commenters said the proposed rule may make the testing process unsafe. One commenter cited general recidivism statistics, while others suggested that those who have broken the law or committed a felony in the past are untrustworthy or more likely to break the law again. One of these commenters cited a 75% recidivism rate over five years from the Bureau of Justice Statistics to oppose the rule's inclusion specifically of crimes of fraud and perjury.

One commenter noted that a person who has knowingly broken a major law in the past may then be put in the position as a tester where they can lie for financial gain. Another commenter suggested that testers with criminal backgrounds may take a bribe from a housing provider so that the provider would ''pass'' the fair housing test. Another suggested that those who have committed felonies are more likely to commit criminal acts like blackmail against landlords.

One commenter noted that although past felony convictions in general may not have any bearing on the integrity of the FHIP and FHAP programs, proven past behavior of fraud and perjury should. The same commenter noted that allowing testers with fraud or perjury convictions would impact the integrity of the program, and that such a rule would be akin to, or lead to a slippery slope of, allowing contractors and others on the debarment list to participate in future endeavors.

Positive Impacts

Some commenters stated that people with criminal histories are just as capable as those without criminal histories. One of these commenters said that justice involved individuals can be trustworthy, effective communicators, reliable, and brilliant. Several commenters dismissed concerns about the lack of credibility that may be attributed to a person with certain criminal convictions, noting that because most fair housing tests are now recorded, there is less concern that someone—including someone with a criminal conviction—is fabricating a narrative. One commenter said there are more reliable indicators of an individual tester's credibility than a prior criminal conviction. Another commenter said that a criminal conviction has no bearing on a person's credibility or potential as a tester. Commenters said the other restrictions on testers, including barring them from having an economic interest in tests and other anti-bias restrictions, are sufficient to demonstrate tester credibility. One commenter pointed out that while some citizens may be guilty of fraud, it is not always a direct result of their character; instead, barriers related to poverty cause survival behaviors that can lead to conviction. Another commenter similarly stated that there are countless reasons why someone may be incarcerated, many of which have no bearing on an individual's character. One person commented that not all those convicted of felonies are ''true criminals,'' noting they know someone convicted of a felony. Other commenters argued that tester applicants deserve an individualized assessment, even if they have a criminal background. One commenter said the vast majority of fair housing testers never testify at trial at all, nor is eliciting trial testimony a primary purpose of testing. The commenter stated that even when cases do go to litigation, only a very small percentage go to trial and a smaller percentage still involve the testimony of a tester.

Commenters pointed out that in some ways, people with criminal convictions bring unique advantages to the role of fair housing tester or otherwise would make more effective housing equity enforcement. Commenters said it is important that people with conviction histories have the chance to work as federally funded fair housing testers because they are closest to the issue and have lived experiences that can benefit investigations. One commenter noted that a job as a tester is perfect for an individual with a felony, explaining that they would have true interest and passion in this role.

One commenter said the proposed rule would ensure that testing efforts are rooted in the community which promotes transparency and trust and encourage the participation of individuals who may have a personal stake in addressing housing discrimination, thereby strengthening the overall impact of FHIP and FHAP funded initiatives. Another commenter said allowing local FHIP and FHAP funded entities the discretion to determine tester qualifications can also lead to increased community engagement by involving community

members, advocates, and local experts in the testing process that will foster a sense of ownership and collaboration.

Many commenters said the proposed rule would ensure that FHIP and FHAP funded entities are able to fully investigate criminal background screening policies that are potentially discriminatory under federal civil rights laws by using testers with actual criminal backgrounds. Commenters explained that testers with backgrounds are necessary to complete effective testing throughout a housing transaction, including during the application phase. Commenters said this is especially important because as more sophisticated landlords have learned about the ways that blanket bans against people with convictions may violate the Fair Housing Act, they have become less likely to openly admit discriminatory policies pre-application. One commenter said it needs to use testers with criminal histories to successfully litigate these types of fair housing cases ''given [their] hostile court system.'' Several commenters said removing these restrictions would make it possible to fully investigate and enforce local and state laws that limit tenant screening based on criminal histories of applicants.

Several commenters said the current regulation needlessly limits the pool of potential fair housing testers who are members of racial minorities, when the very thing that is needed to adequately test for fair housing is a wide variety of people who are members of racial minorities. Other commenters said broadening the scope of persons who can serve as testers—as the proposed rule would do— creates a more diverse and more effective testing pool. One commenter explained that their organization gets many complaints about housing discrimination, and one of the most difficult parts of trying to get justice for their clients is finding testers to do the work. This commenter wrote that allowing formerly incarcerated people to work as fair housing testers might go a long way to increasing the number of available testers in their area. Another commenter stated that due to racial disparities in the local criminal justice system, they have had challenges in recruiting racially diverse testers, especially Native American testers. The commenter stated that this impedes their ability to assist their Native American clients who face housing discrimination. The commenter explained the current restrictions also restrict their ability to use Black testers, and explained how the current regulation is especially harmful to anti-discrimination efforts in rural states by needlessly limiting the pool of testers. Another organization commented that the current restrictions on working with testers with criminal backgrounds has presented obstacles in recruiting effective testers that have prevented their agency from hiring individuals with criminal convictions who would be excellent testers. One commenter said removing barriers to entering the tester workforce can help meet the urgency of the ongoing and evolving need to enforce fair housing.

Commenters said FHIP and FHAP funded entities should decide whether to hire a tester with a conviction record, as they are most equipped to know and be able to weigh the risk that a tester's past involvement in the criminal legal system poses in relation to the methods used in testing. One commenter noted that the proposed rule would not require FHIP and FHAP funded entities to hire testers with criminal convictions, it would just give them that discretion. Another commenter stated that FHIP and FHAP funded entities should have sufficient latitude to identify and select testers that meet minimum training standards and support their work without undue interference, restrictions, and burdensome requirements.

HUD Response: HUD appreciates the comments related to the impacts of the rule on the quality of fair housing tests and the integrity of the FHIP and FHAP. HUD has considered how this rule may impact fair housing testing negatively and how this rule may impact fair housing testing positively and believes that the positive impacts will outweigh any potential negative impacts.

HUD believes that FHIP and FHAP funded entities, who are responsible for the conduct of their testers, are well positioned to decide whether there is a risk in employing an applicant with a particular criminal conviction as a tester. This rule leaves them free to make the same kind of discretionary determination, based on the totality of the circumstances (including how long ago the conviction was, the circumstances surrounding the conviction, and life someone has lived since) that employers, landlords, and others are free to—and often—make. Far from posing a risk to public safety, providing opportunities to those with criminal convictions to be employed as fair housing testers opens up meaningful employment opportunities, and may actually reduce the risk of recidivism among ex-offenders, increasing public safety overall.[29]

HUD disagrees with commenters that individuals with felony and convictions involving fraud or perjury should be barred to serve as testers because they are more likely to accept bribes, blackmail landlords, or lie for financial gain. HUD believes that the local FHIP or FHAP funded entity—rather than HUD—is in the best position to know the extent to which applicants with certain convictions may jeopardize testing and the extent to which local judges and juries may find particular convictions relevant to witness credibility. Those entities can use this local expertise, along with weighing the particulars of the conviction, such as the time that has passed since the conviction, the nature of the conviction, and evidence of post-conviction reform, in making their own local hiring decisions.

Secondly, as HUD explained in the preamble to the proposed rule, under modern day testing methodologies allowed in many states, a tester's main role on the witness stand is testifying that the recording being presented is an authentic recording of the event at issue in the case. Thus, in many cases, the tester merely needs to be credible enough for the judge or jury believe that testimony.

In addition, HUD believes other requirements that are not impacted by this final rule help ensure that testers are objective, credible, and well qualified, regardless of their criminal convictions. For example, testers must

[29] *See, e.g,* Matthew Makarios, Benjamin Steiner, Lawrence F. Travis III. (2010). ''Examining the Predictors of Recidivism among Men and Women Released from Prison in Ohio'', Criminal Justice and Behavior. 37(12): 1377–1391 (finding that ''offenders who maintained stable employment throughout their first year of parole [were] significantly less likely to recidivate than those that did not hold a job at all''); Michele Staton, Megan F. Dickson, Martha Tillson, J. Matthew Webster, Carl Leukefeld. (2019). ''Staying Out: Reentry Protective Factors Among Rural Women Offenders'', Women & Criminal Justice. 29(6) (following a group of women who exited county jails to rural Appalachian communities for 12 months, concluding that having at least part-time employment was one of many ''protective factors'' associated with staying out of jail); Stephen J. Tripodi, Johnny S. Kim, Kimberly Bender. (2010). ''Is employment associated with reduced recidivism? The complex relationship between employment and crime'' International Journal of Offender Therapy and Comparative Criminology, 54(5): 706–720 (overviewing research that ''most criminological research indicates a strong inverse relationship between employment and crime, suggesting that ex-prisoners who obtain employment are at significantly reduced risk for reoffending'' and finding, based on following a group of male parolees released from Texas prisons, a significant association between employment and increased time until reincarceration); Robert Apel, Julie Horney. (2017). ''How and why does work matter? Employment conditions, routine activities, and crime among adult male offenders'', Criminology, 55 (2): 307–343 (finding that having a job that a person is ''very committed to'' verses a job that was ''just a job'' significantly lowers crime risk).

be trained in testing procedures and techniques and they are prohibited from having an economic interest in the outcome of the test, being a relative or acquaintance of any party in the case, having had a recent employment history or other affiliation with the person or organization to be tested, or being a competitor (or licensed competitor) of the person or organization to be tested. 24 CFR 125.107(c) and 115.311(d).

HUD declines to retain restrictions on individuals with convictions involving fraud or perjury in this final rule. While this final rule *allows* FHIP and FHAP funded entities to use HUD funds to hire testers with convictions involving fraud or perjury (in addition to those with felony convictions generally), HUD expects many FHIP and FHAP funded entities will still screen for these convictions and consider whether to hire an applicant on a case-by-case basis, in line with their own needs, investigations, and litigation efforts. A FHIP or FHAP funded entity may, for example, view an applicant with a 40-year-old conviction for writing a bad check much differently than someone more recently convicted of embezzling funds from a non-profit or governmental organization. Whether for fraud or perjury crimes, or for felony convictions more generally, HUD finds that an automatic, blanket ban is unable to account for the numerous different circumstances which may make a particular conviction an inappropriate disqualifier to a testing applicant's candidacy for employment with a FHIP or FHAP funded agency. While HUD notes that recidivism statistics can have value in some contexts, the inferences that can be drawn from these statistics are limited, and HUD believes that these statistics are inappropriate to use here to justify categorical bans against people applying to be testers.[30] HUD reiterates the messages in ''Tenant Screening With Criminal Background Checks: Predictions And Perceptions Are Not Causality'', published on May 17, 2022 by HUD's Office of Policy, Development, and Research, which notes that ''predicting future criminal involvement is a complicated business. Even using the best assessment and screening tools that undergo regular validations and enhancements, predictions are often wrong. . . . prediction is not causality, [and] we have to accept that predictions look backward to estimate an outcome that has not yet occurred and may never occur.'' Further, basing risk assessments on criminal convictions means using ''measures that are inherently biased because of discriminatory criminal justice practices.'' *Id.* Thus, HUD believes that examining each applicant on a case on a case-by-case basis, with full contextual information, is a fairer and more effective means to determine someone's qualification for a job, compared to automatically assuming someone will not be a good candidate based on a conviction for a specific category of crime (here, either a felony or a crime involving fraud or perjury).

HUD believes that integrity of the FHIP and FHAP is jeopardized by: (1) imposing rigid and automatic bans based on convictions that may have no bearing on a person's ability to be a quality tester, (2) forbidding FHIP and FHAP funded entities from taking into account all the relevant information about candidates for testers (including the age of any conviction, evidence of rehabilitation, circumstances surrounding any conviction), and (3) forcing FHIP and FHAP funded entities to make decisions based on convictions that may have been the result of the same kind of discrimination that these entities are meant to combat. HUD believes that these issues pose more of a threat to the integrity of the FHIP and FHAP than allowing FHIP and FHAP funded entities the discretion to allow people with convictions for fraud and perjury become testers. HUD further notes that providing discretion to FHIP and FHAP funded entities to hire testers who have past convictions involving fraud or perjury is consistent with current debarment regulations, which allow federal agencies to debar individuals based on certain criminal convictions (see 2 CFR 180.800), and also allow the government to take into account a long list of mitigating circumstances to decide *not* to debar an individual based on such convictions. *See* 2 CFR 180.860.

HUD agrees with commenters who said testers with actual criminal convictions ranging from misdemeanor to felony convictions are, in certain circumstances, the best suited to obtain evidence of what modern-day criminal record screening practices are and whether these policies are being applied in a discriminatory way. HUD also agrees that engaging individuals with experiences that are relevant to a fair housing investigation is beneficial to both fair housing enforcement and HUD's mission to advance equity more generally. HUD agrees with commenters that broadening the scope of persons who can serve as testers allows FHIP and FHAP funded entities to build and maintain a more diverse testing pool that is best poised to respond to all types of fair housing allegations. The final rule is in line with these goals.

HUD agrees that FHIP and FHAP funded entities are in the best position to make decisions about how to screen their own testers because those entities know the specific characteristics and challenges of their local housing markets and can select the most appropriate testers for their investigations. As stated in the proposed rule, HUD sees no reason to categorically bar those who conduct testing using FHIP or FHAP funds from employing testers with certain criminal convictions. By rescinding the Federal prohibitions on tester criminal convictions, this final rule provides necessary discretion to FHIP and FHAP funded entities.

D. Increased Opportunities and Benefits for People With Criminal Convictions and Society

Commenters noted the struggles of individuals who have made mistakes, and noted that despite being rehabilitated, not a threat, and active members of their community, people with criminal convictions are continually unfairly excluded from desperately needed opportunities, including career opportunities some of which are blocked by the current regulation's stipulations. Commenters said the collateral consequences of felony convictions can lead to mental health issues and recidivism.

Many commenters said that the current regulations unfairly punish those who have already been punished through the criminal justice system and should not be punished further.

[30] First, it should be noted that recidivism rates in the BJS study that the commenter appears to be citing from are measured by *arrest* for *any* offense, including parole and probation violations, and include arrests that do not result in convictions. *See* U.S. Department of Justice Office of Justice Programs Bureau of Justice Statistics, Special Report ''Recidivism of Prisoners Released in 30 States in 2005: Patterns from 2005 to 2010'' (April 2014), *available at https://bjs.ojp.gov/content/pub/pdf/rprts05p0510.pdf.* Of note, this report (and data tables accompanying it) shows that 11.9% of re-arrests within five years were for fraud offenses, and that the overall recidivism rate after 5 years was 55.4 percent if measured by any arrest resulting in a new conviction. Second, even where recidivism is measured in the same way, rates can vary widely depending on the study. *See id.* (detailing that of a cohort of state prisoners released in 2005, those convicted of fraud or forgery offenses had one of the highest recidivism rates (77 percent were re-arrested for *any* offense after five years)) *compare to* Kim Steven Hunt and Robert Dumville, U.S. Sentencing Commission, Recidivism Among Federal Offenders: A Comprehensive Overview 11 (2016), *available at https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2016/recidivism_overview.pdf* (detailing that of a cohort of federal prisoners released in 2015, those convicted of fraud had the lowest recidivism rates (34.2 percent were re-arrested for *any* offense after eight years)).

Commenters said if someone has ''served their time'' and ''paid their debt to society,'' they should be able to put the past behind them and have a second chance, including the chance to assist in positive change and serve in the role of a fair housing tester.

Commenters said the proposed rule will improve the lives of people with criminal convictions by expanding opportunities to develop marketable skills and jobs in order gain self-sufficiency, stability, and contribute positively to society. Commenters specifically talked about the value of those reentering society becoming more involved in their communities through serving in the role of a fair housing tester. Commenters stated that the proposed rule would reduce stigma against people with felony convictions, which commenters noted as an important goal.

One commenter stated that this rule is especially needed to support single fathers and men, especially Black men who are struggling to regain their identity without stability or sources of income because of criminal records.

HUD Response: HUD agrees with commenters that the final rule will expand important opportunities for individuals with criminal convictions because of the compensation these opportunities will provide for individuals who are hired through the FHIP and FHAP programs, the valuable experience these individuals will gain to help further career prospects, and because of the empowerment that comes from employment generally, and particularly employment focused on rooting out discrimination in one's community. HUD notes that opening access to fair housing enforcement should increase housing opportunities more generally by increasing detecting discriminatory policies and practices that impact those with criminal convictions.

HUD agrees with the commenters that by opening up employment opportunities for people with criminal convictions in our FHIP and FHAP programs, this final rule contributes to a stronger, healthier, safer society at large.[31]

[31] While research has demonstrated that employment lowers recidivism risks generally, there is also evidence that meaningful jobs may be the most impactful. *See, e.g.,* Robert Apel, Julie Horney. (2017). ''How and why does work matter? Employment conditions, routine activities, and crime among adult male offenders'', Criminology, 55 (2): 307–343 (finding that having a job that a person is ''very committed to'' verses a job that was ''just a job'' significantly lowers the risk that person will commit a crime).

E. Other

One commenter requested that guidance be issued to clarify to grant managers and FHIP staff that a blanket ban on testers with past convictions will no longer be enforced. Another commenter said HUD should ensure that FHIP and FHAP funded testing programs are actively advertising to people with prior criminal convictions, encouraging people from all backgrounds to apply, and evaluating their applications fairly. One commenter recommended that once the prohibition is removed, HUD should partner with organizations that serve those with felony convictions and convictions involving fraud or perjury to create and fund a training program and pipeline for those with records to become testers.

Several commenters wrote regarding their support for or their opposition to expanding housing opportunities for individuals with criminal convictions.

Other commenters wrote with specific concerns and requests relating to their individual housing situations.

HUD Response: HUD thanks commenters for their recommendations and will take them under advisement.

HUD also appreciates all comments relating to expanding housing opportunities for individuals with criminal histories. However, this final rule does not change any regulation regarding whom landlords —including HUD-assisted housing providers and public housing agencies—may accept as tenants. Instead, this final rule removes prohibitions on the use of HUD funds to hire testers with certain criminal convictions.

Finally, regarding comments outlining specific concerns and requests relating to individual housing situations, HUD thanks these commenters for their thoughts, however, HUD is unable to take any of the requested actions under this rulemaking.

III. Findings and Certifications

Regulatory Review—Executive Orders 12866, 13563, and 14094

Under E.O. 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. E.O. 13563 (Improving Regulations and Regulatory Review) directs Executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' E.O. 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. E.O. 14094 (Modernizing Regulatory Review) amends section 3(f) of E.O. 12866, among other things.

The final rule revises 24 CFR parts 115 and 125 to remove fair housing tester restrictions. The revised regulations would allow FHIP and FHAP funded entities the ability to use HUD funds to compensate testers with felony convictions and convictions for crimes involving fraud or perjury. This rule was not subject to OMB review. This rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866 and is not an economically significant regulatory action.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This final rule will remove tester restrictions from the FHIP and FHAP regulations which prohibit fair housing testers with prior convictions of a felony, fraud, or perjury. This will not create an undue burden on small entities, instead it will allow FHIP and FHAP funded entities the ability to use testers with felony convictions and convictions for crimes involving fraud or perjury. Identifying potential discriminatory screening policies will positively impact small entities and assist with maintaining compliance with the Fair Housing Act. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This final rule does not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt

state law within the meaning of the Executive order.

Environmental Impact

This final rule is a policy document that sets out fair housing and nondiscrimination standards and provides for assistance in enforcing fair housing and nondiscrimination. Accordingly, under 24 CFR 50.19(c)(3), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This rule will not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of the Unfunded Mandates Reform Act of 1995.

List of Subjects

24 CFR Part 115

Administrative practice and procedure, Aged, Fair housing, Grant programs—housing and community development, Individuals with disabilities, Intergovernmental relations, Mortgages, Reporting and recordkeeping requirements.

24 CFR Part 125

Fair housing, Grant programs—housing and community development, Reporting and recordkeeping requirements.

For the reasons described in the preamble, HUD amends 24 CFR 115 and 125 as follows:

PART 115—CERTIFICATION AND FUNDING OF STATE AND LOCAL FAIR HOUSING ENFORCEMENT AGENCIES

■ 1. The authority citation for part 115 continues to read as follows:

Authority: 42 U.S.C. 3601–19; 42 U.S.C. 3535(d).

§ 115.311 [Amended]

■ 2. In § 115.311, remove paragraph (b) and redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

PART 125—FAIR HOUSING INITIATIVES PROGRAM

■ 3. The authority citation for part 125 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 3616 note.

§ 125.107 [Amended]

■ 4. In § 125.107, remove paragraph (a) and redesignate paragraphs (b) and (c) as paragraphs (a) and (b), respectively.

Damon Y. Smith,

General Counsel.

[FR Doc. 2024–06977 Filed 4–2–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 1, 5, 104, 151, 155, 161, 164, 165, 174, and 175

46 CFR Parts 3, 15, 70, 117, 118, 119, and 147

[Docket No. USCG–2023–0759]

Navigation and Navigable Waters, and Shipping; Technical, Organizational, and Conforming Amendments

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: This final rule makes non-substantive, technical, organizational, and conforming amendments to existing Coast Guard regulations. This final rule is a continuation of our practice of periodically issuing rules to keep our regulations up-to-date and accurate. This final rule will have no substantive effect on the regulated public.

DATES: This final rule is effective April 3, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov,* type USCG–2023–0759 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Mr. Dale Murad, Coast Guard; telephone 202–372–3747, email *Dale.Murad@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

CFR Code of Federal Regulations
CG–MER Office of Marine Environmental Response Policy
DDH Document Drafting Handbook
DHS Department of Homeland Security
FR Federal Register
GPO Government Publishing Office
OMB Office of Management and Budget
§ Section
U.S.C. United States Code

II. Regulatory History

We did not publish a notice of proposed rulemaking for this rule. Under Title 5 of the United States Code (U.S.C.), section 553(b)(A), the Coast Guard finds that this final rule is exempt from notice and public comment rulemaking requirements, because these changes involve rules of agency organization, procedure, or practice. In addition, the Coast Guard finds that notice and comment procedures are unnecessary for this final rule under 5 U.S.C. 553(b)(B), as this rule consists of only technical and editorial corrections, and these changes will have no substantive effect on the public. Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that, for the same reasons, good cause also exists for making this final rule effective upon publication in the **Federal Register**.

III. Basis and Purpose

This final rule, which becomes effective on April 3, 2024, makes technical and editorial corrections throughout titles 33 and 46 of the Code of Federal Regulations (CFR). These changes are necessary to update authority citations, correct errors, update contact information, and make other non-substantive amendments that improve the clarity of the CFR. This rule does not create or change any substantive requirements.

This final rule is issued under the authorities of 5 U.S.C. 552(a) and 553; 14 U.S.C. 102 and 503; Department of Homeland Security (DHS) Delegation No. 00170.1, Revision No. 01.3; and authorities listed at the end of this rule for each CFR part this rule amends.

IV. Discussion of the Rule

The Coast Guard periodically issues technical, organizational, and conforming amendments to existing regulations in titles 33 and 46 of the CFR. These technical amendments provide the public with accurate and current regulatory information, but do not change the effect of any Coast Guard regulations on the public.

A. Authority Citation Updates

This final rule updates the authority citations in 33 CFR parts 1, 151, 155, 161, 164, and 175, and 46 CFR parts 3, 15, 70, 117, 118, 119, and 147. Specifically, this final rule implements the updates to DHS Delegation No. 00170.1, Revision No. 01.3 in 33 CFR parts 1, 151, 155, 161,164, and 175, and 46 CFR parts 3, 15, 70, 117, 118, 119, and 147.

B. Formatting Amendments To Accompany Technical Amendments in this Document

The Office of the Federal Register's Document Drafting Handbook (DDH) provides guidance on how to follow the formatting and editorial requirements established in 44 U.S.C. chapter 15 (the **Federal Register** Act) and 1 CFR chapter I. See the Introduction to the DDH, which is at *www.archives.gov/files/federal-register/write/handbook/ddh.pdf*. At page 2–55, the DDH refers readers to the Government Publishing Office (GPO) Style Manual as a guide for punctuation, capitalization, spelling, compounding, and other style matters not addressed in the DDH.

In a note on page 2–29, the DDH states, ''Even if you have only one note, appendix, table, or figure, you must still designate it as 'Note 1', 'Appendix A', etc.'' To comply with this guidance, we have numbered any unnumbered tables and notes, which are otherwise being amended in this document. In an example on page 77, the GPO Style Manual provides that the word ''table'' should be capitalized when the word is part of the title of the table. The GPO Style Manual is at *www.govinfo.gov/content/pkg/GPO-STYLEMANUAL-2016/pdf/GPO-STYLEMANUAL-2016.pdf*. To comply with this guidance, we have capitalized the word ''table'' wherever it is used in these technical amendments as part of the title of the table.

C. Technical Amendments to Title 33 of the CFR

In § 1.05–1(d), this final rule updates language to reflect the new rulemaking delegation memo for rulemakings from Coast Guard Headquarters issued by the Commandant on April 6, 2023. Specifically, these changes reflect current delegations in Commandant Memorandum 16704, which delegates rulemaking authority to the following headquarters individuals and offices: Assistant Commandant of Prevention Policy (CG–5P), the Assistant Commandant for Response Policy (CG–5R), the Assistant Commandant for Resources (CG–8), and the Judge Advocate General (CG–094). The revised language preserves and incorporates verbatim the limitation of this delegation to those regulations determined nonsignificant within the meaning of Executive Order 12866, which had been in what was subparagraph (d)(2). As noted above, the Memo only addresses delegations of rulemaking authorities to headquarters organizations, in this case, those covered in paragraph (d) of 33 CFR 1.05–1; it does not affect delegations to field offices, which are covered in paragraph (e) of § 1.05–1.

In § 5.26(b), this final rule replaces the outdated reference to the Coast Guard Institute with a reference to the Coast Guard Education and Training Quota Management Command. In 2017, the Coast Guard Institute was decommissioned and functionally replaced by the Coast Guard Education and Training Quota Management Command.

In § 104.400(b), this final rule removes an outdated address, as the Marine Safety Center no longer has a location in Arlington, Virginia.

In §§ 151.27 and 151.28, this final rule updates language to reflect the current directorate, office titles, and individuals fulfilling those responsibilities, and corrects mailing, email, and electronic submission addresses. This final rule replaces the outdated ''CG–CVC–1'' title with ''CG–MER'' and updates instructions for submitting plans and revisions electronically. It also removes paragraph (h) in both sections. The paragraphs being removed address the use of forms, which are no longer used.

In the note to what is currently labeled ''Table 155.1050(k)'', and in §§ 155.1065(h), 155.1070(g), 155.5067(c), 155.5075(a), and 155.5075(b), this final rule removes outdated language and replaces it with the names of current directorates, office titles, and individuals fulfilling those responsibilities. The text ''Table 155.1050(k)'' has been changed to ''Table 1 to § 155.1050(k),'' and its note has been changed to ''Note 1'' in accordance with the DDH. In addition, in §§ 155.1065(h), 155.1070(g), and 155.5075(a) and (b), this final rule removes the text, ''Incident Management and Preparedness Policy,'' and replaces that text with ''Emergency Management.'' In addition, it corrects mailing, email, and electronic submission addresses.

In § 155.1065(a), this final rule substitutes ''must'' for the obsolete term ''shall,'' in accordance with direction in the Federal Plain Language Guidelines, March 2011, the use of which has been mandated by the Office of Management and Budget (OMB) Memo M–11–15 (Final Guidance on Implementing the Plain Writing Act of 2010). (*https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2011/m11-15.pdf*.) In addition, in §§ 155.1065(a) and 155.5065(a), this final rule updates instructions for electronically submitting a vessel response plan to the Commandant. It updates the website link for submitting a vessel response plan, and it adds a website link for new user registration (to enable electronic submission). It also updates the postal mailing address to reflect the correct ''Stop'' number and zip code for the Office of Marine Environmental Response Policy (CG–MER).

In § 155.1065(b), this final rule removes the last sentence of the paragraph, and, in § 155.5065(b), this final rule removes the last two sentences of the paragraph. In § 155.5065(b), the penultimate sentence provides an incorrect website link for submitting a vessel response plan electronically. The substance of this sentence has been moved to paragraph (a), with the correct link substituted for the incorrect link currently provided in the sentence being removed from paragraph (b). The very last sentences of both §§ 155.1065(b) and 155.5065(b) refer to a document which is no longer used, and which is not available at the website linked. The document relates to submissions sent to the postal address for CG–MER. Vessel response plans so submitted need not use the form referred to in the sentence, which has been deleted.

In §§ 161.60(d)(2) and (3), this final rule replaces outdated references to redesignated paragraphs. These revisions align the references with the amendments made to § 161.60 in 67 FR 53742 (August 19, 2002), which redesignated paragraphs (b) through (d) as paragraphs (c) through (e), respectively, and added a new paragraph (b). References to the redesignated paragraphs were not updated in other paragraphs of this section at the time the paragraphs were redesignated.

This final rule revises ''Note to paragraph (d)'' in § 164.46 to ''Note 1 to § 164.46(d)'', in accordance with the DDH. In the same note, this final rule

corrects the address of the linked website (which leads to the Navigation Center home page) to take the reader directly to ''FAQ #2'' on the ''AIS Frequently Asked Questions'' page, (which is posted elsewhere on the Navigation Center website). FAQ #2 contains a link to the referenced ''USCG AIS Encoding Guidance.''

In § 164.70, this final rule replaces the outdated acronym for the Army Corps of Engineers ''ACOE'' with its new acronym, ''USACE.''

In § 165.840(a), this final rule updates the coordinates to the entrance of Egmont Channel to its correct location of 28°56′12.619″ N, 088°58′10.303″ W.

In § 165.1704(c), this final rule replaces the reference to § 161.60(c) with the corrected reference to § 161.60(d). As noted in the amendments to § 161.60, 67 FR 53742 redesignated paragraphs (b) through (d) in § 161.60 as paragraphs (c) through (e), respectively, while adding a new paragraph (b). However, references to the redesignated paragraphs were not updated in other sections, which this rule corrects.

This final rule removes paragraph (c) in §§ 174.17 and 174.19, as both paragraphs contained outdated and no longer applicable information on vessel numbering.

In § 175.380(a), this final rule replaces the reference to ''table 2 to § 175.320(b)(1)'' with a reference to ''Table 4.'' There is no ''table 2 to § 175.320.'' Paragraph (a) of § 175.380 involves fire extinguisher capacity, and ''Table 4 to § 175.320(b)(1)'', which establishes the number and size of portable fire extinguishers required aboard a recreational vessel more than 65 feet in length, is the correct reference.

D. Technical Amendments to Title 46 of the CFR

In § 3.03–1, this final rule replaces a reference to the definition of oceanographic research vessel in ''46 U.S.C. 2101(18)'' with ''46 U.S.C. 2101.'' Section 2101 contains a list of definitions in alphabetical order, and because new terms have been added to those already there, the numbering of the subsections in § 2101 has changed. The definition of ''major conversion'' is now found at 46 U.S.C. 2101(18) and the definition of ''oceanographic research vessel'' has moved to 46 U.S.C. 2101(24). We have decided not to specify the subsection in the replacement language, as subsection numbers are likely to continue to change as additional definitions are included in 46 U.S.C. 2101. In §§ 15.605(a) and (b), this final rule replaces outdated references in the statutory definition of ''uninspected passenger vessel'' with the correct reference. Congress added more definitions to 46 U.S.C. 2101 since 46 CFR 15.605 was published. And since definitions are listed there in alphabetical order, subsection numbers have changed.

As §§ 15.605(a) and (b) no longer reference the correct subparagraphs for the statutory definition for ''uninspected passenger vessel,'' this final rule replaces ''46 U.S.C. 2101(42)(A)'' with ''46 U.S.C. 2101(53)(A)'' in § 15.605(a), and with ''46 U.S.C. 2101(53)(B)'' in § 15.605(b). Here, we have retained the subparagraph numbers ''(53)(A)'' and ''(53)(B)'', because the requirements differ depending on which subsection of § 2101 applies.

In §§ 70.05–1(a) and 70.05–3(a), this final rule updates language and corrects a table reference. Originally, § 70.05–3(a) referred to ''column 4 of table 70.05–1(a),'' which existed when the rule was originally published (on December 30, 1965, at 30 FR 16892), but no such table exists today. The correct reference today is to ''column 3 of Table 2.01–7(a).'' In § 70.05–1(a), this final rule adds a reference to that table as well.

In §§ 117.71(d), 118.115(b), and 119.115(c), this final rule removes implementation deadlines for certain life jackets that have passed and are no longer relevant. This rule also adjusts and removes language in § 117.71(d) to reflect the removal of these outdated implementation deadlines.

In § 147.50(d), which provides that ''[l]iquefied or non-liquefied gas is prohibited for cooking, heating, and lighting on ferry vessels, but may be used on other inspected vessels if the system in which it is used meets the applicable requirements of subpart 58.16 or subpart 184.05 of this chapter. . .,'' this final rule replaces ''subpart 184.05'' with ''subpart B of part 184 of this chapter.'' The reference to ''subpart 184.05'' was added to § 147.50 in 1989 (54 FR 6396, 6402, Feb. 10, 1989). In 1996, we issued a rule (61 FR 864, 933, Jan. 10, 1996) that completely revised our regulations affecting small passenger vessels, including those in 46 CFR part 184. Subpart 184.05 became subpart b of part 184.

V. Regulatory Analyses

We developed this final rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes or Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The OMB has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review), and will not affect the Coast Guard's budget or increase Federal spending. A regulatory analysis follows.

This final rule involves non-substantive technical amendments and internal agency practices and procedures; it will not impose any additional costs. The technical amendments in this final rule fit into categories that involve (1) correcting inadvertent typographical errors in the CFR; (2) modifying existing language in the CFR by addition or subtraction to improve the readability or clarity of regulations; (3) removing irrelevant information, such as expired regulatory provisions or cancelled reference material, and replacing outdated regulatory information with current information where applicable; and (4) revising office contact information and mailing addresses. The Coast Guard does not expect that there will be any additional costs conferred on the public or the Federal Government, because none of the technical and editorial changes included in this final rule will change existing regulatory requirements. A summary of these amendments by category and by CFR title and section are presented below in table 1.

The unquantified benefits of the non-substantive technical amendments are increased accuracy of regulatory information by correcting erroneous information, and improved readability and clarity of regulations by removing redundant or confusing language and by removing expired or cancelled provisions that are no longer relevant. In addition, correcting technical items such as office contact details and location coordinates will improve the ability to reference and contact the correct entities.

TABLE 1—SUMMARY OF REGULATORY CHANGES BY CFR TITLE AND SECTION

CFR title	CFR section	Description of changes	Economic impact
33	§ 1.05–1(d)	Reflects changes brought on by the 2023 memo issued by the Commandant that revised the delegation memo for rulemakings.	Improves readability by removing or replacing irrelevant and outdated information.
46	§§ 3.03–1, 15.605(a), 15.605(b), 117.71(d), 118.115(b), 119.115(c), 147.50(d).	Removes outdated instructions and replaces it with updated locations, websites, and email addresses.	Improves readability by removing or replacing irrelevant and outdated information.
33	§§ 5.26(b), 104.400(b)	Removes outdated instructions and replaces it with updated locations, websites, and email addresses.	Improves readability by removing or replacing irrelevant and outdated information.
	§§ 155.1050(k), 155.1065(a), 155.1065(b), 155.1065(h), 155.1070(g), 155.5065(a), 155.5065(b), 155. 5067(c), 155.5075(a), 155.5075(b), 155.1065(a), 161.60(d)(2), 161.60(d)(3), 161.60(d)(4), 164.46(d)(4), 174.17, 174.19.	Removes outdated instructions and replaces it with updated locations, websites, and email addresses.	Improves readability by removing or replacing irrelevant and outdated information.
46	§§ 70.05–1(a), 70.05–3(a)	Improves the accuracy of regulatory information by correcting erroneous information.	Corrects various typographical errors.
33	§§ 151.27, 151.28, 165.1704(c)	Adds clarifying language and removes redundant, confusing, or incorrect language.	Improves readability by removing or replacing irrelevant and outdated information.
	§ 164.70	Improves the accuracy of regulatory information by correcting erroneous information.	Improves readability by removing or replacing irrelevant and outdated information.
	§ 165.173, 165.840(a), 175.380(a)	Improves the accuracy of regulatory information by correcting erroneous information.	Corrects information and conforms text to DDH formatting guidelines.

B. Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, requires federal agencies to consider the potential impact on small entities when they issue a rule after being required to first publish a general notice of proposed rulemaking. Under 5 U.S.C. 604(a), a regulatory flexibility analysis is not required for this final rule because under provision in 553(b)(B) we were not required to publish a general notice of a proposed rulemaking. Therefore, we did not conduct a regulatory flexibility analysis for this rule.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we offer to assist small entities in understanding this final rule so that they can better evaluate its effects on them and participate in the rulemaking. The Coast Guard will not retaliate against small entities that question or complain about this final rule or any policy or action of the Coast Guard.

D. Collection of Information

This final rule calls for no new collection of information nor does it change any existing collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

E. Federalism

A final rule has implications for federalism under Executive Order 13132 (Federalism) if it has a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this final rule under Executive Order 13132 and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

F. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Although this final rule will not result in such expenditure, we do discuss the effects of this final rule elsewhere in this preamble.

G. Taking of Private Property

This final rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

H. Civil Justice Reform

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 (Civil Justice Reform) to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this final rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This final rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this final rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards and Incorporation by Reference

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This final rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this final rule under DHS Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. This final rule is categorically excluded under paragraph A3 and L54 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev 1. Paragraph A3 pertains to ''Promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, advisory circulars, and other guidance documents of the following nature: (a) Those of a strictly administrative or procedural nature; (b) Those that implement, without substantive change, statutory or regulatory requirements; (c) Those that implement, without substantive change, procedures, manuals, and other guidance documents; (d) Those that interpret or amend an existing regulation without changing its environmental effect; (e) Technical guidance on safety and security matters; or (f) Guidance for the preparation of security plans.'' Paragraph L54 pertains to ''Regulations which are editorial or procedural, such as those updating addresses or establishing application procedures.'' This final rule makes non-substantive technical, organizational, and conforming amendments to existing Coast Guard regulations.

This final rule is a continuation of our practice of periodically issuing rules to keep our regulations up-to-date and accurate. This final rule will have no substantive effect on the regulated public.

List of Subjects

33 CFR Part 1

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of information, Penalties.

33 CFR Part 5

Volunteers.

33 CFR Part 104

Maritime security, Reporting and recordkeeping requirements, Security measures.

33 CFR Part 151

Administrative practice and procedure, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

33 CFR Part 155

Alaska, Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 161

Harbors, Navigation (water), Reporting and recordkeeping requirements, Vessels, Waterways.

33 CFR Part 164

Marine, Navigation (water), Reporting and recordkeeping requirements, Waterways.

33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

33 CFR Part 174

Intergovernmental relations, Marine safety, Reporting and recordkeeping requirements.

33 CFR Part 175

Fire prevention, Marine safety.

46 CFR Part 3

Oceanographic research vessels, Reporting and recordkeeping requirements, Research.

46 CFR Part 15

Reporting and recordkeeping requirements, Seamen, Vessels.

46 CFR Part 70

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 117

Marine safety, Passenger vessels.

46 CFR Part 118

Fire prevention, Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 119

Fire prevention, Marine safety, Passenger vessels.

46 CFR Part 147

Hazardous materials transportation, Labeling, Marine safety, Packaging and containers, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 1, 5, 104, 151, 155, 161,164, 165, 174, and 175 and 46 CFR parts 3, 15, 70, 117, 118, 119, and 147 as follows:

Title 33—Navigation and Navigable Waters

PART 1—GENERAL PROVISIONS

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 14 U.S.C. 502, 503, 505; 33 U.S.C. 401, 491, 525, 1321, 2716, and 2716a; 42 U.S.C. 9615; 49 U.S.C. 322; DHS Delegation No. 00170.1, Revision No. 01.3.; section 1.01–70 also issued under the authority of E.O. 12580, 3 CFR, 1987 Comp., p. 193; and sections 1.01–80 and 1.01–85 also issued under the authority of E.O. 12777, 3 CFR, 1991 Comp., p. 351.

■ 2. Revise § 1.05–1(d) to read as follows:

§ 1.05–1 Delegation of rulemaking authority.

* * * * *

(d) The Commandant has redelegated the authority to develop and issue those regulations necessary to implement laws, treaties, and Executive orders to the Assistant Commandant for Prevention Policy, the Assistant Commandant for Response Policy, the Assistant Commandant for Resources, and the Judge Advocate General. The authority redelegated in this paragraph is limited to those regulations determined to be nonsignificant within the meaning of Executive Order 12866.

* * * * *

PART 5—COAST GUARD AUXILIARY

■ 3. The authority citation for part 5 continues to read as follows:

Authority: 14 U.S.C. 503, 3901, 3902, 3903, 3904, 3905, 3907, 3908, 3909, 3910, 3911, 3912, 3913, 4102.

§ 5.26 [Amended]

■ 4. In § 5.26(b), remove the words ''Coast Guard Institute'' and add, in their place, the words ''Coast Guard Education and Training Quota Management Command''.

PART 104—MARITIME SECURITY: VESSELS

■ 5. The authority citation for part 104 continues to read as follows:

Authority: 46 U.S.C. 70051, 70116, Chapter 701; 33 CFR 1.05–1, 6.04–11, 6.14, 6.16, and 6.19; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 104.400 [Amended]

■ 6. In § 104.400(b), remove the text '', 4200 Wilson Boulevard Suite 400, Arlington, VA 22203 for visitors''.

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

■ 7. The authority citation for part 151 is revised to read as follows:

Authority: 33 U.S.C. 1902, 1903, 1908; 46 U.S.C. 6101; 46 U.S.C. 70034; Pub. L. 104–227, 110 Stat. 3034; sec. 623, Pub. L. 108–293, 118 Stat. 1063; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; DHS Delegation No. 00170.1, Revision No. 01.3.

■ 8. Amend § 151.27 as follows:
■ a. Revise paragraphs (b) and (g); and
■ b. Remove paragraph (h).

The revisions read as follows:

§ 151.27 Plan submission and approval.

* * * * *

(b) An owner or operator of a ship to which this part applies shall prepare and submit one English language copy of the shipboard oil pollution emergency plan electronically at *https://vrp.uscg.mil/homeport-vrp/vrp-express/* by signing in using the registered email address and password or by email to *vrp@uscg.mil*. For new user registrations, please follow the process provided in the United States Coast Guard Homeport website at *https://homeport.uscg.mil/Pages/NewUserRegistration.aspx.or* by mail to Commandant (CG–MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593–7501.

* * * * *

(g) Plans, including revisions, should be submitted electronically by using the Vessel Response Plan Electronic Submission Tool available at *https://vrp.uscg.mil/homeport-vrp/vrp-express/* for registered users or by mail to Commandant (CG–MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593–7516 or by email to *vrp@uscg.mil*.

■ 9. Amend § 151.28 as follows:
■ a. Remove the text ''CG–CVC–1'', wherever it appears, and add, in its place, the text ''CG–MER'';
■ b. Revise paragraph (g); and
■ c. Remove paragraph (h).

The revision reads as follows:

§ 151.28 Plan review and revision.

* * * * *

(g) Plans, including revisions, should be submitted electronically by using the Vessel Response Plan Electronic Submission Tool available at *https://vrp.uscg.mil/homeport-vrp/vrp-express/* for registered users or by mail to Commandant (CG–MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593–7516 or by email to *vrp@uscg.mil*.

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

■ 10. The authority citation for part 155 is revised to read as follows:

Authority: 3 U.S.C. 301 through 303; 33 U.S.C. 1321(j), 1903(b), 2735; 46 U.S.C. 70011; 70034; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; DHS Delegation No. 00170.1, Revision No. 01.3. Section 155.1020 also issued under section 316 of Pub. L. 114–120. Section 155.480 also issued under section 4110(b) of Pub. L. 101–380.

§ 155.1050 [Amended]

■ 11. Amend § 155.1050(k) by:
■ a. Removing the text ''Table 155.1050(k)'' and adding, in its place, the text ''Table 1 to § 155.1050(k)'';
■ b. In the new ''Table 1 to § 155.1050(k)'', removing the text ''Note'' and adding, in its place, the text ''Note 1''; and
■ c. In the new ''Note 1 to Table 1 to § 155.1050(k)'', removing the text ''Office of Incident Management & Preparedness (CG–533)'' and adding, in its place, the text ''Office of Marine Environmental Response Policy (CG–MER)''.

§ 155.1065 [Amended]

■ 12. Amend § 155.1065 as follows:
■ a. Revise paragraphs (a) and (b); and
■ b. In paragraph (h), remove the words ''Incident Management and Preparedness Policy'' whenever they appear, and add, in their place, the words ''Emergency Management''.

The revision reads as follows:

§ 155.1065 Procedures for plan submission, approval, requests for acceptance of alternative planning criteria, and appeal.

(a) An owner or operator of a vessel to which this subpart applies must submit one complete English language copy of a vessel response plan to Commandant electronically by using the Vessel Response Plan Electronic Submission Tool available at *https://vrp.uscg.mil/homeport-vrp/vrp-express/* by signing in using the registered email address and password, or by email to *vrp@uscg.mil,* or by mail to Commandant (CG–MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593–7516. For new Homeport user email address and password registrations (to enable electronic submissions), please follow the process provided in the United States Coast Guard Homeport website at *https://homeport.uscg.mil/Pages/NewUserRegistration.aspx*. The plan must be submitted at least 60 days before the vessel intends to handle, store, transport, transfer, or lighter oil in areas subject to the jurisdiction of the United States.

(b) The owner or operator must include a statement certifying that the plan meets the applicable requirements of subparts D, E, F, G, and J of this part and shall include a statement indicating whether the vessel(s) covered by the plan are manned vessels carrying oil as a primary cargo, unmanned vessels carrying oil as a primary cargo, or vessels carrying oil as a secondary cargo.

* * * * *

§ 155.1070 [Amended]

■ 13. In § 155.1070(g), remove the words ''Incident Management and

Preparedness Policy'' whenever they appear, and add, in their place, the words ''Emergency Management''.

■ 14. Amend § 155.5065 by revising paragraphs (a) and (b) to read as follows:

§ 155.5065 Procedures for plan submission and approval.

(a) An owner or operator of a nontank vessel to which this subpart applies must submit one complete English language copy of a vessel response plan to Commandant electronically by using the Vessel Response Plan Electronic Submission Tool for registered users available at *https://vrp.uscg.mil/homeport-vrp/vrp-express/* or by mail to Commandant (CG–MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593–7516 or by email to *vrp@uscg.mil*. The plan must be submitted at least 60 days before the vessel intends to operate upon the navigable waters of the United States.

(b) The owner or operator of a nontank vessel must include a statement certifying that the VRP meets the applicable requirements of this subpart and the requirements of subparts D, E, F, and G, if applicable. The vessel owner or operator must also include a statement certifying that the vessel owner or operator has ensured the availability of, through contract or other approved means, the necessary private response resources to respond, to the maximum extent practicable, to a worst-case discharge or substantial threat of such a discharge from their vessel as required under this subpart.

* * * * *

§ 155.5067 [Amended]

■ 15. In § 155.5067(c), remove the text ''(CG–CVC), Office of Commercial Vessel Compliance'' and add, in its place, the text ''(CG–MER), Office of Marine Environmental Response Policy''.

§ 155.5075 [Amended]

■ 16. In § 155.5075(a) and (b), remove the words ''Incident Management and Preparedness Policy'' whenever they appear, and add, in their place, the words ''Emergency Management''.

PART 161—VESSEL TRAFFIC MANAGEMENT

■ 17. The authority citation for part 161 is revised to read as follows:

Authority: 46 U.S.C. 70001, 70002, 70003, 70034, 70114, 70119; Pub. L. 107–295, 116 Stat. 2064; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 161.60 [Amended]

■ 18. Amend § 161.60 as follows:

■ a. In paragraph (d)(2), remove the text ''(c)(3)'' and add, in its place, the text ''(d)(3)''; and

■ b. In paragraph (d)(3), remove the text ''(c)(2)'' and add, in its place, the text ''(d)(2)''.

PART 164—NAVIGATION SAFETY REGULATIONS

■ 19. The authority citation for part 164 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3703, 70034; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277. Sec. 164.13 also issued under 46 U.S.C. 8502. Sec. 164.46 also issued under 46 U.S.C. 70114 and Sec. 102 of Pub. L. 107–295. Sec. 164.61 also issued under 46 U.S.C. 6101. DHS Delegation No. 00170.1, Revision No. 01.3.

§ 164.46 [Amended]

■ 20. In § 164.46(d), remove the text ''Note to paragraph (d)'' and add, in its place, the text ''Note 1 to § 164.46(d)''; remove the text ''U.S. AIS Encoding Guide'' and add, in its place, the text ''USCG AIS Encoding Guidance''; and remove the text ''*www.navcen.uscg.gov*'' and add, in its place, the text ''*www.navcen.uscg.gov/ais-frequently-asked-questions#2*''.

§ 164.70 [Amended]

■ 21. In § 164.70, amend the definition ''Currently corrected edition'' by removing the text ''(ACOE)'' and adding, in its place, the text ''(USACE)''.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 22. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

§ 165.840 [Amended]

■ 23. In § 165.840(a), remove the text ''008°58′10.303″ W'' and add, in its place, the text ''088°58′10.303″ W''.

§ 165.1704 [Amended]

■ 24. In § 165.1704(c), remove the text ''§ 161.60(c)'' and add, in its place, the text ''§ 161.60(d)''.

PART 174—STATE NUMBERING AND CASUALTY REPORTING SYSTEMS

■ 25. The authority citation for part 174 continues to read as follows:

Authority: 46 U.S.C. 6101 and 12302; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 174.17 [Amended]

■ 26. Remove § 174.17(c).

§ 174.19 [Amended]

■ 27. Remove § 174.19(c).

PART 175—EQUIPMENT REQUIREMENTS

■ 28. The authority citation for part 175 is revised to read as follows:

Authority: 46 U.S.C. 4302; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 175.380 [Amended]

■ 29. In § 175.380(a), remove the text ''table 2'' and add, in its place, the text ''Table 4''.

Title 46—Shipping

PART 3—DESIGNATION OF OCEANOGRAPHIC RESEARCH VESSELS

■ 30. The authority citation for part 3 is revised to read as follows:

Authority: 46 U.S.C. 2113, 3306; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 3.03–1 [Amended]

■ 31. In § 3.03–1, remove the text ''46 U.S.C. 2101(18)'' and add, in its place, the text ''46 U.S.C. 2101''.

PART 15—MANNING REQUIREMENTS

■ 32. The authority citation for part 15 is revised to read as follows:

Authority: 46 U.S.C. 2101, 2103, 3306, 3703, 8101, 8102, 8103, 8104, 8105, 8301, 8304, 8502, 8503, 8701, 8702, 8901, 8902, 8903, 8904, 8905(b), 8906 and 9102; and DHS Delegation No. 00170.1, Revision No. 01.3.

§ 15.605 [Amended]

■ 33. Amend § 15.605 by:

■ a. In paragraph (a), removing the text remove the text ''46 U.S.C. 2101(42)(A)'' and add, in its place, the text ''46 U.S.C. 2101(53)(A)''; and

■ b. In paragraph (b), removing the text remove the text ''46 U.S.C. 2101(42)(B)'' and add, in its place, the text ''46 U.S.C. 2101(53)(B)''.

PART 70—GENERAL PROVISIONS

■ 34. The authority citation for part 70 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277, sec. 1–105; DHS Delegation No. 00170.1, Revision No. 01.3.

■ 35. Revise § 70.05–1(a) introductory text to read as follows:

§ 70.05–1 United States flag vessels subject to the requirements of this subchapter.

(a) This subchapter is applicable to all U.S.-flag vessels indicated in column 3 of Table 2.01–7(a) in § 2.01–7(a) of this chapter that are 100 gross tons or more, except as follows:

* * * * *

■ 36. Revise § 70.05–3(a) introductory text to read as follows:

§ 70.05–3 Foreign vessels subject to the requirements of this subchapter.

(a) Except as specifically noted in paragraphs (b), (e), and (f) of this section, parts 70 to 78, inclusive, of this subchapter, are applicable to the extent prescribed by law to all foreign vessels of the following classifications indicated in column 3 of Table 2.01–7(a) in § 2.01–7(a) of this chapter that are 100 gross tons or over:

* * * * *

PART 117—LIFESAVING EQUIPMENT AND ARRANGEMENTS

■ 37. The authority citation for part 117 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation No. 00170.1, Revision No. 01.3.

■ 38. Amend § 117.71 by revising paragraph (d) to read as follows:

§ 117.71 Life jackets.

* * * * *

(d) Cork and balsa wood life jackets previously approved in accordance with § 106.003 or § 160.004 in subchapter Q of this chapter may not be used to meet the requirements of this section.

* * * * *

PART 118—FIRE PROTECTION EQUIPMENT

■ 39. The authority citation for part 118 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 118.115 [Amended]

■ 40. In § 118.115(b), remove the text ''on or before March 11, 1999''.

PART 119—MACHINERY INSTALLATION

■ 41. The authority citation for part 119 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 119.115 [Amended]

■ 42. In § 119.115(c), remove the text ''On or before March 11, 1999, an'' and add, in its place, the text ''An''.

PART 147—HAZARDOUS SHIPS' STORES

■ 43. The authority citation for part 147 is revised to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation No. 00170.1, Revision No. 01.3.

§ 147.50 [Amended]

■ 44. In § 147.50(d), remove the text ''subpart 184.05'' and add, in its place, the text ''subpart B of part 184 of this chapter.''

Dated: March 28, 2024.

Michael T. Cunningham,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2024–06922 Filed 4–2–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

[Docket No. FWS–R7–SM–2018–0013; FF07J00000–245–FXFR13350700640]

RIN 1018–BC96

Subsistence Management Regulations for Public Lands in Alaska—Applicability and Scope; Tongass National Forest Submerged Lands

AGENCY: Forest Service, Agriculture; Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: To comply with a court order, the Secretaries, through the Federal Subsistence Board (Board), initiated regulatory proceedings to identify those submerged lands within the Tongass National Forest that did not pass to the State of Alaska at statehood and, therefore, remain Federal public lands subject to Federal subsistence provisions. This rule adds to the list of submerged parcels in the Federal subsistence regulations that have been identified through agency review. The purpose of this rule is to complete regulatory proceedings addressing submerged public lands within the Tongass National Forest, as directed by the Court, and will result in increased subsistence harvest opportunities for rural Alaskans. This final rule will also make nonsubstantive changes to present the list of submerged parcels in a tabular format.

DATES: This rule is effective April 3, 2024.

ADDRESSES: Information regarding this final rule, including the Board meeting transcripts, are available for review at the Office of Subsistence Management, 1011 East Tudor Road, Mail Stop 121, Anchorage, AK 99503, or on the Office of Subsistence Management website (*https://www.doi.gov/subsistence/board*).

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Assistant Regional Director, Office of Subsistence Management; (907) 786–3888 or *subsistence@fws.gov.* For questions specific to National Forest System lands, contact Gregory Risdahl, Regional Subsistence Program Leader, USDA, Forest Service, Alaska Region; (907) 302–7354 or *gregory.risdahl@usda.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Under title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program (Program). The Program provides a preference for take of fish and wildlife resources for subsistence uses by rural residents on Federal public lands and waters in Alaska. The Secretaries published temporary regulations to carry out the Program in the **Federal Register** on June 29, 1990 (55 FR 27114), and published final regulations in the **Federal Register** on May 29, 1992 (57 FR 22940). These regulations have subsequently been amended a number of times. Because the Program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): Title 36, ''Parks, Forests, and Public Property,'' and Title 50, ''Wildlife and Fisheries,'' at 36 CFR 242.1–242.28 and 50 CFR 100.1–100.28,

respectively. The regulations contain subparts as follows: Subpart A, General Provisions; Subpart B, Program Structure; Subpart C, Board Determinations; and Subpart D, Subsistence Taking of Fish and Wildlife.

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board (Board) to administer the Program. The Board comprises:

- A Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- The Alaska Regional Director, U.S. Fish and Wildlife Service;
- The Alaska Regional Director, National Park Service;
- The Alaska State Director, Bureau of Land Management;
- The Alaska Regional Director, Bureau of Indian Affairs;
- The Alaska Regional Forester, USDA Forest Service; and
- Two public members appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture.

Through the Board, these agencies participate in the development of regulations for subparts C and D, which, among other things, set forth Program eligibility and specific harvest seasons and limits.

In administering the Program, the Secretaries divided Alaska into 10 subsistence resource regions, each of which is represented by a Federal Subsistence Regional Advisory Council (Council). The Councils provide a forum for rural residents with personal knowledge of local conditions and resource requirements to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Council members represent varied geographical, cultural, and user interests within each region.

Jurisdictional Background and Perspective

The U.S. District Court for Alaska (Court) in its October 17, 2011, order in *Peratrovich et al.* v. *United States and the State of Alaska,* 3:92–cv–0734–HRH (D. Alaska), enjoined the United States ''to promptly initiate regulatory proceedings for the purpose of implementing the subsistence provisions in Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) with respect to submerged public lands within Tongass National Forest'' and directed entry of judgment. The *Peratrovich* case dates to 1992 and has a long and involved procedural history. The plaintiffs in that litigation raised the question of which marine waters in the Tongass National Forest, if any, are subject to the jurisdiction of the Federal Subsistence Management Program. In its May 31, 2011, order, the Court stated that ''it is the duty of the Secretaries [Agriculture & Interior] to identify any submerged lands (and the marine waters overlying them) within the Tongass National Forest to which the United States holds title.'' It also stated that, if such title exists, it ''creates an interest in [the overlying] waters sufficient to make those marine waters public lands for purposes of [the subsistence provisions] of ANILCA.''

Most of the marine waters within the Tongass National Forest were not initially identified in the regulations as public lands subject to the subsistence priority, initially based upon a determination that the submerged lands were State lands, and later through reliance upon a disclaimer of interest filed by the United States in *Alaska* v. *United States,* No. 128 Orig., 546 U.S. 413 (2006). In that case, the State of Alaska had sought to quiet title to all lands underlying marine waters in southeast Alaska, which includes most of the Tongass National Forest. Ultimately, the United States disclaimed ownership to most of the submerged lands in the Tongass National Forest. The Supreme Court accepted the disclaimer by the United States to title to the marine waters within the Tongass National Forest, excepting from that disclaimer several classes of submerged public lands that generally involve small tracts (see *Alaska* v. *United States,* 546 U.S. at 415).

When the United States took over subsistence management in Alaska in 1990 and promulgated the temporary regulations, the Departments of the Interior and Agriculture stated in response to comments on the scope of the program that ''[t]he United States generally does not hold title to navigable waters and thus navigable waters generally are not included within the definition of public lands'' (55 FR 27114 at 27115; June 29, 1990). That position was changed in 1999 when the subsistence priority was extended to inland waters subject to a Federal reserved water right following the *Katie John* litigation. While locating these inland waters, the Board also identified certain submerged marine lands that did not pass to the State and, therefore, were subject to the subsistence priority. However, the Board did not attempt to identify every small parcel of submerged public lands and associated marine waters possibly subject to the Program because of the potentially overwhelming administrative burden. Instead, the Board invited the public to petition to have submerged marine lands included. Over the years, several small areas of submerged marine lands in the Tongass National Forest have been identified as public lands subject to the subsistence priority.

In its May 31, 2011, order, the Court in the *Peratrovich* case stated that the petition process was not sufficient and found that ''concerns about costs and management problems simply cannot trump the congressional policy that the subsistence lifestyle of rural Alaskans be preserved as to public lands.'' The Court acknowledged in its order that inventorying all these lands could be an expensive undertaking, but that it is a burden ''necessitated by the 'complicated regulatory scheme' which has resulted from the inability of the State of Alaska to implement Title VIII of ANILCA.'' The Court then enjoined the United States ''to promptly initiate regulatory proceedings for the purpose of implementing the subsistence provisions in Title VIII of ANILCA with respect to submerged public lands within Tongass National Forest'' and directed entry of judgment.

Following the Court's decision, the Departments published a notice in the **Federal Register** (77 FR 33391; June 6, 2012) announcing the initiation of reviews of pre-statehood withdrawals and reservation in the Tongass National Forest. The Bureau of Land Management (BLM) and the USDA–Forest Service (USDA–FS) started a review of hundreds of potential pre-statehood (January 3, 1959) withdrawals in the marine waters of the Tongass National Forest. These reviews included dock sites, log transfer sites, and other areas that may not have passed to the State at statehood. On June 8, 2016, the Departments published a proposed rule in the **Federal Register** (81 FR 36836) that listed the initial findings identifying pre-statehood withdrawals, and on May 23, 2018, the Departments published a final rule (83 FR 23813) to revise the subsistence management regulations to add those submerged parcels. The Departments published another proposed rule on May 12, 2022 (87 FR 29061), with the intent to complete regulatory proceedings addressing submerged public lands within the Tongass National Forest as directed by the Court. This rule will complete those proceedings.

Current Rule

The Departments published a proposed rule on May 12, 2022 (87 FR 29061), to amend the applicability and scope section of subpart A of 36 CFR part 242 and 50 CFR part 100 and to

complete the actions on the Tongass National Forest submerged lands. The proposed rule opened a comment period, which closed on August 10, 2022, and announced public meetings to be held in several different locations throughout the State. The Departments advertised the proposed rule by mail, email, web page, social media, radio, and newspaper, and comments were submitted via *https://www.regulations.gov* to Docket No. FWS–R7–SM–2018–0013. The Councils received public comments on the proposed rule during their public meetings. The Councils had an opportunity to review the proposed rule and make recommendations to the Board for the final rule as described in more detail below.

The Board held a public meeting on January 31 through February 3, 2023. All briefings and documents presented to the Board were available to the public at *https://www.doi.gov/subsistence,* and the meeting was advertised by mail, email, web page, social media, radio, and newspaper. After a briefing and deliberation, the Board decided on the following recommendation to the Secretaries: ''The Federal Subsistence Board recommends to the Secretaries that the lands listed in the proposed rule of May 12, 2022 (87 FR 29061), be included in the Subsistence Management Regulations for Public Lands in Alaska (36 CFR [part] 242 and 50 CFR [part] 100) for the purpose of implementing the subsistence provisions in Title VIII of the Alaska National Interest Lands Conservation Act.''

These final regulations reflect the Board's recommendation to the Secretaries after review and consideration of Council recommendations, Tribal and Alaska Native corporation consultations, and public comments. The public received extensive opportunity to review and comment on all changes.

Summary of Comments Received and Responses

The Board did not receive any public comments that directly pertain to the primary issue of this rulemaking action. The Southeast Alaska Council did not object to these lands coming under Federal subsistence jurisdiction after maps were provided by the USDA–FS, as had been previously requested. The Southcentral Alaska, Kodiak/Aleutians, Bristol Bay, Yukon-Kuskokwim Delta, Western Interior Alaska, Seward Peninsula, Eastern Interior Alaska, and North Slope Councils had no comments and took no actions. The Kodiak/Aleutian Council requested that the Councils and the public be notified when the final rule has been published and that this information be posted on the Program's website.

Tribal consultation was offered statewide. No tribal entity requested specific consultation and no comments were offered via correspondence, during public hearings, or during consultations on different issues.

Summary of Changes From the Proposed Rule

Following publication of the proposed rule, the USDA–FS cartographer reviewed the table of geographic areas in the proposed rule and noted the following duplicate entries:

- High Point, Woronkofski Island;
- Key Reef, Clarence Strait;
- Lyman Point, Clarence Strait;
- Ship Island, Clarence Strait; and
- Point Hilda, Stephens Passage, Douglas Island.

Accordingly, in this final rule, we have corrected the table of geographic areas by removing those duplicate entries.

Additionally, the latitude information for Lyman Point and Clarence Strait was also revised because the original latitude was inaccurate.

Because this rule concerns public lands managed by an agency or agencies in both the Departments of Agriculture and the Interior, identical text will be incorporated into 36 CFR part 242 and 50 CFR part 100.

Compliance With Statutory and Regulatory Authorities

Administrative Procedure Act

The Departments, through the Board, have provided extensive opportunity for public input and involvement in compliance with Administrative Procedure Act (5 U.S.C. 551 *et seq.*) requirements, including publishing a proposed rule in the **Federal Register**, participation in multiple Council meetings, additional public review and comment on all proposals for regulatory change, and an opportunity for additional public comment before the Board deliberated on its recommendation to the Secretaries. Therefore, the Departments believe that all affected persons have been given sufficient public notice and opportunity for involvement on the Board's recommendation and the final rule.

In the more than 30 years that the Program has been operating, there has never been a benefit to the public by delaying the effective date of the subsistence regulations. A lapse in regulatory control can affect the continued viability of fish or wildlife populations and future subsistence opportunities for rural Alaskans and would generally fail to serve the overall public interest. Therefore, the Departments finds good cause pursuant to 5 U.S.C. 553(d)(3) to make this rule effective upon the date set forth in **DATES** to ensure continued operation of the Program.

National Environmental Policy Act

A draft environmental impact statement that described four alternatives for developing a Federal Subsistence Management Program was distributed for public comment on October 7, 1991. The final environmental impact statement (FEIS) was published on February 28, 1992. The Record of Decision (ROD) on Subsistence Management for Federal Public Lands in Alaska was signed April 6, 1992. The selected alternative in the FEIS (Alternative IV) defined the administrative framework of an annual regulatory cycle for subsistence regulations.

The following **Federal Register** documents pertain to this rulemaking:

SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA, SUBPARTS A, B, AND C: FEDERAL REGISTER DOCUMENTS PERTAINING TO THE FINAL RULE

Federal Register citation	Date of publication	Category	Details
57 FR 22940	May 29, 1992	Final Rule	''Subsistence Management Regulations for Public Lands in Alaska; Final Rule'' was published in the **Federal Register**.

SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA, SUBPARTS A, B, AND C: FEDERAL REGISTER DOCUMENTS PERTAINING TO THE FINAL RULE—Continued

Federal Register citation	Date of publication	Category	Details
64 FR 1276	January 8, 1999	Final Rule	Amended the regulations to include subsistence activities occurring on inland navigable waters in which the United States has a reserved water right and to identify specific Federal land units where reserved water rights exist. Extended the Federal Subsistence Board's management to all Federal lands selected under the Alaska Native Claims Settlement Act and the Alaska Statehood Act and situated within the boundaries of a Conservation System Unit, National Recreation Area, National Conservation Area, or any new national forest or forest addition, until conveyed to the State of Alaska or to an Alaska Native Corporation. Specified and clarified the Secretaries' authority to determine when hunting, fishing, or trapping activities taking place in Alaska off the public lands interfere with the subsistence priority.
66 FR 31533	June 12, 2001	Interim Rule	Expanded the authority that the Federal Subsistence Board may delegate to agency field officials and clarified the procedures for enacting emergency or temporary restrictions, closures, or openings.
67 FR 30559	May 7, 2002	Final Rule	Amended the operating regulations in response to comments on the June 12, 2001, interim rule (66 FR 31533). Also corrected some inadvertent errors and oversights of previous rules.
68 FR 7703	February 18, 2003	Direct Final Rule	Clarified the age a person must be to receive certain subsistence use permits and removed the requirement that Regional Advisory Councils must have an odd number of members.
68 FR 23035	April 30, 2003	Affirmation of Direct Final Rule.	Because no adverse comments were received on the direct final rule (67 FR 30559; May 7, 2002), the direct final rule was adopted.
69 FR 60957	October 14, 2004	Final Rule	Clarified the membership qualifications for Regional Advisory Council membership and relocated the definition of ''regulatory year'' from subpart A to subpart D of the regulations.
70 FR 76400	December 27, 2005.	Final Rule	Revised jurisdiction in marine waters and clarified jurisdiction relative to military lands.
71 FR 49997	August 24, 2006	Final Rule	Revised the jurisdiction of the subsistence program by adding submerged lands and waters in the area of Makhnati Island, near Sitka, AK. These revisions allowed subsistence users to harvest marine resources in this area under seasons, harvest limits, and methods specified in the regulations.
72 FR 25688	May 7, 2007	Final Rule	Revised nonrural determinations.
75 FR 63088	October 14, 2010	Final Rule	Amended the regulations for accepting and addressing special action requests and the role of the Regional Advisory Councils in the process.
76 FR 56109	September 12, 2011.	Final Rule	Revised the composition of the Federal Subsistence Board by expanding the Board to include two public members who possess personal knowledge of and direct experience with subsistence uses in rural Alaska.
77 FR 12477	March 1, 2012	Final Rule	Extended the compliance date for the final rule (72 FR 25688; May 7, 2007) that revised nonrural determinations until the Secretarial review of the Program is complete or in 5 years, whichever comes first.
80 FR 68249	November 4, 2015	Final Rule	Revised the nonrural determination process and allowed the Federal Subsistence Board to define which communities and areas are nonrural.
83 FR 23813	May 23, 2018	Final Rule	Added submerged parcels to the subsistence regulations to ensure compliance with the October 7, 2011, Court order. *Peratrovich et al.* v. *United States and the State of Alaska*, 3:92–cv–0734–HRH (D. Alaska).

A 1997 environmental assessment dealt with the expansion of Federal jurisdiction over fisheries and is available at the office listed under **FOR FURTHER INFORMATION CONTACT**. The Secretary of the Interior, with concurrence of the Secretary of Agriculture, determined that expansion of Federal jurisdiction does not constitute a major Federal action significantly affecting the human environment and, therefore, signed a Finding of No Significant Impact.

Section 810 of ANILCA

An ANILCA section 810 analysis was completed as part of the FEIS process on the Federal Subsistence Management Program in the early 1990s. The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. The final section 810 analysis determination appeared in the April 6, 1992, ROD and concluded that the Program, under Alternative IV with an annual process for setting subsistence regulations, may have some local impacts on subsistence uses, but will not likely restrict subsistence uses significantly.

In accordance with ANILCA section 810, an environmental assessment was prepared in 1997 on the expansion of Federal jurisdiction over fisheries. That evaluation also supported the Secretaries' determination that the rule will not reach the ''may significantly restrict'' threshold that would require notice and hearings under ANILCA section 810(a).

Paperwork Reduction Act of 1995

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This rule does not contain any new collections of information that require OMB approval. OMB has reviewed and approved the collections of information associated with the subsistence regulations at 36 CFR part 242 and 50 CFR part 100, and

assigned OMB Control Number 1018–0075, which expires January 31, 2024 (in accordance with regulations at 5 CFR 1320, the Services are authorized to continue sponsoring the collection while the submission is pending at OMB).

Regulatory Planning and Review (Executive Orders 12866, 13563, and 14904)

Executive Order 12866, as reaffirmed by E.O. 13563 and E.O. 14094 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of regulatory flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. In general, the resources to be harvested under this rule are already being harvested and consumed by the local harvester and do not result in an additional dollar benefit to the economy. However, we estimate that two million pounds of meat are harvested by subsistence users annually and, if given an estimated dollar value of $3.00 per pound, this amount would equate to about $6 million in food value Statewide. Based upon the amounts and values cited above, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Congressional Review Act

Under the Congressional Review Act (5 U.S.C. 804(2)), this rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Takings (Executive Order 12630)

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority on public lands. The scope of the Program is limited by definition to certain public lands. Likewise, these regulations have no potential takings of private property implications as defined by Executive Order 12630.

Unfunded Mandates Reform Act

The Secretaries have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation of this rule is by Federal agencies, and there is no cost imposed on any State or local entities or tribal governments.

Civil Justice Reform (Executive Order 12988)

The Secretaries have determined that these regulations meet the applicable standards provided in sections 3(a) and 3(b)(2) of E.O. 12988, regarding civil justice reform.

Federalism (Executive Order 13132)

In accordance with E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

Consultation and Coordination With Indian Tribal Governments (Executive Order 13175)

The Alaska National Interest Lands Conservation Act, Title VIII, does not provide specific rights to tribes for the subsistence taking of wildlife, fish, and shellfish. However, the Departments, through the Board, provided Federally recognized Tribes and Alaska Native corporations opportunities to consult on this rule. Consultation with Alaska Native corporations are based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Secretaries, through the Board, provided a variety of opportunities for consultation: commenting on proposed changes to the existing rule; engaging in dialogue at the Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process.

The Board provided Federally recognized Tribes and Alaska Native corporations a specific opportunity to consult on this rule prior to the start of its public regulatory meeting held during January and February 2023. Federally recognized Tribes and Alaska Native corporations were notified by mail, email, and telephone and were given the opportunity to attend in person or via teleconference.

Energy Supply, Distribution or Use (Executive Order 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. However, this rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no Statement of Energy Effects is required.

Drafting Information

Theo Matuskowitz drafted these regulations under the guidance of Amee Howard, Assistant Regional Director, Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional assistance was provided by

- Paul McKee, Alaska State Office, Bureau of Land Management;
- Dr. Kim Jochum, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen, Alaska Regional Office, Bureau of Indian Affairs;
- Jill Klein, Alaska Regional Office, U.S. Fish and Wildlife Service; and
- Gregory Risdahl, Alaska Regional Office, USDA–Forest Service.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

Regulation Promulgation

For the reasons set out in the preamble, the Secretaries amend title 36, part 242, and title 50, part 100, of the Code of Federal Regulations, as set forth below.

PART ___—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

■ 1. The authority citation for both 36 CFR part 242 and 50 CFR part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

Subpart A—General Provisions

■ 2. Amend § ____.3 by revising paragraph (b)(5)(ii) to read as follows:

§ ___.3 Applicability and scope.

* * * * *

(b) * * *

(5) * * *

(ii) Tongass National Forest:

TABLE 1 TO PARAGRAPH (b)(5)(ii)

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(A) Beacon Point, Frederick Sound, and Kupreanof Island.	U.S. Coast and Geodetic Survey Chart No. 8210—Sheet No. 16.	The point begins on the low-water line at N 63° W, true and approximately 1,520 feet from Beacon Point beacon; thence due south true 1,520 feet; thence true east 1,800 feet, more or less to an intersection with a low-water line; thence following, is the low-water line round the point to the point of beginning.	Approx. Long. 133°00′ W Lat. 56°56¼′ N.
(B) Bushy Island and Snow Passage.	U.S. Coast and Geodetic Survey Chart, labeled No. 8160—Sheet No. 12.	The reference location is marked as 64 south, 80 east, CRM, SEC. 31/32 on the map labeled, USS 1607. The point begins on a low-water line about ¼ nautical mile and southwesterly from the northwest point of the island, from which a left tangent to an island that is 300 yards in diameter and 100 yards offshore, bears the location—N 60° W, true; thence S 60° E, true and more or less 2,000 feet to an intersection with a low-water line on the easterly side of the island; thence forward along the winding of the low-water line northwesterly and southwesterly to the point of beginning, including all adjacent rocks and reefs not covered at low water.	Approx. Long. 132°58′ W Lat. 56°16½′ N.
(C) Cape Strait, Frederick Sound, and Kupreanof Island.	U.S. Coast and Geodetic Survey Chart No. 8210—Sheet No. 16.	The reference location is marked as 56 south, 77478 east, CRM, on the map labeled as USS 1011. It begins at a point on a low-water line that is westerly from the lighthouse and distant 1,520 feet in a direct line from the center of the concrete pier upon which the light tower is erected; thence South 45° E, true by 1,520 feet; thence east true by 1,520 feet, more or less to an intersection with the low-water line; thence northwesterly and westerly, following the windings of the low-water line to the point of beginning.	Approx. Long. 133°05′ W Lat. 57°00′ N.
(D) Point Colpoys and Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8160—Prince of Wales Island—Sheet No. 12.	The reference location is marked as 64 south, 78 east, CRM, SECs. 10, 11, 12 on the map labeled as USS 1634. Location is north of a true east-and-west line running across the point to 1,520 feet true south from the high-water line at the northernmost extremity. Map includes all adjacent rocks and ledges not covered at low water and also includes two rocks awash about 1¼ nautical miles East and South and 75° East, respectively, from the aforementioned point.	Approx. Long. 133°12′ W Lat. 56°20′ N.
(E) Vank Island and Stikine Strait.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 18. Located at 62 south, 82 east, CRM, SEC 34, on the map labeled as USS 1648.	This part of the island is lying south of a true east-and-west line that is drawn across the island from low water to low water. Island is 760 feet due north from the center of the concrete pier upon which the structure for the light is erected.	Approx. Long. 132°35′ W Lat. 56°27′ N.
(F) High Point, Woronkofski Island.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 18.	The location begins at a point on low water at the head of the first bight easterly of the point and about ⅛ nautical mile distant therefrom; thence south true 1,520 feet; thence west true 1,100 feet, more or less to an intersection with the low-water line; thence northerly and easterly, following the windings of the low-water line to point of beginning.	Approx. Long. 132°33′ W Lat. 56°24′ N.
(G) Key Reef and Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 11.	The reference location is marked as 66 south, 81 east, CRM, SEC 11. The reef lies 1¾ miles S 80° E, true, from Bluff Island and becomes awash at extreme high water. Chart includes all adjacent ledges and rocks not covered at low water.	Approx. Long. 132°50′ W Lat. 56°10′ N.
(H) Low Point, Zarembo Island.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 22.	The location begins at a point on a low-water line that is 760 feet in a direct line, easterly, from the center of Low Point Beacon. The position is located on a point of shoreline about 1 mile easterly from Low Point; thence S 35°, W true 760 feet; thence N 800 feet and W 760 feet, more or less, to an intersection with the low-water line to the point of beginning.	Approx. Long. 132°55½′ W Lat. 56°27½′ N.
(I) McNamara Point and Zarembo Island.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 25.	Location begins at a point on a low-water line that is 1,520 feet in a direct line, northerly, from McNamara Point Beacon—a slatted tripod structure; thence true east 1,520 feet; thence true south, more or less, 2,500 feet to an intersection with the low-water line; thence northwesterly and northerly following the windings of the low-water line to the point of beginning.	Approx. Long. 133°04′ W Lat. 56°20′ N.
(J) Mountain Point and Wrangell Narrows.	U.S. Coast and Geodetic Survey Chart No. 8170—Sheet No. 27.	The location begins at a point on a low-water line southerly from the center of Mountain Point Beacon and distant there from 1,520 feet in a direct line; thence true west 1,520 feet; thence true north, more or less, 3,480 feet to an intersection with the low-water line; thence southeasterly and southerly following the windings of the low-water line to the point of beginning.	Approx. Long. 132°57½′ W Lat. 56°44′ N.
(K) Angle Point, Revillagigedo Channel, and Bold Island.	U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 3.	The reference location is marked as 76 south, 92 east, CRM, USS 1603. The location begins at a point on a low-water line abreast of the lighthouse on Angle Point, the southwestern extremity of Bold Island; thence easterly along the low-water line to a point that is 3,040 feet in a straight line from the beginning point; thence N 30° W True 3,040 feet; thence true west to an intersection with the low-water line, 3,000 feet, more or less; thence southeasterly along the low-water line to the point of beginning.	Approx. Long. 131°26′ W Lat. 55°14′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(L) Cape Chacon, Dixon Entrance, and Prince of Wales Island.	U.S. Coast and Geodetic Survey Chart No. 8074—Sheet No. 29.	The reference location is marked as 83 south, 89 and 90 east, CRM, USS 1608. The location begins at a point at the low-water mark on the shoreline of Dixon Entrance from which the southern extremity of Cape Chacon bears south 64° true east and approximately ¾ nautical miles; thence N 45° true east and about 1 nautical mile, more or less, to an intersection with a low-water line on the shore of Clarence Strait; thence southerly, following the meanderings of the low-water line of the shore, to and around Cape Chacon, and continuing to the point of beginning. Reference includes all adjacent islands, islets, rocks, and reefs that are not covered at the low-water line.	Approx. Long 132° W Lat. 54°42′ N.
(M) Lewis Reef and Tongass Narrows.	U.S. Coast and Geodetic Survey Chart No. 8094—Sheet No. 71.	The reference location is marked as 75 south, 90 east, CRM, SEC 9. The area point begins at the reef off Lewis Point and partly bare at low water. This part of the reef is not covered at low water and lies on the northeast side of a true northwest-and-southeast line that is located 300 feet true southwest from the center of the concrete pier of Lewis Reef Light.	Approx. Long. 131°44½′ W Lat. 55°22′25″ N.
(N) Lyman Point and Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8076—Sheet No. 8.	The reference location is marked as 73 south, 86 east, CRM, SEC 13, on a map labeled as USS 2174 TRC. It begins at a point at the low-water mark. The aforementioned point is 300 feet in a direct line easterly from Lyman Point light; thence due south 300 feet; thence due west to a low-water mark 400 feet, more or less; thence following the winding of the low-water mark to the place of beginning.	Approx. Long. 132°18′ W Lat. 55°32′ N.
(O) Narrow Point, Clarence Strait, and Prince of Wales Island.	U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 9.	The reference location is marked as 70 south, 84 east, CRM, on a map labeled as USS 1628. The point begins at a point on a low-water line about 1 nautical mile southerly from Narrow Point Light, from which point a left tangent to a high-water line of an islet about 500 yards in diameter and about 300 yards offshore, bears south 30° true east; thence north 30° W, true 7,600 feet; thence N 60° E, 3,200 feet, more or less to an intersection with a low-water line; thence southeasterly, southerly, and southwesterly, following the winding of the low-water line to the point of beginning. The map includes all adjacent rocks not covered at low water.	Approx. Long. 132°28′ W Lat. 55°47½′ N.
(P) Niblack Point, Cleveland Peninsula, and Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8102—Sheet No. 6.	The location begins at a point on a low-water line from which Niblack Point Beacon, a tripod anchored to three concrete piers, bears southeasterly and is 1,520 feet in a direct line; thence true northeast 1,520 feet; thence true southeast 3,040 feet; thence true southwest at 600 feet, more or less, to an intersection with a low-water line; thence northwesterly following the windings of the low-water line to the point of beginning.	Approx. Long. 132°07′ W Lat. 55°33′ N.
(Q) Rosa Reef and Tongass Narrows.	U.S. Coast and Geodetic Survey Chart No. 8094—Sheet No. 71.	The reference location is marked as 74 south, 90 east, CRM, SEC 31. That part of the reef is not covered at low water and lies east of a true north-and-south line, located 600 feet true west from the center of the concrete pier of Rosa Reef Light. The reef is covered at high water.	Approx. Long. 131°48′ W Lat. 55°24′15″ N.
(R) Ship Island and Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 9.	The reference location is marked as 72 south, 86 east, CRM, SEC 27. The point begins as a small island on the northwesterly side of the Clarence Strait, about 10 nautical miles northwesterly from Caamano Point and ¼ mile off the shore of Cleveland Peninsula. The sheet includes all adjacent islets and rocks not connected to the main shore and not covered at low water.	Approx. Long. 132°12′ W Lat. 55°36′ N.
(S) Spire Island Reef and Revillagigedo Channel.	U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 3.	The reference location is marked as 76 south, 92 east, CRM, SEC 19. The detached reef, covered at high water and partly bare at low water, is located northeast of Spire Island. Spire Island Light is located on the reef and consists of small houses and lanterns surmounting a concrete pier.	Approx. Long 131°30′ W Lat. 55°16′ N.
(T) Surprise Point and Nakat Inlet.	U.S. Coast and Geodetic Survey Chart No. 8051—Sheet No. 1.	The reference location is marked as 80 south, 89 east, CRM. This point lies north of a true east-and-west line. The true east-and-west line lies 3,040 feet true south from the northernmost extremity of the point together with adjacent rocks and islets.	Approx. Long. 130°44′ W Lat. 54°49′ N.
(U) Caamano Point, Cleveland Peninsula, and Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8102—Sheet No. 6.	Location consists of everything apart of the extreme south end of the Cleveland Peninsula lying on a south side of a true east-and-west line that is drawn across the point at a distance of 800 feet true north from the southernmost point of the low-water line. This includes off-lying rocks and islets that are not covered at low water.	Approx. Long. 131°59′ W Lat. 55°30′ N.
(V) Meyers Chuck and Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8124—Sheet No. 26.	The tidelands and the small island is about 150 yards in diameter and located about 200 yards northwest of Meyers Island.	Approx. Long. 132°16′ W Lat. 55°44½′ N.
(W) Round Island and Cordova Bay.	U.S. Coast and Geodetic Survey Chart No. 8145—Sheet No. 36.	The tidelands and the southwestern island of the group is about 700 yards long, including off-lying rocks and reefs that are not covered at low water.	Approx. Long. 132°30½′ W Lat. 54°46½′ N.
(X) Mary Island	U.S. Coast and Geodetic Survey Chart No. 8145—Sheet No. 36.	The reference location begins at a point that is placed at a low-water mark. The aforementioned point is southward 500 feet from a crosscut on the side of a large rock on the second point below Point Winslow and Mary Island; thence due west ¾ mile, statute; thence due north to a low-water mark; thence following the winding of the low water to the place of beginning.	Approx. Long. 131°11′00″ W Lat. 55°05′55″ N.
(Y) Tree Point	U.S. Coast and Geodetic Survey Chart No. 8145—Sheet No. 36.	The reference location starts at a point of a low-water mark. The aforementioned point is southerly ½ mile from the extreme westerly point of a low-water mark on Tree Point, on the Alaska Mainland; thence due true east, ¾ mile; thence due north 1 mile; thence due west to a low-water mark; thence following the winding of the low-water mark to the place of beginning.	Approx. Long. 130°57′44″ W Lat. 54°48′27″ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(Z) Warm Springs Bay, Chatham Strait, and Baranof Island.	U.S. Coast and Geodetic Survey Chart No. 8243—Sheet No. 51.	The reference location is marked as 55 south, 67 east, CRM, SECS 20 and 21, U.S. Survey No. 1649. The location begins at a point on the low-water line south side of the entrance to Warm Springs Bay, westerly side of Chatham Strait and distant 400 feet westerly in a direct line from the center of the concrete slab, 4 feet square, upon which the structure of the Warm Springs Bay light is erected; thence south true 400 feet; thence east true 600 feet, more or less, to an intersection with the low-water line; thence northerly and westerly, following the windings of the low-water line to the point of beginning.	Approx. Long. 134°46′48″ W Lat. 57°04¾′ N.
(AA) Killisnoo Harbor Southern Entrance and Chatham Strait.	U.S. Coast and Geodetic Survey Chart No. 8285—Sheet No. 53.	The reference location is marked as 50 south, 66 east, CRM. The location is marked at a reef off the southeastern extremity of Killisnoo Island, bare at low water and covered at high water, including all that part of the reef bounded by the low-water line and a northeast-and-southwest true line drawn tangent to the high-water line of the island. Killisnoo Harbor Southern Entrance Light is located upon a concrete pier on the outer part of the reef.	Approx. Long. 134°34′ W Lat. 57°28′ N.
(BB) Killisnoo Harbor and Chatham Strait.	U.S. Coast and Geodetic Survey Chart No. 8285—Sheet No. 53.	The reference location is marked as 51 south, 68 east, CRM, SEC 7. The location is marked at a small rock bare at low water and covered at high water. The point is located 80 yards off the shore of Killisnoo Island in Killisnoo Harbor, 300 yards northwesterly from the wharf, and occupied by a concrete pier and superstructure supporting Killisnoo Harbor Light.	Approx. Long. 134°33¾′ W Lat. 57°28′ N.
(CC) Point Gardner, Chatham Strait, and Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8212—Sheet No. 50.	The reference location is marked as 56 south, 68 east, CRM, SEC 16, U.S. Survey No. 1637. The location begins at a point on the low-water line of Chatham Strait northward of the point and distant 1,000 feet in a straight line from the center of the concrete slab 4 feet square upon which the structure of Point Gardner Light is erected; thence S 80° E true 1,200 feet, more or less, to an intersection with the low-water line on the shore of Surprise Harbor; thence southerly, westerly, and northerly, following the winding of the low-water line to the point of beginning, and including islets and rocks lying within ⅜ mile southward of the Point.	Approx. Long. 134°37′ W Lat. 57°01′ N.
(DD) Point Gambier, Stephens Passage, and Entrance to Gambier Bay.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 18.	The reference location is marked as 51 south, 72 east, CRM, SEC 22, U.S. Survey No. 1638. All that part of Gambier Island lies southeastward of a true northeast-and-southeast line drawn across the island and lies 1,520 feet distant from the high-water mark at the southeastern extremity of the island, including all adjacent rocks and reefs not covered at low water.	Approx. Long. 133°50′ W Lat. 57°26′ N.
(EE) Gambier Bay Entrance, Stephens Passage, and Gambier Bay.	U.S. Coast and Geodetic Survey Chart No. 8224—Sheet No. 72.	The reference location is marked as 51 south, 72 east, CRM, SEC 7. The reef is covered at high water and bare at low water, located about ⅜ nautical mile northeast of northwest point of Gain Island. The proposed reservation includes that part of the reef not covered at low water and lying southeast of a northeast-and-southwest line located at a distance of 600 feet northwest of the Gambier Bay Entrance Light structure, which consists of a small house and skeleton steel tower surmounting a concrete pier.	Approx. Long. 133°55′ W Lat. 57°28′ N.
(FF) False Point Pybus, Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8224—Sheet No. 11.	The location begins at a point 1,285 feet northwest true from the center of False Point Beacon, a slatted tripod located on the point about 1 nautical mile southerly from False Point Pybus, thence east true 1,170 feet, more or less, to an intersection with the low-water line, thence southerly and westerly following the windings and indentations of the low-water line to a point from which the point of beginning bears north true, thence north true, 1,000 feet, more or less, to a point of beginning.	Approx. Long. 133°52½′ W Lat. 57°21′ N.
(GG) The Brothers Island, Stephens Passage.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 18.	The reference location is marked as 49 south, 61 east, CRM. The point is located on the westerly side of the southern end of Stephens Passage. All of the eastern group of islands known as The Brothers, being about ½ nautical mile long and ⅓ nautical mile wide and about 232 feet high, including all adjacent islets and rocks not covered at low water.	Approx. Long. 133°47′ W Lat. 57°17½′ N.
(HH) Cape Fanshaw and Frederick Sound.	U.S. Coast and Geodetic Survey Chart No. 8216—Sheet 17.	The reference location is marked as 54 south, 74 and 75 east, U.S. Survey No. 1610. All of the cape that is west of a true north-and-south line drawn 1,520 feet due east of the westernmost part of the high-water line at the point, including all adjacent rocks and reefs not covered at low water.	Approx. Long. 133°34′21″ W Lat. 57°11′02″ N.
(II) West Point, Kupreanof Island, and the Entrance to Portage Bay.	U.S. Coast and Geodetic Survey Chart No. 8210. See sheet for East Point, No. 9.	All of that part of the point lying east of a true north-and-south line drawn across the point at a distance of 600 feet west of the most easterly part of the low-water line at the point.	Approx. Long. 133°20′ W Lat. 57°00′ N.
(JJ) East Point, Kupreanof Island, and the Entrance to Portage Bay.	U.S. Coast and Geodetic Survey Chart No. 8210—Sheet No. 9.	All of that part of the point lying on the west side of a true north-and-south line drawn across the point at a distance of 600 feet east true from the most westerly part of the low-water line at the point.	Approx. Long. 133°19′ W Lat. 57°00′ N.
(KK) Kingsmill Point, Chatham Strait, Kuiu Island.	U.S. Coast and Geodetic Survey Chart No. 8214—Sheet No. 48.	The reference location is marked as 58 south, 70 east, CRM, SEC 17, U.S. Survey No. 1621. The location begins at a point on a low-water line southward of the point and distant 1,200 feet in a direct line from the center of the concrete slab upon which the structure of Kingsmill Point Light is erected; thence east true 900 feet; thence north true 2,300 feet, more or less, to an intersection with the low-water line northeastward of the point; thence southwesterly and southerly along the windings of a low-water line to the point of beginning.	Approx. Long. 134°25′ W Lat. 56°50½′ N.
(LL) Washington Bay, Chatham Strait, and Kuiu Island.	U.S. Coast and Geodetic Survey Chart No. 8241—Sheet No. 47.	The reference location is marked as 59 south, 70 east, CRM, SEC 33, U.S. Survey No. 1650. All that part of the land on the south side of the entrance to Washington Bay lying on the northwesterly side of the straight line bearing N 55° E and S 55° W true drawn across the land from the low-water line in Chatham Strait to a low-water line in Washington Bay, said line being distant 300 feet S 35° E true from a point on the low-water line between the two headlands, from which a left tangent to the high-water line of a small island lying 130 yards offshore in the bight bears N 35° W true; and including the aforementioned island.	Approx. Long. 134°10′ W Lat. 56°40′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(MM) Point Ellis, Chatham Strait, and Bay of Pillars.	U.S. Coast and Geodetic Survey Chart No. 8241—Sheet No. 46.	The reference location is marked as 43 south, 65 east, CRM. The small island N 58° W true ⅜ mile from Pt. Ellis, including adjacent reefs and rocks not covered at low water.	Approx. Long. 134°19′16″ W Lat. 56°33′28″ N.
(NN) Point Crowley, Chatham Strait, and Kuiu Island.	U.S. Coast and Geodetic Survey Chart No. 8152—Sheet No. 45.	The reference location is marked as 66 south, 72 east, CRM, SECS 22 and 27, U.S. Survey No. 2171. All that part of Kuiu Island in the vicinity of Point Crowley lying west of a true north-and-south line drawn across the point at a distance of 3,040 feet east true from the center of the concrete slab 4 feet by 6 feet upon which the structure for Point Crowley Light is erected, and including all adjacent islets and rocks not covered at low water.	Approx. Long. 134°16′ W Lat. 56°07′ N.
(OO) Strait Island and Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 40.	The reference location is marked as 59 south, 70 east, CRM, SEC 8, U.S. Survey No. 1604. The southeastern island of the group, including adjacent and outlying rocks and reefs not covered at low water.	Approx. Long. 133°42′ W Lat. 56°24′ N.
(PP) Povornotni Island and Peril Strait.	U.S. Coast and Geodetic Survey Chart No. 8282—Sheet No. 31.	The island is about 200 yards long, off Pogibshi Point, including adjacent rocks and reefs not covered at low water.	Approx. Long. 135°33′ W Lat. 57°30½′ N.
(QQ) Tenakee Inlet and Chatham Strait.	U.S. Coast and Geodetic Survey Chart No. 8300—Sheet No. 55.	All of the small islands and associated tidelands are located about 300 yards off South Passage Point, including rock awash shown on the chart ½ nautical mile northeasterly from South Passage Point.	Approx. Long. 134°56′ W Lat. 57°46′ N.
(RR) Danger Point, Chatham Strait, and Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8247—Sheet No. 54.	The reference location is marked as 50 south, 67 east, CRM, SECS 25 and 26, U.S. Survey No. 1613. The location begins at a point on a low-water line southward of Danger Point and distant 700 feet in a direct line from the center of the concrete slab, 4 feet square, upon which the structure of Danger Point Light is erected; thence northeast true 1,000 feet, more or less, to an intersection with the low-water line eastward of Danger Point; thence westerly, etc., following the windings of the low-water line to the point of beginning, including rocks and reefs off the point not covered at low water.	Approx. Long. 134°36′ W Lat. 57°30′ 30″ N.
(SS) Point Hugh, Stephens Passage, Glass Peninsula, and Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 18.	The reference location is marked as 49 south, 72 east, CRM, U.S. Survey No. 1641. The location begins at a point on a low-water line on the easterly side of Glass Peninsula about 1½ nautical miles northerly from Point Hugh 1¼ nautical miles in a direct line southerly from the center of a concrete slab 4 feet square, upon which is erected the structure of Point Hugh Light; thence west true, 1,520 feet; thence N 4° W, true 2¼ nautical miles, more or less, to an intersection with the low-water line; thence southeasterly and southerly, following the windings of the low-water line to the point of beginning.	Approx. Long. 133°52′ W Lat. 57°37′ N.
(TT) Point Styleman, Stephens Passage, and north side of the entrance to Port Snettisham.	U.S. Coast and Geodetic Survey Chart No. 8227—Sheet No. 30.	All of that part of the point lying south of a true east-and-west line drawn across the point at a distance of 700 feet north true from the southernmost part of the high-water line, including adjacent rocks and reefs not covered at low water.	Approx. Long. 133°53½′ W Lat. 57°58½′ N.
(UU) Kakul Narrows and Perils Strait.	U.S. Coast and Geodetic Survey Chart No. 8282—Sheet No. 20.	The two islets are about 150 yards and 100 yards long, respectively, on the east side of Kakul Narrows, and all of the off-lying group of rocks northward named on the Chart Channel Islets, including all adjacent rocks and reefs not covered at low water.	Approx. Long. 135°41′ W Lat. 57°22′ N.
(VV) Channel Rock and Sitka Sound.	U.S. Coast and Geodetic Survey Chart No. 8244—Sheet No. 63.	The reference location is marked as 56 south, 63 east, CRM. The location is marked by a rock covered at high water and bare at low water, located ¼ nautical mile north of Japonski Island.	Approx. Long. 135°22′ W Lat. 57°03½′ N.
(WW) Harbor Rock and Sitka Harbor.	U.S. Coast and Geodetic Survey Chart No. 8244—Sheet No. 63.	The reference location is marked as 56 south, 63 east, CRM. The location is marked at a small rock covered at high water and bare at low water, located 300 yards north of the naval wharf on Japonski Island.	Approx. Long. 135°20′48″ W Lat. 57°03⅛″ N.
(XX) False Point Retreat, Lynn Canal, and Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8302—Sheet No. 12.	The location begins at a point near the west shore of Mansfield Peninsula about 2½ nautical miles southerly from Pt. Retreat, from which the center of False Point Retreat Beacon, a slatted tripod anchored to concrete piers, bears west true, distant 900 feet, thence southwest true 900 feet, more or less, to an intersection with the low-water line, thence northwesterly, northerly, and northeasterly, following the winding of the low-water line, to a point from which the point of the beginning bears southeast true, thence southeast true 600 feet, more or less, to the point of beginning.	Approx. Long. 134°58′ W Lat. 58°22′ N.
(YY) Shelter Island, Stephens Passage, and the Southeastern Part of Shelter Island.	U.S. Coast and Geodetic Survey Chart No. 8302—Sheet No 23.	The reference location is marked as 40 south, 64 east, CRM, SEC 26, U.S. Survey No. 1645. The location begins at a point on a low-water line on the eastern side of the island about 1,000 yards northward of the extreme southeastern point of the island, from which the center of a concrete slab 4 feet square, upon which Shelter Island Light is erected, is distant 1,000 feet in a straight line bearing S 23° E approximately; thence S 65° W true 600 feet; thence S 23° E, true, 2,000 feet, more or less, to an intersection with a low-water line; thence northeasterly, northerly, and northwesterly, following the windings of the low-water line, to the point of beginning.	Approx. Long. 134°48′ W Lat. 58°22½″ N.
(ZZ) Clear Point, Lynn Canal, the Entrance to Funter Bay, and Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8302—Sheets No. 23 & No. 24.	The reference location is marked as 42 south, 64 east, CRM, SEC 10, U.S. Survey No. 1612. The location begins at a point on a low-water line about 700 feet northerly from the southern extremity of Clear Point, from which a right tangent to the high-water line, distant about 500 feet bears east true; thence west true, 800 feet, more or less, to an intersection with a low-water line; thence southerly, etc., following the windings of the low-water line around the Point to the point of beginning.	Approx. Long. 134°55′ W Lat. 58°15′ N.
(AAA) Point Augusta, Chatham Strait, and Chichagof Island.	U.S. Coast and Geodetic Survey Chart No. 8300—Sheet No. 55.	The reference location is marked as 44 south, 64 east, CRM, U.S. Survey No. 1633. All of that part of the land in the vicinity of Point Augusta bounded by the low-water line and a straight line bearing N 42° W and S 42° E true, distant 2,280 feet S 48° W true, from the center of the concrete slab 4 feet square upon which the structure of Point Augusta Light is erected, including all adjacent rocks and reefs not covered at low water.	Approx. Long. 134°58′ W Lat. 58°03′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(BBB) Middle Point, Stephens Passage and Douglas Island.	U.S. Coast and Geodetic Survey Chart No. 8235—Sheet No. 22.	The reference location is marked as 42 south, 66 east, CRM, SEC 9, U.S. Survey No. 2170. This area is about 4½ miles northwesterly from Point Hilda. The location begins at a point on a low-water line from which the center of a concrete slab 4 feet square upon which Middle Point Light is erected, is distant 400 feet in a straight line and bearing southerly; thence east true 900 feet; thence south true 500 feet, more or less, to an intersection with the low-water line; thence westerly, following the windings of the low-water line to the point of beginning.	Approx. Long. 134°37′ W Lat. 58°15′ N.
(CCC) Point Hilda, Stephens Passage, and Douglas Island.	U.S. Coast and Geodetic Survey Chart No. 8235—Sheet No. 112.	The reference location is marked as 42 south, 67 east, CRM, SECS 19 and 20, U.S. Survey No. 1640. That part of the Point, including tide lands not covered at low water, lying south of a true east-and-west line drawn across the Point at a distance of 600 feet north, true, from the high-water line at the southernmost part of the point.	Approx. Long. 134°30′ W Lat. 58°13′ N.
(DDD) Point Arden, Stephens Passage, and Admiralty Island.	U.S. Coast and Geodetic Survey Chart No. 8300—Sheet No. 20.	The reference location is marked as 43 south, 68 and 69 east, CRM, U.S. Survey No. 1632. The location begins at a point on a low-water line southward of Point Arden from which the center of a concrete slab upon which Point Arden Light is erected, is distant 3,040 feet in a straight line; thence N 60° W true, 8,000 feet, more or less, to an intersection with the low-water line; thence northeasterly, southeasterly, easterly, and southerly, following the winding of a low-water line to the point of beginning.	Approx. Long. 134°10′ W Lat. 58°9½′ N.
(EEE) Grand Island and Stephens Passage.	U.S. Coast and Geodetic Survey Chart No. 8300—Sheet No. 15.	The location begins at a point on a low-water line, east shore of Grand Island, 1,520 feet in a direct line, southerly, from the center of Grand Island Beacon, a slatted tripod anchored to concrete piers, thence west true 1,520 feet, thence north true 1,824 feet more or less, to an intersection with a low-water line to the point of beginning.	Approx. Long. 134°06′ W Lat. 58°06′ N.
(FFF) Grave Point and Stephens Passage.	U.S. Coast and Geodetic Survey Chart No. 8229—Sheet No. 19.	The reference location is marked as 44 south, 70 east, CRM, SEC 7, U.S. Survey No. 1617. The location begins at a point at a low-water line on the northwesterly side of the entrance to Taku Harbor, from which a left tangent to the high-water line at the northern extremity of Stockade Point, distant about 700 yards, bears S 75° E, true; thence N 75° W, true 4,000 feet, more or less to an intersection with a low-water line northward of Grave Point; thence southerly, easterly, and northeasterly, following the windings of a low-water line to the point of beginning.	Approx. Long. 134°03′ W Lat. 58°04′ N.
(GGG) Low Point, Chilkoot Inlet.	U.S. Coast and Geodetic Survey Chart No. 8303—Sheet No. 27.	The reference location is marked as 30 south, 60 east, CRM, SECS 18 and 19, U.S. Survey No. 1625. The location begins at a point on the low-water line northeasterly from Low Point Light and 900 feet in a direct line from the center of the slab 4 feet square upon which the structure for the light is erected; thence S 60° E, true, 1,560 feet; thence S 30° W, true, 1,000 feet, more or less, to an intersection with the low-water line; thence northwesterly and northeasterly, following the windings of the low-water line to the point of beginning.	Approx. Long. 135°21′ W Lat. 59°16′ N.
(HHH) Point St. Mary, Lynn Canal, North Side of Entrance to Berners Bay.	U.S. Coast and Geodetic Survey Chart No. 8302—Sheet No. 29.	All that part of the point lying south of a true east-and-west line drawn across the same at a distance of 3,040 feet north true from the high-water line at the southernmost part of the point; including off-lying rocks not covered at low water.	Approx. Long. 135°01′ W Lat. 58°44′ N.
(III) Little Island, Lynn Canal	U.S. Coast and Geodetic Survey Chart No. 8302—Sheet No. 25.	The reference location is marked as 38 south, 63 east, CRM, SEC 29. The location begins as a small island ½ mile N 16° W from Ralston Island, including adjacent rocks and ledges not covered at low water.	Approx. Long. 135°02′ W Lat. 58°32½′ N.
(JJJ) Lemesurier Island, Icy Strait.	U.S. Coast and Geodetic Survey Chart No. 8304—Sheet No. 59.	The reference location is marked as 41 south, 57 west, CRM, SECS 14 and 15, U.S. Survey No. 1623. All that part of the northeastern extremity of the island lying north of a true east-and-west line drawn across the point at a distance of 1,520 feet south true from the center of the concrete slab 4 feet square upon which the structure of the light is erected, including all adjacent rocks and islets not covered at low water.	Approx. Long. 136°02′ W Lat. 58°19′ N.
(KKK) The Sisters, Icy Strait	U.S. Coast and Geodetic Survey Chart No. 8302. See sheet for Spasskaia Island, No. 42.	The island is about 6½ nautical miles westerly from Point Couverden, about ½ mile long and 150 feet high, including adjacent rocks and islets not covered at low water, and Sisters Reef, located 1 mile to westward.	Approx. Long. 135°15½′ W Lat. 58°11′ N.
(LLL) Spasskaia Island, Icy Strait.	U.S. Coast and Geodetic Survey Chart No. 8302—Sheet No. 42.	The location begins as two small islets about 30 feet high located about 7¾ nautical miles southwesterly from Point Couverden, including adjacent rocks and reefs not covered at low water.	Approx. Long. 135°10′ W Lat. 58°07½′ N.
(MMM) Lord Rock, Dixon Entrance.	U.S. Coast and Geodetic Survey Chart No. 8051—Sheet No. 1.	The reference location is marked as 82 south, 98 east, CRM, SEC 30. The location is a small bare rock about 10 feet high, lying about ¾ mile SW from the south group of Lord Island.	Approx. Long. 130°49′ W Lat. 54°44′ N.
(NNN) Boat Rock, Dixon Entrance.	U.S. Coast and Geodetic Survey Chart No. 8051—Sheet No. 1.	The reference location is marked as 82 south, 98 east, CRM, SEC 8. The point is a small barren rock about 5 feet high, located about 200 yards offshore, about 2 miles northeasterly from Cape Fox, west side of Nakat Bay.	Approx. Long. 130°48′ W Lat. 54°47′ N.
(OOO) Black Rock, Revillagigedo Channel.	U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 2.	The reference location is marked as 79 south, 95 east, CRM, SEC 14. Barren rock about 26 feet height located 3½ nautical miles southwest true, from Kah Shakes Point.	Approx. Long. 131°04′ W Lat. 55°01′ N.
(PPP) Hog Rocks, Revillagigedo Channel.	U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 3.	The reference location is marked as 77 south, 94 east, CRM, SEC 20. The location consists of a group of barren rocks 1.6 nautical miles N 70° true east from Middy Point, Ham Island.	Approx. Long. 131°17′ W Lat. 55°10′30″ N.
(QQQ) Mountain Point, Revillagigedo Channel.	U.S. Coast and Geodetic Survey Chart No. 8094—Sheet No. 4.	The reference location is marked as 76 south, 91 east, CRM, SEC 11. The location begins at a point on the low-water line 900 feet from the southernmost extremity of Mountain Point, and bearing approximately N 70° true east, therefrom; thence N 45° true west, 2,100 feet; thence west true, 2,400 feet, more or less, to an intersection with the low-water line; thence along a low-water line, southeasterly, easterly, and northeasterly to the beginning point.	Approx. Long. 131°32′ W Lat. 55°17½′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(RRR) Peninsula Point, Tongass Narrows.	U.S. Coast and Geodetic Survey Chart No. 8094—Sheet No. 5.	The reference location is marked as 75 south, 90 east, CRM, SEC 9. The location consists of a small island about 100 yards southwest of Peninsula Point.	Approx. Long. 131°44′ W Lat. 55°23′ N.
(SSS) Channel Island, Tongass Narrows.	U.S. Coast and Geodetic Survey Chart No. 8094—Sheet No. 5.	The reference location is marked as 75 south, 90 east, CRM, SEC 5. The point is a small island in Tongass Narrows about 1¼ nautical miles NW from Peninsula Point.	Approx. Long. 131°46′ W Lat. 55°23¾′ N.
(TTT) Bluff Point, Behm Canal, Entrance to Yes Bay.	U.S. Coast and Geodetic Survey Chart No. 8105—Sheet No. 6.	The reference location is marked as 69 south, 89 east, CRM, SEC 15, U.S. Survey No. 1605. Location consists of everything apart of the point lying east of a true north-and-south line 570 feet westerly from a high-water line of the easterly extremity of the Bluff.	Approx. Long. 131°45′ W Lat. 55°53′ N.
(UUU) Moira Rock, Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 7.	The reference location is marked as 78 south, 89 east, CRM, SEC 33. The location is a small rock in the entrance to Moira Sound about 30 feet high, about 1.6 miles due true south from Adams Point.	Approx. Long. 132°00′ W Lat. 55°04′ N.
(VVV) Skin Island, Clarence Straits.	U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 7.	The reference location is marked as 76 south, 88 east, CRM, SEC ⅝. The location is a small island in the entrance to Cholmondeley Sound, about 1 mile off the western shore in Clarence Strait.	Approx. Long. 132°04′ W Lat. 55°18′ N.
(WWW) Hump Island, Cholmondeley Sound.	U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 7.	The reference location is marked as 76 south, 90 east, CRM. The location is a small island in Cholmondeley Sound, about 4½ nautical miles from Chasina Point.	Approx. Long. 132°05′ W Lat. 55°13½′ N.
(XXX) Ratz Harbor, Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8124—Sheet No. 10.	The reference location is marked as 69 south, 84 east, CRM, SEC 18. The location is the outermost small islet on the northwest side of the entrance to Ratz Harbor.	Long. 132°36′ W Lat. 55°53½′ N.
(YYY) Beck Island, Kashevarof Passage.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 11.	The reference location is marked as 67 south, 81 east, CRM, SEC 22. The location consists of an island lying ¾ mile N 36° W, true from Coffman Island.	Approx. Long. 132°52′ W Lat. 56°03′ N.
(ZZZ) Vichnefski Rock, Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 12.	The reference location is marked as 63 south, 79 east, CRM, SEC 1. The location is indicated by a rock awash at extreme high water, located ¾ mile NW of Point St. John, Zarembo Island.	Approx. Long. 133°01′ W Lat. 56°26′ N.
(AAAA) Point Alexander, Wrangell Strait, Mitkof Island.	U.S. Coast and Geodetic Survey Chart No. 8170—Sheet No. 13.	The reference location is marked as 62 south, 80 east, CRM, SEC 8. The point is indicated by a small rocky ledge lying about 75 yards offshore at Point Alexander, Mitkof Island.	Approx. Long. 132°57′ W Lat. 56°30½′ N.
(BBBB) Midway Rock, Wrangell Strait.	U.S. Coast and Geodetic Survey Chart No. 8170—Sheet No. 13.	The reference location is marked as 62 south, 80 east, CRM, SEC 5. The location is indicated by a rock 400 yards from easterly shore and about 1¼ miles from the southerly entrance to the strait.	Approx. Long. 132°58′ W Lat. 56°31¼′ N.
(CCCC) Anchor Point, Wrangell Strait.	U.S. Coast and Geodetic Survey Chart No. 8170—Sheet No. 14.	The reference location is marked as 60 south, 79 east, CRM, SEC 26, USS 1601. The location is at the south side of Blind Slough. The location consists of everything apart of the point north of a true east-and-west line lying 300 feet south true from the high-water mark at the northern extremity of the point.	Approx. Long. 132°55½′ W Lat. 56°38¼′ N.
(DDDD) Mitkof Island, Wrangell Strait.	U.S. Coast and Geodetic Survey Chart No. 8170—Sheet No. 15.	The location consists of everything apart of the northern extremity of Mitkof Island, at the entrance to Wrangell Strait, north of a true east-and-west line lying 200 feet south true from the high-water mark at the northernmost point of the shoreline.	Approx. Long. 132°56′ W Lat. 56°49¼′ N.
(EEEE) Duck Point, Fanshaw Bay.	U.S. Coast and Geodetic Survey Chart No. 8216—Sheet No. 17.	The reference location is marked as 54 south, 75 east, CRM, SEC 9. The point starts at a small rock close to shore off Duck Point, Whitney Island, and on which a light is being maintained.	Approx. Long. 133°30½′ W Lat. 57°12½′ N.
(FFFF) Marmion Island, Gastineau Channel.	U.S. Coast and Geodetic Survey Chart No. 8235—Sheet No. 21.	The reference location is marked as 42 south, 68 east, CRM, SEC 26, USS 1740. The location is a small island about 200 yards long by 100 yards wide, near Point Tantallon, and the westerly side of the entrance to Gastineau Channel.	Approx. Long. 134°15′ W Lat. 56°12′ N.
(GGGG) Little Chilkat Island, Chilkoot Inlet.	U.S. Coast and Geodetic Survey Chart No. 8303—Sheet No. 26.	The reference location is marked as 32 south, 60 east, CRM, SECS 22, 23, and 26. This location is the most northerly island of the Chilkat group, the same being about ⅝ nautical mile long and located about 1 nautical mile southeast of Seduction Point.	Approx. Long. 135°15′ W Lat. 59°05′ N.
(HHHH) Barren Island, Dixon Entrance.	U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 28.	The island is bare rock, about 20 feet high, and lies off the west side entrance to Revillagigedo Channel, approximately 6½ miles south of the southern extremity of Duke Island.	Approx. Long. 131°20′ W Lat. 54°45′ N.
(IIII) Dewey Rocks, Cordova Bay.	U.S. Coast and Geodetic Survey Chart No. 8152—Sheet No. 30.	The reference location is marked as 15 south, 3 west, CRM. The location is marked by a small rock about 12 feet high, about 1½ miles S 5° E, from Round Island in the entrance to Cordova Bay.	Approx. Long. 132°30′ W Lat. 54°45′ N.
(JJJJ) Mellen Rock, Cordova Bay.	U.S. Coast and Geodetic Survey Chart No. 8152—Sheet No. 30.	The reference location is marked as 79 south, 85 east, CRM, SEC 7. The location is marked by a small rock about 12 feet high, in Cordova Bay, ¾ mile off the eastern shore of Sukkwan Island.	Approx. Long. 132°40′ W Lat. 55°02′ N.
(KKKK) Sukkwan Narrows, Sukkwan Island.	U.S. Coast and Geodetic Survey Chart No. 8153—Sheet No. 31.	The reference location is marked as 77 south, 83 east, CRM, SECS 12 and 13, USS 1647. The location begins at a point of a low-water line on the north end of Sukkwan Island, eastern part of Sukkwan Narrows, from which a rock awash 150 yards offshore bears north true; thence S 60° W, true, 750 feet, more or less, to an intersection with the low-water line; thence northerly, northeasterly, and easterly, following the windings of the low-water line to the point of the beginning. The location includes adjacent rocks not covered at low water.	Approx. Long. 132°50′30″ W Lat. 55°12′ N.
(LLLL) Rose Inlet, Tlenak Strait.	U.S. Coast and Geodetic Survey Chart No. 8152—Sheet No. 32.	The location consists of all of the outer island located in the entrance to Rose Inlet.	Approx. Long. 132°56′ W Lat. 54°57½′ N.
(MMMM) Klawock Reef, San Alberto Bay.	U.S. Coast and Geodetic Survey Chart No. 8155—Sheet No. 33.	The reference location is marked as 73 south, 81 east, CRM, SEC 9. The location is indicated by a rock covered at high water and bare at low water, located 800 yards N 28° W true, from the northern extremity of Fish Egg Island. The structure supporting the light is erected on a concrete pier.	Approx. Long. 133°10½′ W Lat. 55°30½′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(NNNN) Point McCartey, Nichols Passage.	U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 34.	The reference location is marked as 78 south, 91 east, CRM, SECS 9 and 16. The location is at the southeasternmost islet in Bronaugh Island Group. Islet is on the west side of the entrance to Nichols Passage, 1½ miles S 54° E from Dall Head.	Approx. Long. 131°43′ W Lat. 55°07′ N.
(OOOO) Warburton Island, Nichols Passage.	U.S. Coast and Geodetic Survey Chart No. 8074—Sheet No. 35.	The reference location is marked as 78 south, 91 east, CRM, SEC 1. The location consists of all of the island, which is located about 2 miles west of Metlakatla.	Approx. Long. 131°38′ W Lat. 55°08′ N.
(PPPP) Blank Island, Nichols Passage.	U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 36.	The reference location is marked as 76 south, 91 east, CRM, SEC 19. The location consists of the southern island of the group in the north end of Nichols Passage, at the entrance of Blank Inlet, Gravina Island.	Approx. Long. 131°38′ W Lat. 55°16′ N.
(QQQQ) Stikine Strait Island, Stikine Strait.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 37.	The reference location is marked as 65 south, 82 east, CRM, SEC 22. The location consists of a small island about ½ mile N 16° E, true, from Steamer Point, Elolin Island.	Approx. Long. 132°43′ W Lat. 56°13′ N.
(RRRR) Point Craig, Sumner Strait, Zarembo Island.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 38.	The reference location is marked as 62 south, 81 east, CRM, USS 1635. The location consists of everything apart of Zarembo Island in the vicinity of Point Craig lying on the north side of a true east-and-west line drawn across the point 750 feet due south of the northernmost extremity of the point.	Approx. Long. 132°44′ W Lat. 56°27½′ N.
(SSSS) The Eye Opener, Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 39.	The reference location is marked as 63 south, 78 east, CRM, SEC 20. The location is indicated by a bare rock in the middle of Sumner Strait, 3 miles due north from Pine Point, Prince of Wales Island.	Approx. Long. 133°16′ W Lat. 56°23′ N.
(TTTT) Beauclerc Island, Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 40.	The reference location is marked as 65 south, 75 east, CRM, SEC 5. The location starts at a small island in the entrance to Port Beauclerc, located about 4 nautical miles south of Boulder Point.	Approx. Long. 133°50½′ W Lat. 56°15′ N.
(UUUU) Shakan Bay, Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8176—Sheet No. 41.	The reference location is marked as 66 south, 76 east, CRM, SEC 14. The location consists of all of the island named Station Island, located ¼ mile northwest of Kosciusko Island and ¼ mile east of Shakan Islands, south side of the entrance to Shakan Strait.	Approx. Long. 133°37′ W Lat. 56°09′ N.
(VVVV) Spanish Island, Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8152—Sheet No. 42.	The reference location is marked as 68 south, 73 east, CRM, SECS 10 and 15. The location consists of the northernmost island in the group, about 1½ miles S 44° E from Cape Decision, Kuiu Island.	Approx. Long. 134°06′ W Lat. 55°59′ N.
(WWWW) Turnabout Island, Frederick Sound.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 43.	The reference location is marked as 55 south, 72 east, CRM, SEC 4. The location is a small island about ¼ mile long, located 4½ miles N 22° E from Cape Bendel, Kupreanof Island, being the northwestern island of the group.	Approx. Long. 133°59′ W Lat. 57°07½′ N.
(XXXX) Pybus Bay, Frederick Sound.	U.S. Coast and Geodetic Survey Chart No. 8218—Sheet No. 18.	The reference location is marked as 55 south, 63 east, CRM. The location consists of all of the small island in Pybus Bay, located 3⅛ nautical miles N 77° W true from Point Pybus.	Approx. Long. 134°04½′ W Lat. 57°19′ N.
(YYYY) Murder Cove, Frederick Sound.	U.S. Coast and Geodetic Survey Chart No. 8242—Sheet No. 43A.	The reference location is marked as 56 south, 68 east, CRM, SEC 11. The location begins as a small rocky islet located on the east side of Murder Cove, ⅜ nautical mile N 45° W true from Walker Point, Admiralty Island.	Approx. Long. 134°33′ W Lat. 57°01½′ N.
(ZZZZ) Cape Ommaney, Chatham Strait.	U.S. Coast and Geodetic Survey Chart No. 8250—Sheet No. 44.	The reference location is marked as 66 south, 69 east, CRM, SEC 12. The location consists of all of Wooden Island, located about ½ mile southeasterly from Cape Ommaney, Baranof Island.	Approx. Long. 134°40′ W Lat. 56°09½′ N.
(AAAAA) Red Bluff Bay, Baranof Island, Chatham Strait.	U.S. Coast and Geodetic Survey Chart No. 8242—Sheet No. 49.	The reference location is marked as 43 south, 65 east, CRM. The location begins at the first and most southeasterly island in the entrance to the Bay.	Approx. Long. 134°42½′ W Lat. 56°50½′ N.
(BBBBB) Point Craven, Peril Strait.	U.S. Coast and Geodetic Survey Chart No. 8283—Sheet No. 52.	The reference location is marked as 51 south, 66 east, CRM, SEC 8. The location consists of a small island about 300 yards S 52° E true from the southeastern point of Chichagof Island on the west side of the entrance to Sitkoh Bay.	Approx. Long. 134°51½′ W Lat. 57°27′ N.
(CCCCC) Tenakee, Tenakee Inlet, Chichagof Island.	U.S. Coast and Geodetic Survey Chart No. 8300—Sheet No. 55.	The reference location is marked as 47 south, 63 east, CRM, SEC 22. The location consists of all of a small island located just off the north shore of the inlet, about ¾ nautical mile eastward of Tenakee Village.	Approx. Long. 135°12′ W Lat. 57°47′ N.
(DDDDD) Hawk Inlet Entrance, Chatham Strait.	U.S. Coast and Geodetic Survey Chart No. 8300—Sheet Nos. 55 and 56.	The reference location is marked as 47 south, 61 east, CRM. The location starts at a small island on the south side of the entrance to Hawk Inlet upon which Hawk Inlet Entrance Light is maintained.	Approx. Long. 134°46′ W Lat. 58°05′ N.
(EEEEE) Rocky Island, Icy Strait.	U.S. Coast and Geodetic Survey Chart No. 8302—Sheet No. 57.	The location begins at an island that is about 50 feet high and 600 feet long, located ¾ mile S 10° E, true, from Point Couverden.	Approx. Long. 135°02½′ W Lat. 58°11′ N.
(FFFFF) Inner Point Sophia, Icy Strait, Chichagof Island.	U.S. Coast and Geodetic Survey Chart No. 8304—Sheet No. 58.	The reference location is marked as 43 south, 61 east, CRM, SEC 20, USS 1620. The location consists of everything apart of the Point bounded by a low-water line, and a true north-and-south line and a true east-and-west line, 200 feet east and 200 feet south, respectively, from the center of the structure supporting the light, consisting of a skeleton tower on four concrete piers.	Approx. Long. 135°28′ W Lat. 58°08′ N.
(GGGGG) North Inian Pass, Icy Strait.	U.S. Coast and Geodetic Survey Chart No. 8304—Sheet No. 60.	The reference location is marked as 41 south, 55 east, CRM, SEC 34, USS 1629. The location consists of everything apart of all the northwestern extremity of North Inian Island lying on the northwestern side of a true northeast-and-southwest line drawn across the island at a distance of 1,520 feet southeast true from the center of the concrete slab 4 feet by 6 feet, upon which the structure of the North Inian Pass Light is erected.	Approx. Long. 136°24′ W Lat. 58°16′ N.
(HHHHH) Vitskari Rocks, Sitka Sound.	U.S. Coast and Geodetic Survey Chart No. 8240—Sheet No. 61.	The reference location is marked as 56 south, 62 east, CRM, SEC 22. The location consists of all of a group of rocks located about 3 nautical miles easterly from Point of Shoals.	Approx. Long. 135°32½′ W Lat. 57°00′ N.
(IIIII) The Eckholms, Sitka Sound.	U.S. Coast and Geodetic Survey Chart No. 8244—Sheet No. 62.	The reference location is marked as 56 south, 63 east, CRM, SEC 14, USS 3926. The location consists of a group of three small islands and including also a fourth islet called Liar Rock on the charts and located 150 yards N 75° W from the Eckholms.	Approx. Long. 135°21½′ W Lat. 57°00′30″ N.
(JJJJJ) Old Sitka Rocks, Sitka Sound.	U.S. Coast and Geodetic Survey Chart No. 8281—Sheet No. 64.	The reference location is marked as 55 south, 63 east, CRM, SEC 9. The location starts at a group of rocks about ¾ mile (nautical) north of Halibut Point.	Approx. Long. 135°24′ W Lat. 57°07′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(KKKKK) Sergius Point, Peril Strait, Chichagof Island.	U.S. Coast and Geodetic Survey Chart No. 8282—Sheet No. 65.	The reference location is marked as 51 south, 61 east, CRM, SEC 33, USS 1644. The location consists of everything apart of Sergius Point lying south of a true east-and-west line drawn across the point at a distance of 300 feet north true from the high-water line at the southernmost extremity of the point.	Approx. Long. 135°38′ W Lat. 57°24½′ N.
(LLLLL) Deep Bay Entrance, Peril Strait.	U.S. Coast and Geodetic Survey Chart No. 8282—Sheet No. 66.	The point begins at a small islet in the middle of the entrance to Deep Bay, about midway between Little Island and Big Island.	Approx. Long. 135°35½′ W Lat. 57°26′ N.
(MMMMM) Rose Channel Rock, Rose Channel, Peril Strait.	U.S. Coast and Geodetic Survey Chart No. 8282—Sheet No. 66.	The reference location is marked as 80 south, 83 east, CRM, SEC 5. The location begins at a small rock 250 yards northwest of Little Rose Island.	Approx. Long. 135°33′ W Lat. 57°27½′ N.
(NNNNN) Otstoia Island, Peril Strait.	U.S. Coast and Geodetic Survey Chart No. 8283—Sheet No. 67.	The location begins at an island about 500 yards long and 200 yards wide, located 1 mile west of Nismeni Point.	Approx. Long. 135°26′34″ W Lat. 57°33′ N.
(OOOOO) McClellan Rock, Peril Strait.	U.S. Coast and Geodetic Survey Chart No. 8283—Sheet No. 68.	The reference location is marked as 51 south, 65 east, CRM, SEC 17. The location begins at a rock about 600 feet S 22° W, true off Lindenberg Head.	Approx. Long. 135°01′ W Lat. 57°27′ N.
(PPPPP) Klag Bay Entrance, Klag Bay.	U.S. Coast and Geodetic Survey Chart No. 8280—Sheet No. 69.	The reference location is marked as 49 south, 58 east, CRM, SECS 21 and 22. The location is marked by the two islands lying on either side of the narrow entrance to Klag Bay, known as ''The Gate,'' the one on the western side being, about ¾ mile by ¾ mile in extent, and the one on the eastern side being about 200 yards in diameter.	Approx. Long. 136°06½′ W Lat. 57°36½′ N.
(QQQQQ) Cape Edwards, Kukkan Bay.	U.S. Coast and Geodetic Survey Chart No. 8250—Sheet No. 70.	The reference location is marked as 54 south, 63 east, CRM. The location consists of everything apart of the point lying on the west side of a true north-and-south line located 1,520 feet east true from the center of the concrete slab upon which Cape Edward Entrance Light is erected.	Approx. Long. 136°15′ W Lat. 57°40′ N.
(RRRRR) Lisianski Strait Entrance, Outside Coast.	U.S. Coast and Geodetic Survey Chart No. 8250—Sheet No. 70.	The reference location is marked as 46 south, 55 east, CRM, SECS 25 and 36. The location is shown as a small island ⅓ nautical mile long located in the southeast entrance to Lisiaunski Strait about ¾ nautical mile east of Point Theodore.	Approx. Long. 136°26′ W Lat. 57°50′ N.
(SSSSS) Ocean Cape, Yakutat Bay.	U.S. Coast and Geodetic Survey Chart No. 8455—Sheet No. 73.	The reference location is marked as 27 south, 33 east, CRM, SECS 32. The location begins at a point on the low-water line southeasterly from the Cape and distant from Ocean Cape Light 1,520 feet in a straight line; thence northeast true 600 feet, more or less, to an intersection with the low-water line in Ankau Creek; thence following the windings of the low-water line of Ankau Creek northerly, etc., to the intersection with an east-and-west line located 3,040 feet north of the light; thence west true 400 feet, more or less, to an intersection with the low-water line; thence along the low-water line to the point of beginning.	Approx. Long. 139°52′ W Lat. 59°32½′ N.
(TTTTT) Point Carrew, Yakutat Bay.	U.S. Coast and Geodetic Survey Chart No. 8455—Sheet No. 73.	The reference location is marked as 27 south, 33 east, CRM, SECS 29. The location consists of everything apart of the Point lying north of a true east-and-west line located 1,000 feet south true from the high-water line at the northernmost extremity of the point.	Approx. Long. 139°50′ W Lat. 59°33½′ N.
(UUUUU) Point Francis, Behm Canal.	U.S. Coast and Geodetic Survey Chart No. 8105—Sheet No. 110.	The reference location is marked as 76 south, 88 east, CRM. The location includes that part of the Point lying east of a true north-and-south line drawn across the Point at a distance of 1,200 feet west true from the high-water line at the easternmost extremity of the Point, including the island lying close to the south side of the Point.	Approx. Long 131°50′ W Lat. 55°40′ N.
(VVVVV) Cape Decision, Chatham Strait, Kuiu Island.	U.S. Coast and Geodetic Survey Chart No. 8152—Sheet No. 111.	The reference location is marked as 67 and 68 south, 73 east, CRM, USS 1609. The location includes that part of the southern extremity of Kuiu Island lying south of a true east-and-west line located at a distance of 4,560 feet north true from the high-water line at the southernmost extremity of the Point.	Approx. Long 134°08′ W Lat. 56°00′ N.
(WWWWW) Point Adolphus, Icy Strait, Chichagof Island.	U.S. Coast and Geodetic Survey Chart No. 8304—Sheet No. 113.	The reference location is marked as 41 south, 59 east, CRM, SECS 28, 29, and 30, USS 1631. The location includes all of that part of the point lying north of a true east-and-west line drawn across the same at a distance of 1,520 feet south true from the high-water line at the northernmost extremity of the Point.	Approx. Long 135°47½′ W Lat. 58°13′ N.
(XXXXX) The Twins, Sitka Sound.	U.S. Coast and Geodetic Survey Chart No. 8244—Sheet No. 114.	The reference location is marked as 56 south, 63 east, CRM, SEC 12, USS 3255–TRH and USS 3926–L111A. The location is three small islands about 75 by 150 yards in extent altogether located about ⅜ nautical mile northeast of Galankin Island, the eastern island of the group.	Approx. Long 135°18¾′ W Lat. 57°02′ N.
(YYYYY) Althorp Rock, Port Althorp.	U.S. Coast and Geodetic Survey Chart No. 8304—Sheet No. 1.	The location is indicated by a small rock about 15 feet high, near the middle of Port Althorp.	Approx. Long. 136°21½′ W Lat. 58°10′ N.
(ZZZZZ) Amelius Island, Sumner Strait.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 2.	The location is indicated by a small island about 400 yards in diameter 1¾ nautical miles 147° true from Point Amelius and associated tidelands.	Approx. Long. 133°52′ W Lat. 56°10½′ N.
(AAAAAA) Bluff Island, Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 5.	The location is an island about ¾ mile long and one of the easterly islands of the Kashevarof group.	Approx. Long. 132°53′ W Lat. 56°10′ N.
(BBBBBB) Fannie Island, Port Snettisham.	U.S. Coast and Geodetic Survey Chart No. 8227—Sheet No. 13.	The location is an island off Prospect Point, about ¼ nautical mile long by about 150 yards wide and associated tidelands.	Approx. Long. 133°47′ W Lat. 58°02½′ N.
(CCCCCC) Goat Island, Tlevak Strait.	U.S. Coast and Geodetic Survey Chart No. 8151—Sheet No. 14.	The location includes all of that part of the southeastern extremity of Goat Island lying south of a true east-and-west line drawn across the point at a distance of 1,200 feet north of the southernmost extremity of the island and associated tidelands.	Approx. Long. 132°53′ W Lat. 55°10′ N.
(DDDDDD) Guide Island, Tlevak Strait.	U.S. Coast and Geodetic Survey Chart No. 8151—Sheet No. 4.	The location is an island in the northerly part of Tlevak Strait, between Prince of Wales Island and Dall Island and associated tidelands.	Approx. Long. 133°04′ W Lat. 55°13′ N.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(EEEEEE) Kasaan Bay, Clarence Strait.	U.S. Coast and Geodetic Survey Chart No. 8084—Sheet No. 21.	The location is indicated by an unnamed island about 840 yards long by 340 yards wide located near the head of Kasaan Bay 1⅜ nautical miles 66° true from Mound Point and associated tidelands.	Approx. Long. 132°31¼′ W Lat. 55°35′ N.
(FFFFFF) McFarland Island, Tlevak Strait.	U.S. Coast and Geodetic Survey Chart No. 8148—Sheet No. 24.	The location is on the southern part of one of the westerly islands of the group about 2 nautical miles long; all that part of the island lying south of a true east-and-west line drawn across the island at a distance of 3,040 feet north from the southernmost part of the high-water line at the south end of the island, including the small islet near the southeast side and associated tidelands.	Approx. Long. 132°55′ W Lat. 55°03′ N.
(GGGGGG) Peep Rock, Karheen Passage.	U.S. Coast and Geodetic Survey Chart No. 8171—Sheet No. 28.	The location consists of a small islet located ¾ nautical mile 306° true from the cannery wharf at Karheen and associated tidelands.	Approx. Long. 133°20′ W Lat.55°49′ N.
(HHHHHH) Round Point, Southeastern Shore of Zarembo Island.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 37.	The location is indicated by a southwestern island of the group about 700 yards long, including off-lying rocks and reefs not covered at low water.	Approx. Long. 132°39½′ W Lat. 56°16½′ N.
(IIIIII) Round Rock, Frederick Sound.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 38.	The location consists of a barren rock about 40 feet high located 3 nautical miles 254° true from the south end of West Brother Island.	Approx. Long. 133°56′ W Lat. 57°15½′ N.
(JJJJJJ) Snipe Rock, Ogden Passage.	U.S. Coast and Geodetic Survey Chart No. 8280—Sheet No. 40.	The location consists of a small barren rock occupied by the structure of Snipe Rock Light, located 340 yards 147° true from the south point of Herbert Graves Island.	Approx. Long. 136°10½′ W Lat. 57°38′ N.
(KKKKKK) South Craig Point, Zarembo Island.	U.S. Coast and Geodetic Survey Chart No. 8160—Sheet No. 41.	The location consists of all of that part of the point lying on the easterly side of a true north-and-south line drawn across the point at a distance of 800 feet west true from the most easterly projection of the low-water line.	Approx. Long. 132°37½′ W Lat. 56°23′ N.
(LLLLLL) Sukoi Islets, Frederick Sound.	U.S. Coast and Geodetic Survey Chart No. 8200—Sheet No. 43.	The location consists of the western group of islands and associated tidelands.	Approx. Long. 132°56′ W Lat. 56°54′ N.
(MMMMMM) Three Hill Island, Cross Sound.	U.S. Coast and Geodetic Survey Chart No. 8304. See sheet for Althorp Rock, No. 1.	The location consists of Pinnacle rock about 32 feet high on the north shore of Three Hill Island occupied by Three Hill Island Light.	Approx. Long. 136°24′ W Lat. 58°11′ N.
(NNNNNN) Turn Point, Portland Canal.	U.S. Coast and Geodetic Survey Chart No. 8051—Sheet No. 44.	The location begins at a point on the low-water line, west shore of Portland Canal, 3,040 feet in a direct line, southerly from the center of Turn Point Beacon, a tripod anchored to concrete piers, thence west true 1,520 feet, thence north true, 5,050 feet, more or less, to an intersection with the low-water line, thence southeasterly and southerly following the windings of a low-water line to the point of beginning.	Approx. Long. 130°03½′ W Lat. 55°26½′ N.
(OOOOOO) Turn Rock, Tlevak Strait.	U.S. Coast and Geodetic Survey Chart No. 8151. See sheet for Goat Island, No. 14.	The location includes a small rock, awash at the highest tide, located near the south shore Goat Island and occupied by Turn Rock Beacon; a spindle and concrete pier.	Approx. Long. 132°55′ W Lat. 55°10′ N.
(PPPPPP) Woronkofski Point, Woronkofski Island.	U.S. Coast and Geodetic Survey Chart No. 8160. See sheet for High Point, No. 18.	The location begins at a point from which Woronkofski Beacon, a white slatted tripod, bears west true, distant 1,520 feet, thence south true 1,100 feet, thence west true 1,824 feet, more or less, to an intersection with a low-water line, thence northeasterly and easterly, following the windings of the low-water line, to a point from which point of beginning bears south true, thence south true, 420 feet, more or less, to point of beginning.	Approx. Long. 132°30′ W Lat. 56°26′ N.
(QQQQQQ) Old Edna Bay ..	Section 28, T. 68 S., R. 76 E., Copper River Meridian.	The location begins in Section 28 at a point described as N 55°56′59.3412″ W 133°39′50.9538″, thence easterly to N 55°56′59.5176″ W 133°39′49.1904″, thence southerly to N 55°56′55.7802″ W 133°39′48.0054″, thence westerly to N 55°56′55.6044″ W 133°39′49.7736″, thence northerly to the point of beginning.	Approx. N 55°56′59.3412″ W 133°39′50.9538″.
(RRRRRR) Fick Cove LTF ..	Sections 17 and 18, T. 49 S., R. 61 E., Copper River Meridian.	The location begins in section 17 at a point described as N 57°37′35.5542″ W 135°40′22.5588″, thence southeasterly to N 57°37′33.3804″ W 135° 40′15.9198″, thence southwesterly to N 57°37′29.0922″ W 135°40′20.802″, thence northwesterly to N 57°37′31.2666″ W 135°40′27.4398″, thence northeasterly to the point of beginning.	Approx. N 57°37′35.5542″ W 135°40′22.5588″.
(SSSSSS) Fick Cove Road	Section 18, T. 49 S., R. 61 E., Copper River Meridian.	The location begins in Section 18 at a point described as N 57°37′23.1672″ W 135°40′40.9182″, thence easterly to N 57°37′23.7318″ W 135°40′31.6482″, thence southerly to N 57°37′22.0332″ W 135°40′31.2918″, thence westerly to N 57°37′21.468″ W 135°40′40.5582″, thence northerly to the point of beginning.	Approx. N 57°37′23.1672″ W 135°40′40.9182″.
(TTTTTT) Fish Bay	Section 17, T. 52 S., R. 62 E., Copper River Meridian.	The location begins in Section 17 at a point described as N 57°21′27.6768″ W 135° 30′35.949″, thence northeasterly to N 57°21′28.9506″ W 135°30′29.8548″, thence southeasterly to N 57°21′27.7596″ W 135°30′29.0016″, thence southwesterly to N 57°21′26.4852″ W 135°30′35.0958″, thence northwesterly to the point of beginning.	Approx. N 57°21′27.6768″ W 135°30′35.949″.
(UUUUUU) Hollis LTF	Section 4, T. 74 S., R. 84 E., Copper River Meridian.	The location begins in Section 4 at a point described as N 55°28′51.2724″ W 132°39′13.4532″, thence easterly N 55°28′51.4884″ W 132°39′06.0660″, thence southerly N 55°28′51.4884″ W 132°39′05.9580″, thence westerly N 55°28′50.0700″ W 132°39′13.3452″, thence northerly to the point of beginning.	Approx. N 55°28′51.2724″ W 132°39′13.4532″.
(VVVVVV) Hollis Road	Section 4, T. 74 S., R. 84 E., Copper River Meridian.	The location begins in Section 4 at a point described as N 55°28′59.6748″ W 132°39′04.9644″, thence easterly N 55°28′59.4084″ W 132°39′01.1304″, thence southerly N 55°28′58.2456″ W 132°39′01.3824″, thence westerly N 55°28′58.5120″ W 132°39′05.2164″, thence northerly to the point of beginning.	Approx. N 55°28′59.6748″ W 132°39′04.9644″.
(WWWWWW) Klu Bay	Section 33, T. 69 S., R. 91 E., Copper River Meridian.	The location begins in Section 33 at a point described as N 55°50′41.5068″ W 131°28′02.4924″, thence northeasterly N 55°50′41.6400″ W 131°28′01.6788″, thence southeasterly N 55°50′40.1172″ W 131°28′00.8868″, thence southwesterly N 55°50′39.9804″ W 131°28′01.7004″, thence northwesterly to the point of beginning.	Approx. N 55°50′41.5068″ W 131°28′02.4924″.

TABLE 1 TO PARAGRAPH (b)(5)(ii)—Continued

Name	Chart No. or meridian name	Area description	Longitude/ latitude
(XXXXXX) Patterson Bay—Road Location 1.	Section 5, T. 49 S., R. 60 E., Copper River Meridian.	The location begins in Section 5 at a point described as N 57°39′18.2448″ W 135°48′42.4836″, thence easterly N 57°39′18.3312″ W 135°48′39.5748″, thence southerly N 57°39′17.6472″ W 135°48′39.5028″, thence westerly N 57°39′17.5608″ W 135°48′42.4116″, thence northerly to the point of beginning.	Approx. N 57°39′18.2448″ W 135°48′42.4836″.
(YYYYYY) Patterson Bay—Road Location 2.	Section 4, T. 49 S., R. 60 E., Copper River Meridian.	The location begins in Section 4 at a point described as N 57°39′21.5244″ W 135°48′20.7036″, thence southeasterly N 57°39′21.0564″ W 135°48′19.9764″, thence southwesterly N 57°39′20.0700″ W 135°48′22.1940″, thence northwesterly N 57°39′20.5380″ W 135°48′22.9212″, thence northeasterly to the point of beginning.	Approx. N 57°39′21.5244″ W 135°48′20.7036″.
(ZZZZZZ) Patterson Bay LTF.	Section 36, T. 48 S., R. 59 E., and Section 4, T. 49 S., R. 60 E., Copper River Meridian.	The location begins in Section 36, T. 48 S., R. 59 E., CRM at a point described as N 57°39′26.6544″ W 135°47′42.2844″, thence easterly N 57°39′27.2520″ W 135°47′30.6852″, thence southerly N 57°39′25.5960″ W 135°47′30.3900″, thence westerly N 57°39′25.0020″ W 135°47′41.9892″, thence northerly to the point of beginning.	Approx. N 57°39′26.6544″ W 135°47′42.2844″.
(AAAAAAA) Thorne Bay—Davidson Landing.	Section 34, T. 72 S., R. 84 E., Copper River Meridian.	The location begins in Section 34 at a point described as N 55°40′13.1628″, W 132°31′26.3388″, thence easterly to N 55°40′13.2312″, W 132°31′23.8332″, thence southerly to N 55°40′10.9056″, W 132°31′23.6388″, thence westerly to N 55°40′10.8372″, W 132°31′26.1444″, thence northerly to the point of beginning.	Approx. N 55°40′13.1628″, W 132°31′26.3388″.

* * * * *

Chad Van Ormer,

Acting Regional Forester, Alaska Region, U.S. Forest Service.

Joan M. Mooney,

Principal Deputy Assistant Secretary, Policy, Management, and Budget, U.S. Department of the Interior.

[FR Doc. 2024–07012 Filed 4–2–24; 8:45 am]

BILLING CODE 4333–15–P; 3411–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0620; FRL–11601–02–R9]

Air Plan Revisions; Arizona; Arizona Department of Environmental Quality; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing two revisions to the Arizona Department of Environmental Quality (ADEQ) portion of the Arizona State Implementation Plan (SIP). In this action, we are finalizing the approval of revisions submitted by the ADEQ governing the issuance of permits for stationary sources in accordance with changes that EPA has made to its New Source Review (NSR) program regulations under the Clean Air Act (CAA or ''the Act''). We are also finalizing the determination that with these revisions, the ADEQ's NSR program satisfies the requirements for the preconstruction review and permitting of major sources and major modifications under part D of title I of the Act for areas designated nonattainment with the 2015 ozone National Ambient Air Quality Standards (NAAQS) with a Marginal classification, for areas and sources within the ADEQ's permitting jurisdiction.

DATES: This rule is effective May 3, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket No. EPA–R09–OAR–2023–0620. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Camille Cassar, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; by phone: (415) 947–4164; or by email to *cassar.camille@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

The rules that are the subject of the EPA's current action were adopted by the ADEQ and submitted to the EPA on December 6, 2022 (''December 2022 NSR submittal''). On January 2, 2024 (89 FR 39), the EPA proposed to approve these rules, listed in Table 1 below, into the ADEQ portion of the Arizona SIP.

TABLE 1—SIP SUBMITTAL

Rule citation	Title	State effective date of rule to be added
R18–2–101 (except 20).	Definitions	05/04/2022
R18–2–404	Offset Standards.	05/04/2022

The ADEQ's December 2022 NSR submittal also requested that, as part of this action, the EPA remove from the ADEQ portion of the Arizona SIP the previous SIP-approved versions of the same rules. The rules that the ADEQ requested be removed from the SIP, and which the EPA proposed to remove from the SIP, are listed in Table 2 below.

TABLE 2—CURRENT SIP APPROVED RULES

Rule addressed in this rulemaking	Title	Existing SIP rule(s) requested to be removed from SIP (state effective date)
R18–2–101 (except 20)	Definitions	R18–2–101 (except 20) (02/01/2020).
R18–2–404	Offset Standards	R18–2–404 (03/21/2017).

In our proposed action, we also proposed to determine that with these rule revisions, the ADEQ's SIP-approved NSR program satisfies the requirements for the preconstruction review and permitting of major sources and major modifications under part D of title I of the Act for areas designated nonattainment with the 2015 ozone NAAQS with a Marginal classification, for areas and sources within the ADEQ's permitting jurisdiction. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Action

The EPA's proposed action provided a 30-day public comment period. During this period, no comments were submitted on our proposal. Therefore, the EPA continues to find that the submitted rules should be approved into the Arizona SIP because they fulfill all relevant CAA requirements. We have concluded that our approval of the submitted rules will comply with the relevant provisions of CAA sections 110(a)(2), 110(l), 165, 172(c)(5), 173, and 193, and 40 CFR 51.160–51.166. We also find that with the submitted rule revisions, the ADEQ's NSR program satisfies the requirements for the preconstruction review and permitting of major sources and major modifications under part D of title I of the Act for areas designated nonattainment with the 2015 ozone NAAQS with a Marginal classification, for the areas and sources within ADEQ's permitting jurisdiction. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving the submitted rules listed in Table 1 into the Arizona SIP and removing the versions listed in Table 2 from the SIP.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is incorporating by reference the following ADEQ rules: A.A.C. R18–2–101 (except 20) (effective 5/4/2020) and R18–2–404 (effective 5/4/2022), which govern the issuance of permits for stationary sources. These rules are intended to address the CAA's statutory and regulatory requirements for New Source Review permit programs for major sources emitting nonattainment air pollutants and their precursors under parts C and D of title I of the CAA. The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 3, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 27, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart D—Arizona

■ 2. Section 52.120, paragraph (c), Table 2 is amended by revising the entries for ''R18–2–101 (except 20)'' and ''R18–2–404'' to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 2—EPA-APPROVED ARIZONA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
Arizona Administrative Code				
* * * * * * *				
Title 18 (Environmental Quality) Chapter 2 (Department of Environmental Quality Air Pollution Control) Article 1 (General)				
R18–2–101 (except 20)	Definitions	May 4, 2022	April 3, 2024, [INSERT **Federal Register** CITATION].	Submitted electronically on December 6, 2022, as an attachment to a letter dated November 30, 2022.
* * * * * * *				
Article 4 (Permit Requirements for New Major Sources and Major Modifications to Existing Major Sources)				
* * * * * * *				
R18–2–404	Offset Standards	May 4, 2022	April 3, 2024, [INSERT **Federal Register** CITATION].	Submitted electronically on December 6, 2022, as an attachment to a letter dated November 30, 2022.
* * * * * * *				

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[FR Doc. 2024–06878 Filed 4–2–24; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 538 and 552

[GSAR Case 2020–G511; Docket No. GSA–GSAR–2023–0019; Sequence No. 1]

RIN 3090–AK21

General Services Administration Acquisition Regulation; Updated Guidance for Non-Federal Entities Access to Federal Supply Schedules

Correction

552.238–113 [Corrected]

In rule document, 2024–03605, which published on Thursday February 22, 2024, on pages 13282 to 13287, make the following corrections:

■ On page 13287, in the first column, the twelfth line down reading ''(b) [Reserved]'' should be deleted.

[FR Doc. C1–2024–03605 Filed 4–2–24; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 240327–0090]

RIN 0648–BM75

Pacific Halibut Fisheries of the West Coast; 2023 Catch Sharing Plan and Recreational Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This final rule approves changes to the Pacific Halibut Catch Sharing Plan for the International Pacific Halibut Commission (IPHC)'s regulatory Area 2A off of Washington, Oregon, and California. In addition, this final rule implements management measures governing the 2024 recreational fisheries that are not implemented through the IPHC. These management measures include the recreational fishery seasons and subarea allocations for Area 2A. This rule also adds a new inseason management provision to transfer anticipated uncaught recreational fishery allocation between the Area 2A states. Additionally, the rule establishes a new management line at Point Arena, CA, creating two subareas with separate allocations off California. These actions are intended to conserve Pacific halibut and provide angler opportunity where available.

DATES: This rule is effective April 4, 2024.

ADDRESSES: Additional information regarding this action may be obtained by contacting the Sustainable Fisheries Division, NMFS West Coast Region, 501 W Ocean Blvd., Long Beach, CA 90802. For information regarding all halibut fisheries and general regulations not contained in this rule, contact the International Pacific Halibut Commission, 2320 W Commodore Way, Suite 300, Seattle, WA 98199–1287.

FOR FURTHER INFORMATION CONTACT: Melissa Mandrup, phone: 562–980–3231 or email: *melissa.mandrup@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Northern Pacific Halibut Act of 1982 (Halibut Act), 16 U.S.C. 773–773k, gives the Secretary of Commerce responsibility for implementing the provisions of the Convention between Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Halibut Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979). The Halibut Act requires that the Secretary of Commerce adopt regulations to carry out the purposes and objectives of the Halibut Convention and Halibut Act (16 U.S.C. 773c). Additionally, as provided in the Halibut Act, the Regional Fishery Management Councils having authority for the geographic area concerned may develop, and the Secretary of Commerce may implement, regulations governing Pacific halibut fishing in in U.S. waters that are in addition to, and not in conflict with, approved IPHC regulations (16 U.S.C. 773c(c)).

At its annual meeting held January 22–26, 2024 the IPHC adopted an Area 2A catch limit also known as the fishery constant exploitation yield (FCEY) of 1.47 million pounds (lb; 666.8 metric tons [mt]) of Pacific halibut. The FCEY was derived from the total constant exploitation yield (TCEY) of 1.65 million lb (748.4 mt) for Area 2A, which includes commercial discards and bycatch estimates calculated using a formula developed by the IPHC. The Area 2A catch limit and commercial fishery allocations were adopted by the IPHC and were accepted by the Secretary of State, with concurrence from the Secretary of Commerce, in accordance with 50 CFR 300.62 on March 9, 2024. This final rule contains 2024 recreational fishery subarea allocations based on the Area 2A catch limit adopted by the IPHC that were published in the **Federal Register** on March 18, 2024 (89 FR 19275). Additionally, the March 18, 2024 (89 FR 19275) final rule contains annual domestic management measures and IPHC regulations that are published each year under NMFS' authority to implement the Halibut Convention (50 CFR 300.62).

Since 1988, the Pacific Fishery Management Council (Council) has developed a Catch Sharing Plan that allocates the IPHC regulatory Area 2A Pacific halibut catch limit between treaty tribal and non-tribal harvesters and among non-tribal commercial and recreational (sport) fisheries. NMFS has implemented at 50 CFR 300.63 *et seq.* certain provisions of the Catch Sharing Plan and implemented in annual rules annual management measures consistent with the Catch Sharing Plan. In 1995, the Council recommended and NMFS approved a long-term Area 2A Catch Sharing Plan (60 FR 14651; March 20, 1995). NMFS has been approving adjustments to the Area 2A Catch Sharing Plan based on Council recommendations each year to address the changing needs of these fisheries. While the full Catch Sharing Plan is not published in the **Federal Register**, it is made available on the Council website: *https://www.pcouncil.org/documents/2024/01/2024-pacific-halibut-catch-sharing-plan.pdf/.*

This rule approves the changes the Council recommended at its November 2023 meeting to the Catch Sharing Plan for Area 2A. The recommended changes to the Catch Sharing Plan were developed through the Council's public process. The changes to the Catch Sharing Plan were detailed in the proposed rule and are not repeated here.

This rule also implements recreational Pacific halibut fishery management measures for 2024, which include season opening and closing dates, bag limits, a new subarea off California, and a new inseason action to reallocate or transfer recreational fishery allocation between states. These management measures are consistent with the recommendations made by the Council for the 2024 Catch Sharing Plan and the season dates recommended by the states during the proposed rule's public comment period, where applicable, and which are detailed below.

2024 Recreational Fishery Management Measures

NMFS is implementing recreational fishery management measures consistent with the Council's recommendations for the 2024 Catch Sharing Plan. If there is any discrepancy between the Catch Sharing Plan and federal regulations, federal regulations take precedence. These provisions may be modified through inseason action consistent with 50 CFR 300.63(c). All recreational fishing in Area 2A is managed on a ''port of landing'' basis, whereby any halibut landed into a port counts toward the allocation for the area in which that port is located, and the regulations governing the area of landing apply, regardless of the specific area of catch. The 2024 recreational fishing subareas, allocations, fishing dates, and daily bag limits are described below:

Washington Puget Sound and the U.S. Convention Waters in the Strait of Juan de Fuca

The allocation for landings into ports in Puget Sound and the U.S. waters in the Strait of Juan de Fuca is 81,729 lb (37.1 mt).

(a) The Puget Sound is open 7 days a week from April 4 through June 30. If the subarea allocation remains for at least another full day of fishing after June 30, NMFS may take inseason action to reopen the fishery in August, up to 7 days per week, through September. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

(b) The daily bag limit is one Pacific halibut of any size per person.

Washington North Coast Subarea

The allocation for landings into ports in the Washington North Coast subarea is 132,366 lb (60.0 mt).

(a) The Washington North Coast is open:

- May 2, 3, 4;
- May 9, 10, 11;
- May 16, 17, 18;
- May 24;
- May 26;
- May 30, 31, June 1;
- June 6, 7, 8;
- June 13, 14, 15;
- June 20, 21, 22; and
- June 27, 28, 29.

If the subarea allocation remains for at least another full day of fishing after June 30, NMFS may take inseason action to reopen the fishery in August, up to 7 days per week, through September. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

(b) daily bag limit is one Pacific halibut of any size per person.

Washington South Coast Subarea

The allocation for landings into ports in the Washington South Coast subarea is 67,074 lb (30.4 mt) with 65,074 lb (29.5 mt) allocated to the primary fishery and 2,000 lb (0.9 mt) to the nearshore fishery.

(a) The Washington South Coast primary fishery is open:

- May 2, 5, 7;
- May 9, 12, 14;
- May 16, 19, 21; and
- May 23.

If sufficient subarea allocation remains for at least another full day of fishing after May 30, the primary fishery will reopen:

- June 13, 16, 18;
- June 20, 23, 25;
- June 27, and 30; or
- until there is not sufficient subarea allocation for another full day of fishing.

If the subarea allocation remains for at least another full day of fishing after June 30, NMFS may take inseason action to reopen the fishery in August, up to 7 days per week, through September. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

When the Washington South Coast subarea primary fishery does not have sufficient allocation to open for at least another full day of fishing, any remaining primary fishery allocation will be used to open a nearshore fishery. The nearshore fishery will open for 7 days a week the first Saturday after the closure of the primary fishery. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

If the primary fishery is closed prior to September 30 and there is not sufficient allocation remaining for at least a full day of fishing in the nearshore fishery, NMFS may take inseason action to transfer any remaining subarea allocation to another Washington coastal subarea, in accordance with Federal regulations at 50 CFR 300.63(c).

(b) The daily bag limit is one Pacific halibut of any size per person.

Columbia River Subarea

The allocation for landings into ports in the Columbia River subarea is 18,612 lb (8.4 mt), with 18,112 lb (8.2 mt) allocated to the all-depth fishery and 500 lb (0.2 mt) allocated to the nearshore fishery.

(a) The all-depth fishery is open:

- May 2, 5, 7;
- May 9, 12, 14;
- May 16, 19, 21;
- May 23, 26;
- May 30, June 2, 4;
- June 6, 9, 11;
- June 13, 16, 18;
- June 20, 23, 25; and
- June 27, 30.

The nearshore fishery is open:

- May 6, 7, 8;
- May 13, 14, 15;
- May 20, 21, 22;
- May 27, 28, 29;
- June 3, 4, 5;
- June 10, 11, 12;
- June 17, 18, 19;
- June 24, 25, 26;
- July 1, 2, 3;
- July 8, 9, 10;
- July 15, 16, 17;
- July 22, 23, 24;
- July 29, 30, 31;
- August 5, 6, 7;
- August 12, 13, 14;
- August 19, 20, 21;
- August 26, 27, 28;
- September 2, 3, 4;
- September 9, 10, 11;
- September 16, 17, 18;
- September 23, 24, 25; and
- September 30.

The area will close when there is not sufficient subarea allocation for another full day of fishing. Any remaining subarea allocation may be transferred inseason to other Washington or Oregon subareas, by NMFS, in accordance with Federal regulations at 50 CFR 300.63(c). Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825. Any remaining subarea allocation would be transferred to each state in proportion to the allocation formula in the Catch Sharing Plan.

(b) The daily bag limit is one Pacific halibut of any size per person.

Oregon Central Coast Subarea

The allocation for landings into ports in the Oregon Central Coast subarea is

266,161 lb (120.7 mt). The nearshore fishery allocation is 31,393 lb (14.5 mt), the spring all-depth fishery allocation is 167,681 lb (76.1 mt), and the summer all-depth fishery allocation is 66,540 lb (30.2 mt).

(a) The nearshore fishery is open 7 days a week from May 1 through October 31. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

The spring all-depth fishery is open 7 days a week from May 1 through June 30. In the event that there is remaining subarea allocation after June 30, NMFS may take inseason action to reopen the fishery, up to 7 days a week, during the month of July. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

The summer all-depth fishery is open:

- August 1, 2, 3;
- August 15, 16, 17;
- August 29, 30, 31;
- September 12, 13, 14;
- September 26, 27, 28;
- October 10, 11, 12;
- October 24, 25, 26; and
- October 31.

The area will close when the remaining combined spring all-depth fishery and summer all-depth fishery allocations in the Oregon Central Coast subarea is not sufficient for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

(b) The daily bag limit is two Pacific halibut of any size per person. NMFS will announce bag limits in accordance with notice procedures at 50 CFR 300.63(c)(3) and on the NMFS hotline (206) 526–6667 or (800) 662–9825.

Southern Oregon Subarea

The allocation for landings into ports in the Southern Oregon subarea is 8,000 lb (3.6 mt).

(a) The fishery is open 7 days a week from May 1 through October 31. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

(b) The daily bag limit is two Pacific halibut of any size per person. NMFS will announce bag limits in accordance with notice procedures at 50 CFR 300.63(c)(3) and on the NMFS hotline (206) 526–6667 or (800) 662–9825.

Northern California Coast Subarea

The allocation for landings into ports in the Northern California Coast subarea is 37,720 lb (17.1 mt).

(a) The fishery is open May 1 through November 15. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

(b) The daily bag limit is one Pacific halibut of any size per person.

South of Point Arena Subarea

The allocation for landings into ports in the South of Point Arena subarea is 500 lb (0.2 mt).

(a) The fishery is open May 1 through December 31. The area will close when there is not sufficient subarea allocation for another full day of fishing. Any inseason action, including closures, will be announced in accordance with Federal regulations at 50 CFR 300.63(c) and on the NMFS hotline at (206) 526–6667 or (800) 662–9825.

(b) The daily bag limit is one Pacific halibut of any size per person.

Comments and Responses

NMFS published a proposed rule on February 9, 2024 (89 FR 9105) and accepted public comments on the 2024 Area 2A Catch Sharing Plan and the proposed 2024 annual management measures through March 11, 2024. NMFS received four responsive comments, one from the Oregon Department of Fish and Wildlife (ODFW) and three from the public, and has responded to those below. NMFS also received one comment from a member of the public that was not responsive to the proposed action and is therefore not addressed here.

Comment 1: ODFW submitted a comment recommending final recreational fishing season dates for the 2024 season for the Central Oregon Coast subarea. ODFW conducted an online survey and public meeting following the IPHC annual meeting. Based on the resulting stakeholder input, past fishing effort and harvest rates, other fishing opportunities, weather impacts, and the risk of exceeding the combined spring and summer all-depth fishery allocations, ODFW recommended season dates for the spring and summer Central Oregon Coast all-depth fisheries. For spring, ODFW recommended open dates of May 1 through June 30, 7 days per week. In the event that there is remaining subarea allocation following the initial open dates, ODFW recommended the spring fishery open July 1–31, 7 days a week. ODFW recommended summer fishery dates of August 1–3; August 15–17; August 29–31; September 12–14; September 26–28; October 10–12; and October 24–26; and October 31, or until the total 2024 all-depth catch limit for the subarea is taken. ODFW also recommended a two-fish Pacific halibut bag limit per angler per day beginning May 1 for the Oregon Central Coast and Southern Oregon subareas.

Response: NMFS concurs that the ODFW-recommended season dates are appropriate. There are a few differences between the spring and summer all-depth season dates NMFS published in the proposed rule and those recommended by ODFW. However, based on the rationale provided by ODFW, NMFS has modified the recreational fishery season dates off of Oregon, approved in this final rule, to those recommended by ODFW.

Comment 2: NMFS received public comment on the recreational allocations, which requested a greater allocation for the California recreational fishery.

Response: Allocations to various sectors and states that are established in the Catch Sharing Plan and implemented through annual IPHC regulations were not considered through this action. As part of the Council process, the NMFS will consider modifications to the Area 2A Catch Sharing Plan, which includes the allocation schemes for the tribal and the non-tribal commercial and recreational fisheries. Interested parties can comment directly on state-specific allocations as part of that process, which is described at *https://www.pcouncil.org/.*

Comment 3: NMFS received a comment from the Crescent City Fishing Group, which indicated support for the proposed measures to conserve and manage the Pacific halibut fisheries, but also expressed concern that climate change is a stressor on the marine ecosystem and that fisheries management should respond with greater caution to the impacts of climate change.

Response: Overall fishery limits were not part of this action; however, this action is based on the best scientific information available. NMFS agrees that

there are increased stressors on marine ecosystems due to climate change and, consistent with its statutory and other obligations, works to manage all federally regulated fisheries, including Pacific halibut fisheries off the coasts of Washington, Oregon, and California, in a sustainable manner. In making their recommendation for the 2024 Pacific halibut fishing limits, the IPHC noted that the uncertainty associated with ongoing changes to the relevant ecosystem and climate remains high, and that the IPHC intends to continue to evaluate the effects of climate change on Pacific halibut as part of its ongoing management actions.

Comment 4: NMFS received comment from a member of the public, expressing the opinion that larger Pacific halibut should not be allowed to be kept when caught, due to those larger halibut's reproductive capacity. The comment also made a statement on halibut bycatch that is not related to this action.

Response: NMFS has determined that this action is based on the best scientific information available and will appropriately conserve and manage Pacific halibut stocks off the coasts of Washington, Oregon, and California consistent with the requirements of Federal law. As part of its ongoing biological research activities, the IPHC is examining the factors that influence (1) the biomass of the Pacific halibut population (*e.g.,* distribution and movement of fish among IPHC regulatory areas; growth patterns and environmental influences on growth in larval, juvenile and adult fish; drivers of changes in size-at-age); (2) the spawning (female) population (*e.g.,* reproductive maturity, skipped spawning, reproductive migrations); and (3) any resulting changes in population dynamics in order to ensure proper management of the Pacific halibut resource now and in the future. Consistent with its statutory and other obligations, NMFS will continue to keep abreast of the IPHC's ongoing research and to ensure that its regulatory actions, including its approval of annual Pacific halibut management measures, are based on the best scientific information available.

Classification

Under section 773 of the Halibut Act, the Council may develop, and the Secretary of Commerce may implement, regulations governing Pacific halibut fishing by U.S. fishermen in Area 2A that are in addition to, and not in conflict with, approved IPHC regulations (16 U.S.C. 773c(c)). The final rule is consistent with the Council and NMFS's authority under the Halibut Act.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

NMFS finds good cause to waive the 30-day delay in the date of effectiveness and make the 2024 Area 2A recreational fishery management measures (*i.e.,* season dates and bag limits) in this rule effective in time for the start of the recreational Pacific halibut fisheries off the coasts of Washington, Oregon, and California on April 4, 2024, pursuant to 5 U.S.C. 553(d)(3). The 2024 Catch Sharing Plan provides the framework for the annual management measures and for setting subarea allocations based on annual catch limits set by the IPHC. This rule implements 2024 Area 2A subarea allocations as published in the proposed rule (89 FR 9105; February 9, 2024) for the recreational Pacific halibut fishery, based on the formulas set in the Catch Sharing Plan, and using the 2024 Area 2A catch limit for Pacific halibut set by the IPHC and accepted by the Secretary of State, with concurrence from the Secretary of Commerce, in accordance with 50 CFR 300.62, on March 9, 2024. Relatively few comments were received in response to the proposed rule; the comments raised few issues within the scope of this rulemaking, and minor changes were made to accommodate the comments received from the State of Oregon. With few changes from the proposed rule, there is less need for a delay in effective date.

Delaying the effective date of the annual management measures would be contrary to the public interest. The Council's 2024 Catch Sharing Plan includes changes that respond to the needs of the fisheries in each state, including fisheries that begin in early April. The 2024 Catch Sharing Plan and management measures were developed through multiple Council meetings in 2023, which are open to the public and where public comment was accepted. Additionally, the 2024 Catch Sharing Plan and management measures were described at the January 2024 IPHC meeting, where public comment was also accepted. A delay in the effectiveness of these measures for 30 days would result in the West Coast's Pacific halibut recreational fisheries not being opened on their intended timelines and, thus, the fisheries not being open on the dates that the affected public is expecting. The recreational Pacific halibut fisheries have high participation, and some subareas close months before the end of the season due to subarea allocation attainment. If the fisheries do not open on their intended timelines, fishing opportunity is lost, potentially causing social and economic harm to communities at recreational fishing ports.

As a result of the potential harm to fishing communities that could be caused by delaying the effectiveness of these management measures, NMFS finds good cause to relieve a regulatory restriction as per 5 U.S.C. 553(d)(1) and waive the 30-day delay in the date of effectiveness and make this final rule effective on April 4, 2024.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities for purposes of the Regulatory Flexibility Act. The factual basis for the certification was published in the proposed rule and is not repeated here. As a result, a regulatory flexibility analysis was not required for this action and none was prepared.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Antarctica, Canada, Exports, Fish, Fisheries, Fishing, Imports, Indians, Labeling, Marine resources, Reporting and recordkeeping requirements, Russian Federation, Transportation, Treaties, Wildlife.

Dated: March 28, 2024.

Carrie Diane Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 300, subpart E, as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart E—Pacific Halibut Fisheries

■ 1. The authority citation for part 300, subpart E, continues to read as follows:

Authority: 16 U.S.C. 773–773k.

■ 2. Amend § 300.63 by revising paragraph (c)(5)(iii), adding paragraph (c)(6)(i)(F), revising paragraph (c)(6)(ii) introductory text and paragraphs (c)(6)(ii)(E) and (c)(6)(ii)(F), and adding paragraph (c)(6)(ii)(G), to read as follows:

§ 300.63 Catch sharing plan and domestic management measures in Area 2A.

* * * * *

(c) * * *

(5) * * *

(iii) *California.* The California recreational fishery is divided into the following subareas:

(A) *Northern California Coast Subarea.* The Northern California Coast subarea is located south of the OR/CA border (42°00.00′ N lat.) to Point Arena (38°57.5′ N lat.).

(B) *South of Point Arena Subarea.* The South of Point Area subarea is located south of Point Arena (38°57.5′ N lat.) to the U.S./Mexico border.

(6) * * *

(i) * * *

(F) If any state is projected to not utilize its respective recreational allocation by the end of the fishing season, NMFS may take inseason action to transfer any projected unused allocation to another state. After a state notifies NMFS of the amount of their recreational subarea allocation in net pounds that is projected to be unused after accounting for state management objectives, NMFS may take inseason action to reallocate the amount of net pounds available equally to the other two states. If a state eligible to receive the additional pounds declines all or part of the additional pounds, or NMFS determines a state is unlikely to use additional allocation, a portion or the full amount of the remainder would go to the other state.

(ii) Inseason management provisions include, but are not limited to, the following:

* * * * *

(E) Modification of state recreational allocation, including a shift in recreational allocation from one state to another;

(F) Modification of subarea allocation; and

(G) Modification of the Stonewall Bank Yelloweye Rockfish Conservation Area (YRCA) restrictions off Oregon using YRCA expansions as defined in groundfish regulations at 50 CFR 660.70(g) or (h).

* * * * *

[FR Doc. 2024–07015 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 65
Wednesday, April 3, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 54, and 301

RIN 1545–BQ98

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2510, 2520, and 2550

RIN 1210–AC09

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4000, 4007, 4010, 4041, 4041A, 4043, 4050, 4062, 4063, 4204, 4211, 4219, 4231, 4245, 4262, and 4281

RIN 1212–AB58

Request for Information—SECURE 2.0 Section 319—Effectiveness of Reporting and Disclosure Requirements

AGENCY: Internal Revenue Service, U.S. Department of the Treasury. Employee Benefits Security Administration, U.S. Department of Labor. Pension Benefit Guaranty Corporation.

ACTION: Request for information; extension of comment period.

SUMMARY: This document extends the comment period for the request for information entitled ''SECURE 2.0 Section 319—Effectiveness of Reporting and Disclosure Requirements'' that was published in the January 23, 2024, issue of the **Federal Register**. The comment period for the request for information, which had been scheduled to close on April 22, 2024, is extended 30 days to May 22, 2024.

DATES: The comment period for the request for information published January 23, 2024, at 89 FR 4215, is extended. To be assured consideration, comments must be received at one of the addresses provided below no later than May 22, 2024.

ADDRESSES: Written comments, identified by RIN 1210–AC09, may be submitted to one of the addresses specified below. Any comment that is submitted will be shared with the Department of the Treasury, the Internal Revenue Service (IRS), and the Pension Benefit Guaranty Corporation (PBGC). Please do not submit duplicates.

- *Federal eRulemaking Portal: www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Please address to ''Attention: Comment Extension; Request for Information—SECURE 2.0 Section 319—Effectiveness of Reporting and Disclosure Requirements.'' Office of Regulations and Interpretations, Employee Benefits Security Administration, U.S. Department of Labor, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: Persons submitting comments electronically are encouraged not to submit paper copies. Comments will be available to the public, without charge, at *www.regulations.gov,* on the Department of Labor's website at *www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments,* and at the Public Disclosure Room, EBSA, U.S. Department of Labor, Suite N–1515, 200 Constitution Avenue NW, Washington, DC 20210. Comments may also be accessed from PBGC's website at *www.pbgc.gov*.

Warning: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records and can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: Kristen Zarenko, Office of Regulations and Interpretations, EBSA, Labor Department, (202) 693–8500. Jamie Dvoretzky, Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes (CC:EEE)), IRS, Treasury Department, at (202) 317–4102. David Simonetti, Legal Policy Division, Office of the General Counsel, PBGC, (202) 229–4362.

SUPPLEMENTARY INFORMATION: In the request for information (RFI), entitled ''Request for Information—SECURE 2.0 Section 319—Effectiveness of Reporting and Disclosure Requirements,'' released by the Department of Labor (Labor Department), Department of the Treasury (Treasury Department), and Pension Benefit Guaranty Corporation (PBGC) (collectively, the Agencies), the Agencies requested commenters' input in response to a series of 24 questions relevant to section 319 of the SECURE 2.0 Act of 2022 (SECURE 2.0).[1] Specifically, SECURE 2.0 section 319 includes a wide-ranging directive to the Agencies to review each Agency's existing reporting and disclosure requirements under the Internal Revenue Code (Code) and the Employee Retirement Income Security Act (ERISA) for retirement plans. The Agencies are directed to then report to Congress on the effectiveness of these reporting and disclosure requirements, including recommendations to consolidate, simplify, standardize, and improve such requirements. The comment period for the RFI is scheduled to close on April 22, 2024.

Since the publication of the RFI in the **Federal Register**, interested parties have expressed concern with their ability to respond fully to the RFI by April 22, given the breadth of the topics and the significant number of questions raised in the RFI. These parties observe that significant work must be done to consider these topics adequately, including the collection and coordination of relevant data and information, research of the considerable laws, regulations, and other guidance implicated by the questions in the RFI, and preparation of meaningful responses to the Agencies' questions. The Agencies value robust public feedback as part of their mandated review of the effectiveness of Code and ERISA reporting and disclosure requirements. This feedback will be an integral resource for the Agencies in preparing the report to Congress, no later than December 29, 2025, as required by section 319 of SECURE 2.0. In response to these requests, the Agencies are extending the period for submitting comments on the RFI by an additional 30 days. To be assured consideration, comments on the RFI must be received no later than May 22, 2024.

[1] The SECURE 2.0 Act of 2022, Division T of the Consolidated Appropriations Act, 2023, Public Law 117–328, 136 Stat. 4459 (2022).

Signed at Washington, DC.

Rachel D. Levy,

Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), Internal Revenue Service, Department of the Treasury.

Helen H. Morrison,

Benefits Tax Counsel, Department of the Treasury.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Gordon Hartogensis,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. 2024–07018 Filed 4–2–24; 8:45 am]

BILLING CODE 4510–29–P; 4830–01–P; 7709–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2024–0085; FRL–5398–05–OCSPP]

RIN 2070–AJ64

Lead Wheel Weights; Regulatory Investigation Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is requesting comments and information to assist in the potential development of regulations for the manufacture (including importing), processing (including recycling), and distribution in commerce of lead for wheel-balancing weights (''lead wheel weights'') under the Toxic Substances Control Act (TSCA). To inform this consideration, EPA is requesting comment and information from all stakeholders on the use and exposure to lead from the manufacture (including importing), processing (including recycling), distribution in commerce, use, and disposal of lead wheel weights, as well as information on their substitutes, to help determine if there is unreasonable risk to human health and the environment associated with this use. This action is relevant to a petition for a writ of mandamus filed in August 2023, by the Ecology Center, Center for Environmental Health, United Parents Against Lead & Other Environmental Hazards, and Sierra Club in the United States Court of Appeals for the Ninth Circuit requesting the court to direct EPA to conduct a rulemaking regulating lead wheel weights under TSCA.

DATES: Comments must be received on or before May 3, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2024–0085, through *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/* dockets.

FOR FURTHER INFORMATION CONTACT:

Technical information contact: Sofie Sonner, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 565–2414; email address: *sonner.sofie@epa.gov.*

General information contact: The TSCA Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process (including recycling), distribute in commerce, dispose of, or use lead wheel weights, or their substitutes. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Lead Ore and Zinc Ore Mining (NAICS code 212231);
- Primary Smelting and Refining of Nonferrous Metal (except Copper and Aluminum) (NAICS code 331419);
- Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum) (NAICS code 331492);
- Lead die-castings, unfinished, manufacturing (NAICS code 331523);
- Automobile Manufacturing (NAICS code 336111);
- Light Truck and Utility Vehicle Manufacturing (NAICS code 336112);
- Heavy Duty Truck Manufacturing (NAICS code 336120);
- All Other Motor Vehicles Parts Manufacturing (NAICS code 336399);
- Motorcycle, Bicycle, and Parts Manufacturing (NAICS code 336991);
- Automobile and Other Motor Vehicle Merchant Wholesalers (NAICS code 423110);
- Motor Vehicle Supplies and New Parts Merchant Wholesalers (NAICS code 423120);
- Tire and Tube Merchant Wholesalers (NAICS code 423130);
- Motor Vehicle Parts (Used) Merchant Wholesalers (NAICS code 423140);
- New Car Dealers (NAICS code 441110);
- Used Car Dealers (NAICS code 441120);
- Recreational Vehicle Dealers (NAICS code 441210);
- Motorcycle, Boat, and Other Motor Vehicle Dealers (NAICS code 441220);
- Automotive Parts and Accessories Stores (NAICS code 441310);
- Tire Dealers (NAICS code 441320);
- General Automotive Repair (NAICS code 811111);
- Other Automotive Mechanical and Electrical Repair and Maintenance (NAICS code 811118);
- Automotive Oil Change and Lubrication Shops (NAICS code 811191); and
- All Other Automotive Repair and Maintenance (NAICS code 811198).

If you have any questions regarding the applicability of this action, please consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT.**

B. What is the Agency's authority for taking this action?

This action is being taken under the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

TSCA section 21 allows citizens to petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8 or an order under TSCA sections 4 or 5(e) through (f). If EPA grants such a petition, the Agency must promptly commence an appropriate proceeding.

Under TSCA section 6(a), if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance presents an unreasonable risk to human health or the environment, it must ''apply one or more of the [TSCA section 6(a)] requirements . . . to the extent necessary so that the chemical substance . . . no longer presents such risk,'' which may range from prohibiting or otherwise restricting the manufacturing, processing, or

distribution in commerce of the chemical substance (or a particular use), to commercial use requirements or disposal restrictions, to labeling and recordkeeping.

C. What action is the Agency taking?

Through this ANPRM, EPA is seeking comment and information on specific issues regarding potential exposure to lead during manufacturing, processing (including recycling), distribution in commerce, use, or disposal of lead wheel weights, as well as information on substitutes for lead wheel weights. This information will help inform the Agency's determinations regarding potential unreasonable risk to human health and the environment from exposure to lead wheel weights. If unreasonable risk is determined, EPA will initiate a proposed rulemaking under TSCA section 6(a) to address the unreasonable risk.

D. What are the incremental costs and benefits of this action?

This action does not impose or propose any requirements, and instead seeks comments and suggestions that will help the Agency identify whether and to what extent there is a potential need for a TSCA section 6 rule and/or other administrative action. If EPA decides to propose a rule, it will conduct the appropriate assessments of the costs and benefits of those changes and provide opportunities for public comment.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR parts 2 and 703.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.html.*

II. Background

A. 2009 TSCA Section 21 Petition

In May 2009, Sierra Club, Ecology Center, and several other non-governmental organizations submitted a TSCA section 21 petition requesting EPA ''to establish regulations prohibiting the manufacture, processing, and distribution in commerce of lead wheel balancing weights ('wheel weights')'' (Ref. 1). Petitioners raised concerns that lead wheel weights result in pervasive lead exposure to children. EPA acknowledged receipt and requested public comment on the petition on July 15, 2009 (74 FR 34342 (FRL–8424–7)). EPA granted the petition on August 26, 2009 (Ref. 2). EPA has not issued any regulatory action relating to this petition since granting the petition.

B. 2023 Writ of Mandamus

In August 2023, Ecology Center, Center for Environmental Health, United Parents Against Lead & Other Environmental Hazards, and Sierra Club sought a writ of mandamus in the United States Court of Appeals for the Ninth Circuit and asked the court to direct EPA to conduct a rulemaking regulating lead wheel weights under TSCA section 6.

C. What are lead wheel weights?

Wheel weights are small pieces of metal or other material used to correct imbalances in the weight distribution of motor vehicle tires. Lead has historically been a primary component of many wheel weights because of its malleability, high density, and relatively low cost. These wheel weights can separate from the wheel due to failure of the adhesive or clip attaching them, or due to impact of the wheel with a pothole or road debris or during a crash, or due to other chronic and acute strains. Lead wheel weights that separate from vehicle wheels, or are not properly disposed of, may be a source of lead exposure to humans and the environment under various circumstances (Ref. 3), for example by being ground into fine particles by traffic. Additionally, there may be lead exposures associated with manufacturing, processing, distribution, recycling, or disposal of lead wheel weights.

III. Request for Comment and Information

EPA is providing this opportunity for the public to comment on or provide any additional information relevant to the use of and exposure to lead from the manufacture (including importing), processing (including recycling), distribution in commerce, use, and disposal of lead wheel weights. In order for the Agency to consider such comments, EPA must receive the comments by the date indicated under **DATES**. In particular, EPA seeks information on the following:

1. Quantitative information, data and/or case examples (*e.g.,* recent scientific and technical studies, including datasets, analyses of environmental impacts, and statistical analyses) associated with lead releases to air, surface water, ground water, soil, dust, and any other environmental medium (particularly regarding releases within one mile of roadways, communities near industrial sites, and releases to sensitive human and ecological populations) from the manufacture, processing (including recycling), distribution in commerce, use, or disposal of lead wheel weights.

2. Quantitative information, data and/or case examples (*e.g.,* recent scientific and technical studies, including datasets, analyses of environmental impacts, and statistical analyses) associated with plastic or metal releases to air, surface water, ground water, soil, dust, and any other environmental medium (particularly regarding releases within one mile of roadways, communities near industrial sites, and releases to sensitive human and ecological populations) from the manufacture, processing (including recycling), or distribution, of lead wheel weight alternatives including: steel wheel weights; zinc alloy wheel weights; plastic metal composite wheel weights; mercury wheel balancing weights; and tin wheel weights.

3. Quantitative information on the relative and absolute bioavailability of lead from new and/or weatherized lead wheel weights.

4. Information on potential human and ecological exposure routes associated with lead releases from the manufacture (including importing), processing (including recycling), disposal and distribution in commerce of lead wheel weights, including residential exposures associated with take-home of lead from occupational sites by workers who manufacture, process, or dispose of lead wheel weights.

5. Information on the current availability and suitability of lead-free wheel weights as alternatives, in both original equipment and aftermarket settings, particularly any comparisons between lead-free and lead wheel weights in terms of price, ease of installation, durability, and other attributes of performance and suitability.

6. Information on the comparative lead weight by product and use rate of lead and lead-free wheel weights, both in original equipment and aftermarket settings over time, and information on the comparative use rate of clip-on versus adhesive wheel weights.

7. Information on the chemical composition of lead and lead-free wheel weights including percentages of lead

and other constituents by weight, such as zinc and mercury.

8. Quantitative information and data about the volume of lead wheel weights imported to the United States relative to lead wheel weights manufactured domestically.

9. Quantitative information and data (*e.g.,* recent scientific and technical studies, including statistical analyses) on the loss or failure rate of lead, non-lead, clip-on, and adhesive wheel weights (*i.e.,* the rate at which wheel weights fall off of vehicle wheels onto roadways).

10. Quantitative information and data (*e.g.,* recent scientific and technical studies, including statistical analyses) on the abrasion or decomposition rate of both clip-on and adhesive lead wheel weights on roadways, including the rate at which abraded lead dust may migrate to other media including road dust, soil, and air. Additionally, data on other mechanisms for removal of wheel weights from roadways including the rate of wash-out by rainfall, removal by street sweeping, ejection from the roadway by vehicle impact, *etc.*

11. Quantitative information and data (*e.g.,* recent scientific and technical studies, including statistical analyses) on the geographical distribution of dislodged lead wheel weights in terms of proximity to population centers (*e.g.,* differences between urban and non-urban environments) along with information on possible ingestion of lead wheel weights by children living in these urban centers.

12. Quantitative information and data (*e.g.,* recent scientific and technical studies, including statistical analyses) relating to occupational hazards and exposure associated with the manufacture(including importing), processing (including recycling), and distribution in commerce of lead wheel weights including workplace lead exposure from air/inhalation, dust ingestion, dermal contact, potential take-home exposures and blood lead levels of workers exposed to lead wheel weights, such as workers at entities outlined above, as well as transportation construction, management, or maintenance workers (*e.g.,* street cleaning, road repair, and auto repair), including those in auto shops that install and remove lead wheel weights.

13. Information and data (*e.g.,* recent scientific and technical studies, including statistical analyses) related to hazards and exposures associated with the collection of and repurposing of lead wheel weights by home hobbyists, including information related to practices for at-home melting and lead recasting activities (*e.g.,* frequency, duration, quantity of lead melted and recast, temperatures used, sociodemographic characteristics of the subpopulations engaged in these practices, as well as the form in which the weights are repurposed), data on impacts to children's health, and associated contamination of air, dust, soil, and other environmental media, as well as contamination on surfaces (*e.g.,* clothes and furniture).

IV. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these references and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the reference is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

1. Ecology Center. TSCA Section 21 Petition Requesting EPA to Establish Regulations Prohibiting the Manufacture, Processing, and Distribution in Commerce of Lead Wheel Balancing Weights. May 28, 2009. *https://www.epa.gov/sites/default/files/2015-10/documents/petition4.pdf.*

2. EPA. EPA Response to TSCA Section 21 Petition. August 26, 2009. *https://www.epa.gov/sites/default/files/2015-10/documents/document.pdf.*

3. California Environmental Protection Agency Department of Toxic Substances Control. Wheel Weight Alternatives Assessment. November 2011. *https://dtsc.ca.gov/wp-content/uploads/sites/31/2017/05/AAWheelWeights.pdf.*

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/regulations/and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to a requirement for Executive Order 12866 review.

B. Other Regulatory Assessment Requirements

Because this action does not impose or propose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various other review requirements in statutes and Executive Orders that apply when an agency imposes requirements do not apply to this ANPRM. Should EPA subsequently determine to pursue a rulemaking, EPA will address the requirements in the statutes and Executive Orders as applicable to that rulemaking.

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Reporting and recordkeeping.

Michael S. Regan,

Administrator.

[FR Doc. 2024–06804 Filed 4–2–24; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 89, No. 65
Wednesday, April 3, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by May 3, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 0583–0151.

Summary of Collection: Food Safety and Inspection Service has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and correctly labeled and packaged. Under Executive Order (E.O.) 12862 Setting Customer Service Standards. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Need and Use of the Information: Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Description of Respondents: Business-for-not for-profit; Farms; State, Local or Tribal Government.

Number of Respondents: 4,000.

Frequency of Responses: Reporting; Other (one-time).

Total Burden Hours: 2,000.

Rachelle Ragland-Greene,

Acting Departmental Information Collection Clearance Officer.

[FR Doc. 2024–07021 Filed 4–2–24; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0016]

Privacy Act of 1974; System of Records

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget Circular No. A–108, the U.S. Department of Agriculture (USDA) gives notice that an agency component, the Animal and Plant Health Inspection Service (APHIS), proposes to modify an existing system of records notice titled, APHIS Animal Health Surveillance and Monitoring System, USDA/APHIS–15. Among other changes, the system will be renamed Animal Health, Disease, and Pest Surveillance and Management System, USDA/APHIS–15. This system is used by APHIS to collect, manage, and evaluate animal health data for

disease and pest control and surveillance programs.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice will become applicable upon publication, subject to a 30-day notice and comment period in which to comment on the routine uses described in the routine uses section of this system of records notice. Please submit any comments by May 3, 2024.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Enter APHIS–2020–0016 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2020–0016, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Any comments we receive on this docket may be viewed at *http://www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact Mr. Chris Quatrano, CFI Director, Center for Informatics, Center for Epidemiology and Animal Health, VS, APHIS, USDA, 2150 Centre Ave., Bldg. B, Fort Collins, CO 80526; *vs.dataservices@usda.gov*. For Privacy Act questions concerning this system of records notice, please contact Director, Freedom of Information and Privacy Act Staff, 4700 River Road Unit 50, Riverdale, MD 20737; (301) 851–4076; email: *APHISPrivacy@usda.gov*. For USDA Privacy Act questions, please contact the USDA Chief Privacy Officer, Information Security Center, Office of Chief Information Officer, USDA, Jamie L. Whitten Building, 1400 Independence Ave. SW, Washington, DC 20250; email: *USDAPrivacy@usda.gov*.

SUPPLEMENTARY INFORMATION: The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is modifying an existing system of records notice for the APHIS Animal Health Surveillance and Monitoring System, USDA/APHIS–15, which was last published on November 28, 2011, in its entirety in the **Federal Register** (76 FR 72897–72900, Docket No. APHIS–2010–0007). APHIS is modifying the system of records notice to rename the system as ''Animal Health, Disease, and Pest Surveillance and Management System, USDA/APHIS–15.'' Also, APHIS is expanding the system to include records of activities maintained in the Comprehensive and Integrated Animal Health Surveillance System (CIAHSS), which consists of multiple information technology platforms that exchanges data and that contains animal health and surveillance data. Expansion of the system also includes any electronic or hard copies of forms or other records used to enter data into CIAHSS or that may be saved in a CIAHSS application.

In addition to the above, APHIS is making the following changes to the system of records:

- Updating the system location and system manager;
- Updating the authority for maintenance of the system to remove reference to the Bovine Johne's Disease Control Program (7 U.S.C. 7629), which was repealed on February 7, 2014, and add references to the Farm Security and Rural Investment Act of 2002, 7 U.S.C. 7901 *et seq.,* the Homeland Security Presidential Directives 7 and 9, and Farm Bills (The Farm Bill is an omnibus, multiyear law that governs an array of agricultural and food programs. Titles in a recent farm bill encompassed farm commodity revenue supports, agricultural conservation, trade and foreign food assistance, farm credit, research, rural development, forestry, bioenergy, horticulture, and domestic nutrition assistance. Typically renewed about every 5 or 6 years by Congress, the Farm Bill provides a predictable opportunity for policymakers to comprehensively and periodically address agricultural and food issues);
- Updating the purpose of the system to further explain the purpose of the system and the use of the information collected by the system;
- Expanding the categories of individuals to include additional individuals who participate in animal disease or pest prevention, surveillance, management, and animal disease emergency activities, and those who are mentioned or referenced in any documents entered into USDA/APHIS–15 by a user (such as, vendors, industry, agents, other business personnel, etc.);
- Expanding the categories of records to include additional records relating to animal disease or pest prevention, surveillance, management, and animal disease emergency activities;
- Revising the record source categories to more accurately identify the sources of information maintained in the system;
- Updating the policies and practices for storage, retrievability, and retention and disposal of records in the system;
- Updating the system safeguards;
- Updating the notification, record access, and contesting record procedures; and
- Providing an updated full list of routine uses in the routine uses section of the document published with this notice.

SYSTEM NAME AND NUMBER:

Animal Health, Disease, and Pest Surveillance and Management System, USDA/APHIS–15.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Paper files are held at the Animal and Plant Health Inspection Service's (APHIS) Veterinary Services (VS) national, district, field offices, and laboratories. Electronic files are stored and maintained electronically on secure U.S. Department of Agriculture (USDA)-owned and operated servers located at 4700 River Road, Riverdale, MD 20737; 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; and 2150 Centre Ave., Bldg. B, Fort Collins, CO 80526. Files are also kept on the originator's computer. In some cases, copies may be stored as part of an email on USDA email servers and in the email archive. The applications/systems are housed within Microsoft Azure Cloud, and personally identifiable information data is shared with Amazon Web Services via interconnection with the VS Data Integration Services (VS DIS) system.

SYSTEM MANAGER(S):

For National Animal Health Reporting System and Laboratory Messaging Service: National Animal Health Laboratory Network Coordinator, Diagnostics and Biologics, VS, APHIS, USDA, 2150 Centre Ave., Bldg. B, MSC 3E13, Fort Collins, CO 80526–8117.

For Veterinary Services Laboratory Submission Service, Surveillance Collaborative Services (includes Mobile Information Management, Mi-Corporation, and National Animal Health Reporting), VS Integration Surveillance Modules and the CS Analytics Warehouse component, VS DIS, Data Integration and Reporting Software, other related systems, and paper and electronic records not in application databases: Director, Center for Informatics, VS, APHIS, USDA, 2150

Centre Ave., Bldg. B, MSC 3E13, Fort Collins, CO 80526–8117.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

- The Animal Damage Control Act of 1931, 7 U.S.C. 8351 *et seq.*;
- The Animal Health Protection Act, 7 U.S.C. 8301–8317;
- The Farm Security and Rural Investment Act of 2002, 7 U.S.C. 7901 *et seq.*;
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 116 Stat. 674–678;
- Homeland Security Presidential Directive 7: Critical Infrastructure Identification, Prioritization, and Protection;
- Homeland Security Presidential Directive 9: Defense of United States Agriculture and Food; and
- Farm Bills, as required, (The Farm Bill is an omnibus, multiyear law that governs an array of agricultural and food programs. Titles in a recent farm bill encompassed farm commodity revenue supports, agricultural conservation, trade and foreign food assistance, farm credit, research, rural development, forestry, bioenergy, horticulture, and domestic nutrition assistance. Typically renewed about every 5 or 6 years by Congress, the Farm Bill provides a predictable opportunity for policymakers to comprehensively and periodically address agricultural and food issues).

PURPOSE(S) OF THE SYSTEM:

The Animal Health, Disease, and Pest Surveillance and Management System supports VS' mission of protecting and improving the health, quality, and marketability of animals within the United States and response to animal health emergencies. The information is collected and stored to support animal health, disease, and pest surveillance and management activities that VS administers in cooperation with the States and Tribes. VS and its State and Tribal partners (or their cooperators and contractors) enter and maintain the data in the system to effectively manage animal health programs and disease and pest surveillance programs. This system allows for monitoring, early detection, and response to domestic, emerging, and foreign animal diseases or pests of concern such as viral hemorrhagic septicemia, brucellosis, tuberculosis, chronic wasting disease, pseudorabies, scrapie, bovine spongiform encephalopathy, classical swine fever, cattle fever ticks, screwworms, avian influenza, etc.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered in this system include individuals identified as animal premises owners or managers, livestock haulers, individuals involved in animal production, movement, marketing, rendering, slaughter, product processing or points of contact for these categories, and all other individuals that are covered by the regulated activity of APHIS animal health or disease or pest surveillance, monitoring, or control program; collectors or submitters of samples for testing; USDA and State/Tribal animal health employees and their contractors or cooperators with signed agreements; Federal, State/Tribal, and local public health employees and their contractors or cooperators with signed agreements working with USDA on zoonotic disease activities; Federal, State/Tribal, and local wildlife agency employees and their contractors or cooperators with signed agreements working with USDA on diseases affecting both wild and domestic animals; and accredited and other veterinarians and their employees working with USDA or covered entities or animals. In addition, individuals, even if they are not users of the Animal Health, Disease, and Pest Surveillance and Management System, who are mentioned or referenced in any documents entered into USDA/APHIS–15 by a user are also covered. This group may include vendors, industry, agents, and other business personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records include:

Contact information: This is information that may be used to contact individuals for official purposes such as disease investigation or follow up. Contact information may include, names, phone numbers, physical addresses, mailing addresses, or electronic mail addresses. Individuals' information may also include their roles such as owners, managers, employees, or representatives of animals, animal premises, and animal related businesses; veterinarians; contractors and cooperators; and local, State, Tribal, or Federal officials, including APHIS officials.

Animal or herd health status: Historical or current information relating to the exposure, infection, or infestation status of an animal or group of animals. These records may include observations for presence or absence of clinical signs; laboratory test orders and results; disease or pest elimination or treatment plans; vaccination plans; and records of participation in and compliance with a disease or pest management, health management, or certification program and associated activities. These records may also include information about the pathogens or pests identified, such as antibiotic resistance or pathogen or pest genetic data.

Animal, herd or operation characteristics: Information about animal or herd characteristics and management practices, which may be associated with different disease spread risks. This may include the type of business operation, species, breeds, classes, and ages of animals, intended uses, and animal inventories or estimated or observed numbers of animals present. This also includes activities such as livestock shipping or other animal relocations.

Dates and times: Specific dates or date ranges or times of activities, events or planned events, such as, specimen collection and testing, observations of clinical signs or environmental conditions, vaccination, treatment, inspections or other visits, animal or specimen shipments, start and end dates of program participation, or dates and times when changes were made in animal or herd health status.

Identifiers: Codes, numbers, or descriptions used to connect data about entities such as, animals, groups of animals, premises, biological specimens, or test results. Identifiers can include flock or premises identification numbers; animal identification numbers such as ear tag or other identification device numbers, implant or tattoo numbers, brands, animal group or lot numbers; accredited veterinarian numbers; veterinary license numbers; and specimen numbers.

Location: Information about where an activity or event took place, or where a premises or animal is or was. This may include a physical address, geographic coordinates, county, State, ZIP Code, plat map references, or distances from other premises or landmarks.

Operational records: These records include animal health activities that include State, Tribal, or Federal visits, inspections, vaccination, treatments, application of official identification and testing performed by VS employees, State animal health employees, contractors, cooperators, or veterinarians. This information can also include personnel and other resources involved, and numbers and types of samples collected.

Miscellaneous: This information may include narrative reports, such as epidemiological reports or herd histories and disease elimination or management plans for specific herds or premises.

RECORD SOURCE CATEGORIES:

Sources of information for this system include USDA and State/Tribal animal health employees and their contractors or cooperators with signed agreements; Federal, State/Tribal, and local public health employees and their contractors or cooperators with signed agreements working with USDA on zoonotic disease activities. Federal, State/Tribal, and local wildlife agency employees and their contractors or cooperators with signed agreements working with USDA on diseases affecting both wild and domestic animals; individuals identified as owners, managers, or contacts for premises (locations), groups of animals or individual animals, or animal-related businesses or operations involved with or covered by an APHIS animal health or disease or pest surveillance, monitoring, or control program; collectors or submitters of samples for testing; and accredited and other veterinarians and their employees working with covered entities or animals or with USDA.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, records contained in this system may be disclosed outside USDA as a routine use under 5 U.S.C. 552a(b)(3) to the extent that such uses are compatible with the purposes for which the information was collected. Such permitted routine uses include the following:

(1) To State/Tribal animal health officials and their contractors and other cooperators authorized access by State/Tribal animal health officials, data from their State/Tribe as co-owners of the data to: (a) Collaborate with USDA in conducting, managing, and evaluating animal health, disease, or pest surveillance or control programs, and monitoring for animal health, diseases or pests; (b) aid in containing and responding to a foreign or domestic animal disease or pest outbreak, bioterrorism, or other animal health emergency; (c) disseminate information and solicit feedback on emergency preparedness and response guidelines and the system itself for the purpose of educating and involving these officials in program development, program requirements, and standards of conduct; and (d) States/Tribes may share their information on premises, persons, or animals within their State or Tribe in accordance with State or Tribal laws and regulations via public websites or other means;

(2) To Federal, State/Tribal, or local wildlife agencies to collaborate with USDA in conducting, managing, or evaluating animal health, disease or pest surveillance or control programs, and monitoring for animal health issues, diseases, or pests affecting both wildlife and domestic animals or respond to emergencies impacting wildlife and domestic animals;

(3) To Federal, State/Tribal, or local government agencies involved with public health such as the Departments of Health and Human Services and Homeland Security (DHS) for the purposes of collaborating with USDA to conduct, manage, or evaluate zoonotic disease or pest awareness, surveillance, response or reporting activities, or to respond to emergencies impacting humans and domestic animals;

(4) To any agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function;

(5) To contractors and cooperators and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the USDA, when necessary to accomplish an agency function related to this system of records;

(6) To the public through USDA websites: (a) Lists of participants in voluntary animal disease certification or quality assurance programs; (b) lists of individuals or entities not in compliance with animal disease regulations to reduce the potential risk of animal disease spread; and (c) list the herds of origin of exposed or potentially exposed animals when needed to notify individuals who may have acquired exposed or potentially exposed animals when other means of contact are unavailable;

(7) To other individuals when needed to aid in containing or responding to a foreign or domestic animal disease or pest outbreak, bioterrorism, or other animal health emergency;

(8) When a record on its face, or in conjunction with other records indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program, statute, or by regulation, rule, or order issued pursuant thereto, USDA may disclose the record to the appropriate agency, whether Federal, foreign, State, Tribal, local, or other public authority responsible for enforcing, investigating, or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity;

(9) To the Department of Justice when: (a) USDA or any component thereof; or (b) any employee of USDA in his or her individual capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and USDA determines that the records are relevant and necessary to the litigation and the use of such records by the Department of Justice is deemed by USDA to be for a purpose that is compatible with the purpose for which USDA collected the records;

(10) In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when USDA or other Agency representing USDA determines that the records are both relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding;

(11) To appropriate agencies, entities, and persons when: (a) USDA suspects or has confirmed that there has been a breach of the system of records; (b) USDA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USDA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with USDA's efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm;

(12) To another Federal agency or Federal entity, when information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(13) To a Congressional office in response to an inquiry from that Congressional office made at the written request of the individual about whom the records pertain;

(14) To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for USDA, when necessary to accomplish an agency function related to this system of records. Individuals providing information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to USDA officers and employees; and

(15) To the National Archives and Records Administration (NARA) or other Federal Government agencies pursuant to records management activities being conducted under 44 U.S.C. 2904 and 2906.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Server hard drives are backed up nightly. The Digital Infrastructure Services Center retains incremental and full system tape backups for 1 month. Backup media is regularly sent to an offsite backup storage facility for contingency purposes. The hard copy components of the system, including any paper records, and computer files, tapes, and disks are kept in a safeguarded environment with access only by authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records can be retrieved by any recorded data field. However, records are mainly retrieved by the first and last name, address, or phone number of the listed contact person for, or the owner or manager of, the premises or animals subject to animal disease control or surveillance programs, animal, flock, herd, sample, or premises numbers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records will be retained permanently pending approval of a records retention schedule by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The system is physically secured in a locked facility accessible only to authorized USDA personnel. Badges are required. Visitors must be accompanied by authorized staff at all times. Data is stored and backed up using protocols established by Digital Infrastructure Service Center (DISC). Access to the records in this system is limited to those individuals who need to know the information to perform their official duties and who have appropriate clearances or permissions. Users must have USDA eAuthentication credentials and sign in using authorized logins and passwords. Annually, all users must undergo information security training and sign rules of behavior. The Information Technology staff must additionally complete specialized role-based training and sign rules of behavior to ensure privacy integrity. Failure to comply with rules of behavior can result in corrective actions, including written reprimands, temporary suspension from duty, reassignment, demotion, or termination, suspension of system privileges, and possible criminal prosecution. The system administrators maintain and monitor audit trails.

The hard copy components of the system, and computer files, tapes, and disks are kept in a safeguarded environment with access only by authorized personnel.

RECORD ACCESS PROCEDURES:

All requests for access to records must be in writing and should be submitted to the APHIS Privacy Act Officer, 4700 River Road Unit 50, Riverdale, MD 20737; or by facsimile (301) 734–5941; or by email *APHISPrivacy@usda.gov*. In accordance with 7 CFR 1.112 (Procedures for requests pertaining to individual records in a record system), the request must include the full name of the individual making the request; the name of the system of records; and preference of inspection, in person or by mail. In accordance with 7 CFR 1.113, prior to inspection of the records, the requester shall present sufficient identification (*e.g.,* driver's license, employee identification card, credit cards) to establish that the requester is the individual to whom the records pertain. In addition, if an individual submitting a request for access wishes to be supplied with copies of the records by mail, the requester must include with his or her request sufficient data for the agency to verify the requester's identity.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records maintained in this system of records must direct their request to the address indicated in the ''RECORD ACCESS PROCEDURES'' paragraph, above and must follow the procedures set forth in 7 CFR 1.116 (Request for correction or amendment to record). All requests must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

NOTIFICATION PROCEDURES:

Individuals may be notified if a record in this system of records pertains to them when the individuals request information utilizing the same procedures as those identified in the ''RECORD ACCESS PROCEDURES'' paragraph above.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HISTORY:

On November 28, 2011 (76 FR 72897, APHIS–2010–0007), USDA/APHIS–15, ''APHIS Animal Health Surveillance and Monitoring System,'' was published as a new system of records and effective on January 9, 2012.

A report on the modified system of records, required by 5 U.S.C. 552a(r), as implemented by Office of Management and Budget Circular A–108, was sent to the Chairman and Ranking Members of the Senate Committee on Homeland Security and Governmental Affairs, the Chairwoman and Ranking Members of the House Committee on Oversight and Government Reform, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.

Done in Washington, DC, this 27th day of March 2024.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2024–06941 Filed 4–2–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #: RBS–24–CO–OP–0002]

Notice of Funding Opportunity for the Socially Disadvantaged Groups Grant for Fiscal Year 2024

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces that the Rural Business-Cooperative Service (RBCS or the Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA), invites applications for grants under the Socially Disadvantaged Groups Grant (SDGG) program for Fiscal Year (FY) 2024. This notice is being issued to allow applicants sufficient time to leverage financing, prepare and submit their applications, and give the Agency time to process applications within FY 2024. A total of $3,000,000 in grant funding will be available for FY

2024. Successful applications will be selected by the Agency for funding and subsequently awarded to the extent that funding may ultimately be made available through appropriations. All applicants are responsible for any expenses incurred in developing and submitting their applications.

DATES: Complete applications for grants must be submitted electronically by 11:59 p.m. Eastern Time (ET) on June 3, 2024, through *www.grants.gov* to be eligible for grant funding. Applications received after the deadline are not eligible for funding under this notice and will not be evaluated. Applicants are advised to not wait until the application deadline date to begin the application process through *Grants.gov*.

ADDRESSES: Applicants are encouraged to contact the USDA RD State Office prior to May 3, 2024 to discuss the project and ask any questions about the application process. Contact information for USDA RD State Offices can be found at *www.rd.usda.gov/contact-us/state-offices.*

Program guidance as well as application templates may be obtained at *www.rd.usda.gov/programs-services/socially-disadvantaged-groups-grant* or by contacting the USDA RD State Office. To submit an electronic application, follow the instructions for the SDGG funding announcement located at *www.grants.gov.* Applicants are strongly encouraged to file applications early to allow sufficient time to manage any technical issues.

FOR FURTHER INFORMATION CONTACT: Arti Kshirsagar at *arti.kshirsagar@usda.gov,* Program Management Division, RBCS, USDA, 1400 Independence Avenue SW, Mail Stop 3226, Washington, DC 20250–3226 or call (202) 720–1400.

SUPPLEMENTARY INFORMATION:

Overview

Federal Awarding Agency Name: Rural Business-Cooperative Service.

Funding Opportunity Title: Socially Disadvantaged Groups Grant.

Announcement Type: Notice of Funding Opportunity.

Funding Opportunity Number: RBCS–SDGG–22024.

Assistance Listing Number: 10.871.

Dates: Complete applications for grants must be submitted electronically no later than 11:59 p.m. ET on June 3, 2024, through *www.grants.gov* to be eligible for grant funding. Applications received after the deadline are not eligible for funding under this notice and will not be evaluated.

Rural Development Key Priorities. The Agency encourages applicants to consider projects that will advance the following key priorities (more details available at *www.rd.usda.gov/priority-points*):

- Addressing Climate Change and Environmental Justice; Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.
- Advancing Racial Justice, Place-Based Equity, and Opportunity; Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects.
- Creating More and Better Market Opportunities; Assisting rural communities recover economically through more and better market opportunities and through improved infrastructure.

A. Program Description

1. *Purpose of the Program.* The primary objective of the SDGG program is to provide technical assistance for cooperative development to socially disadvantaged groups through cooperatives and cooperative development centers. Grants must be used to provide technical assistance to socially disadvantaged groups in rural areas. Eligible applicants are cooperative development centers, individual cooperatives, or groups of cooperatives (i) that serve socially disadvantaged groups and (ii) of which a majority (*i.e.,* greater than 50 percent rounded to the nearest tenth) of the board of directors or governing board is comprised of individuals who are members of socially disadvantaged groups.

2. *Statutory and Regulatory Authority.* The SDGG program is authorized by the Consolidated Farm and Rural Development Act (7 U.S.C. 1932(e)(11)).

Section 736 of Division B of the Consolidated Appropriations Act, 2024, Public Law 118–42 (the ''2024 Appropriations Act''), designates funding for projects in persistent poverty counties. Persistent poverty counties as defined in Section 736 is ''any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial censuses, and 2007–2011 American Community Survey 5-year average, or any territory or possession of the United States''. Another provision in Section 736 expands the eligible population in persistent poverty counties to include any county seat of such a persistent poverty county that has a population that does not exceed the authorized population limit by more than 10 percent. This provision expands the current 50,000 population limit to 55,000 for county seats located in persistent poverty counties. Therefore, applicants and/or beneficiaries of technical assistance services located in persistent poverty county seats with populations up to 55,000 are eligible.

3. *Definitions.* The following are the definitions for terms used in this notice. Additional terms used in this notice are found in the applicable laws and regulations, in particular 2 CFR part 200 and 7 CFR part 11. The first letter of each word in a defined term is capitalized throughout this notice for easy identification.

Agency. RBCS, an agency of the USDA RD or a successor agency.

Board of Directors/Governing Board—The group of individuals that govern, manage or direct a cooperative development center, cooperative, or group of cooperatives.

Conflict of Interest. A Conflict of Interest occurs in a situation in which a person or entity has a competing, or the appearance of a competing, personal, professional, or financial interests that makes it difficult for the person or entity to act impartially. No Conflict of Interest or appearance thereof will be allowed.

For purposes of this program, contractual relationship/payment from grant funds among the following individuals constitute a Conflict of Interest or appearance of a Conflict of Interest: (1) Applicant Board of Directors, employees, consultants, and contractors, (2) Subrecipients and their employees, consultants, and contractors, and (3) Immediate family members of the above.

Federal procurement standards prohibit transactions that involve a real or apparent Conflict of Interest for owners, employees, officers, agents, or their immediate family members having a financial or other interest in the outcome of the project or that restrict open and free competition for unrestrained trade. Specifically, project funds may not be used for services or goods going to, or coming from, a person or entity with a real or apparent Conflict of Interest, including, but not limited to, owner(s) and their Immediate family members.

Conflicts of Interest must be handled in accordance with 2 CFR parts 200 and 400. The following are examples of Conflicts of Interest and are intended to serve as a nonexclusive list of situations where a real or apparent Conflict of Interest is present: (1) Using grant funds to pay a member on the applicant's Board of Directors to provide proposed technical assistance to socially disadvantaged groups, (2) Applicant paying a member of a cooperative to

provide proposed technical assistance to other members of the same cooperative, or (3) Paying an Immediate family member of the applicant to provide proposed technical assistance to socially disadvantaged groups.

Cooperative. A business or organization owned, democratically governed, controlled and operated by those who use and benefit from it. Profits and losses generated by the organization are distributed in proportion to use as patronage to the user-owners, also known as members. Investment returns to non-members are limited. Eligible Cooperatives for the SDGG program are those where a majority (*i.e.,* greater than 50 percent rounded to the nearest tenth) of the Board of Directors or Governing Board are comprised of individuals who are members of socially disadvantaged groups.

Cooperative Development. A type of technical assistance that establishes and promotes Cooperative businesses through hands-on activities, often but not exclusively, assisting a group through a series of stages. These stages include but are not limited to the following: idea exploration by a group with shared needs, member-use analysis, identifying a steering committee and guiding them through the development process, modeling effective democratic processes and good governance practices, creation of legal and policy documents, conducting a membership drive, raising member equity, acquiring sufficient capital, supporting operations, ongoing education and training, ongoing board development and relations with management, supporting decision-making regarding patronage, and fostering an environment that is supportive of Cooperatives.

Cooperative Development Center—A nonprofit institution or institution of higher education operated by the grantee to start or continue Cooperative Development. An eligible Cooperative Development Center for the SDGG program is one where a majority (*i.e.,* greater than 50% rounded to the nearest tenth) of the Board of Directors or Governing Board is comprised of individuals who are members of socially disadvantaged groups. It may or may not be an independent legal entity separate from the grantee.

Feasibility Study. An analysis of the economic, market, technical, financial, and management feasibility of a proposed project.

Group of Cooperatives. A Group of Cooperatives whose primary focus is to provide assistance to socially disadvantaged groups; each Cooperative must meet the eligibility requirements set forth in the definition of ''Cooperative'' herein. One of the Cooperatives must be designated as the lead entity and have legal authority to contract with the federal government.

Immediate Family(ies). A group of individuals who live in the same household or who are closely related by blood, marriage, or adoption, such as a spouse, domestic partner, parent, child, sibling, aunt, uncle, grandparent, grandchild, niece, nephew, or first cousin.

Key Personnel. Employees, new hires, consultants, and/or contractors of the Cooperative Development Center who provide technical assistance including Cooperative Development.

Nonprofit Institution. Any organization or institution, including an accredited institution of higher education, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

Operating Cost. The day-to-day expenses of running a business; for example: utilities, rent on the office space a business occupies, salaries, depreciation, marketing and advertising, and other basic overhead items.

Participant Support Costs. Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences or training projects.

Persistent Poverty County(ies). Is any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial censuses, and 2007–2011 American Community Survey 5-year average, or any territory or possession of the United States.

Project. Eligible activities to be funded by the SDGG grant.

Rural and Rural Area. As described in 7 U.S.C. 1991(a)(13), any area not in a city or town that has a population of more than 50,000 inhabitants, according to the latest decennial census of the United States, or in any urbanized area (note that the Agency has determined that the reference to ''urbanized area'' should be read as a reference to ''urban area'' because the Census Bureau no longer identifies urbanized areas individually and instead refers to qualifying areas as ''urban areas'') that is contiguous and adjacent to a city or town that has a population of more than 50,000 inhabitants, and any area that has been determined to be ''rural in character'' by the Under Secretary for RD, or as otherwise identified in this definition as follows:

(1) An area that is attached to the urbanized area of a city or town with more than 50,000 inhabitants by a contiguous area of urbanized census blocks that is not more than two (2) census blocks wide. Applicants from such an area should work with their RD State Office to request a determination of whether their Project is located in a Rural Area under this provision.

(2) Any portion of a Census Bureau-defined ''Urban Area'' that is not geographically contiguous and that is also neither adjacent nor contiguous to a city or town that has a population of more than 50,000.

(3) For the purposes of this definition, cities and towns are incorporated population centers with definite boundaries, local self-government, and legal powers set forth in a charter granted by the State.

(4) For the purposes of this definition, populations of individuals incarcerated on a long-term or regional basis shall not be included in determining whether an area is ''rural'' or a ''rural area''.

(5) For the purposes of this definition, the first 1,500 individuals who reside in housing located on a military base shall not be included in determining whether an area is ''rural'' or a ''rural area''.

(6) For the Commonwealth of Puerto Rico, the island is considered Rural and eligible for Business Programs assistance, except for the San Juan Census Designated Place (CDP) and any other CDP with greater than 50,000 inhabitants. CDPs with greater than 50,000 inhabitants, other than the San Juan CDP, may be determined to be eligible if they are ''not urban in character.''

(7) For the State of Hawaii, all areas within the County of Honolulu are considered Rural and eligible for Business Programs assistance, except for the Urban Honolulu CDP (''the East Honolulu CDP'' OR ''other areas deemed to be urban in character'').

(8) For the purpose of defining a Rural Area in the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands, the Agency shall determine what constitutes Rural and Rural Area based on available population data.

(9) The determination that an area is ''rural in character'' will be made by the Under Secretary of RD. The process to request a determination under this provision is outlined in paragraph (6)(ii) of this definition.

(i) The determination that an area is ''rural in character'' under this definition will apply to areas that are within:

(A) An urbanized area that has two points on its boundary that are at least

40 miles apart, which is not contiguous or adjacent to a city or town that has a population of greater than 150,000 inhabitants or the urbanized area of such a city or town; or

(B) An urbanized area contiguous and adjacent to a city or town of greater than 50,000 inhabitants that is within one-quarter mile of a Rural Area.

(ii) Units of local government may petition the Under Secretary of RD for a ''rural in character'' designation by submitting a petition to both the appropriate RD State Director and the Administrator on behalf of the Under Secretary. The petition shall document how the area meets the requirements of paragraph (6)(i)(A) or (B) above and discuss why the petitioner believes the area is ''rural in character,'' including, but not limited to, the area's population density, demographics, and topography and how the local economy is tied to a Rural economic base. Upon receiving a petition, the Under Secretary will consult with the applicable Governor or leader in a similar position and request comments to be submitted within 5 business days, unless such comments were submitted with the petition. The Under Secretary will release to the public a notice of a petition filed by a unit of local government not later than 30 days after receipt of the petition by way of publication in a local newspaper and posting on the Agency's website, and the Under Secretary will make a determination not less than 15 days, but no more than 60 days, after the release of the notice. Upon a negative determination, the Under Secretary will provide to the petitioner an opportunity to appeal a determination to the Under Secretary, and the petitioner will have 10 business days to appeal the determination and provide further information for consideration *Rural Development (RD).* A mission area within USDA consisting of the Office of Under Secretary for RD, RBCS, Rural Housing Service, and Rural Utilities Service, and any successors.

Socially Disadvantaged Group. A group whose members have been subjected to racial, ethnic, or gender prejudice because of their identity as members of a group without regard to their individual qualities.

State. Includes each of the 50 States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. References in this program to State, State government, or State agency are meant to include the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and, as may be determined by the Secretary to be feasible, appropriate, and lawful, the Freely Associated States and the Federated States of Micronesia.

Technical Assistance. The process of providing targeted support for the startup, expansion and operational improvement of cooperatively and mutually owned businesses typically delivered via multiple contacts over a period of time. It includes the transfer of skills and knowledge through research and collection of information to provide guidance and advice; assessment and analysis through feasibility studies and business plans, customized training, written information, in person or virtual exchanges, web-based curriculums, and webinars.

4. *Application of Awards.* The Agency will review, evaluate, and score applications received in response to this notice based on Section E of this notice. Awards under the SDGG program will be made on a competitive basis using specific selection criteria contained in Section E.1 of this notice. The Agency advises all interested parties that the applicant bears the full burden in preparing and applying in response to this notice.

B. Federal Award Information

Type of Award: Grants.

Fiscal Year Funds: FY 2024.

Available Funds: $3,000,000 will be available for FY 2024. The Agency may, at its discretion, increase the total level of funding available in this funding round (or in any category in this funding round) from any available source provided the awards meet the requirements of the statute which made the funding available to the Agency.

Award Amount: Maximum is $175,000.

Anticipated Award Date: September 30, 2024.

Performance Period: One (1) year. See Section C.3(c) of this notice for additional guidance on the grant period.

Renewal or Supplemental Awards: None.

Type of Assistance Instrument: Financial Assistance Agreement.

C. Eligibility Information

1. *Eligible Applicants.* Grants may be made to individual Cooperatives, Groups of Cooperatives, or Cooperative Development Centers that serve Socially Disadvantaged Groups and of which a majority (*i.e.,* greater than 50 percent rounded to the nearest tenth) of the Board of Directors or Governing Board of the applicant is comprised of individuals who are members of Socially Disadvantaged Groups. An advisory board for the proposed Project does not meet this requirement.

Federally recognized Tribes have a government-to-government relationship with the United States. Therefore, Tribes may consider using a separate entity, such as a tribally-owned business, tribal authority, tribal non-profit, tribal college, or university to apply for SDGG funding that would provide Technical Assistance to members of the Tribe.

Applications submitted must include the following for eligibility determination:

(a) Applicants must verify their legal structure in the State or the Tribe under which the applicants are legally organized or incorporated.

(b) Applicants must demonstrate that all defined requirements for one of the three eligible applicant types have been met (see Section D.2. of this notice). The three eligible applicant types are: individual Cooperatives, Groups of Cooperatives, or Cooperative Development Centers.

An applicant is ineligible if:

(a) It is a public body or individual.

(b) It has been debarred or suspended or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order (E.O.) 12549. The Agency will check the Do Not Pay (DNP) system to determine if the applicant has been debarred or suspended at the time of application and prior to funding any grant award.

(c) It has an outstanding judgment obtained by the U.S. in a Federal Court (other than U.S. Tax Court), is delinquent on the payment of Federal income taxes, or is delinquent on Federal debt. The applicant must certify, as part of the application, that there are no outstanding judgments against them. The applicant is responsible for resolving any issues that are reported in the DNP System and if issues are not resolved by the deadline found in this notice, the Agency may proceed to award funds to other eligible applicants.

(d) Any corporation or Cooperative (i) that has been convicted of a felony criminal violation under any Federal law within the past 24 months or (ii) that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance provided with funds appropriated by the 2024 Appropriations Act, unless a Federal

agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government. Certification of compliance with this provision is now completed during registration or annual recertification in the System for Award Management (SAM) at *SAM.gov* via the Financial Assistance General Certifications and Representations.

2. *Cost Sharing or Matching.* There is no cost sharing or matching requirement associated with this grant.

3. *Other Eligibility Requirements.*

(a) *Use of funds.* Applications must propose Technical Assistance that will benefit Socially Disadvantaged Groups. Any recipient of Technical Assistance must have a membership that consists of a majority of members from Socially Disadvantaged Groups. Please review Section D.6 of this notice carefully.

(b) *Project eligibility.* Proposed Projects must only serve members of Socially Disadvantaged Groups located in Rural Areas.

(c) *Grant period eligibility.* Applications must include a grant period of one-year or less or it will not be considered for funding. The proposed time frame should begin no earlier than October 1, 2024, and end no later than December 31, 2025. Applications that request funds for a time period ending after December 31, 2025, will not be considered for funding. Projects must be completed by December 31, 2025, or within 12 months of award funding, whichever is earlier.

The Agency may approve requests to extend the grant period for up to an additional 12 months at its discretion. However, applicants may not have more than one SDGG award during the same grant period. If you extend the period of performance for your current award, you may be deemed ineligible to receive an SDGG in the next grant cycle. Further guidance on grant period extensions will be provided in the award document.

(d) *Satisfactory performance eligibility.* If applicants have an existing SDGG award, current performance must be satisfactory to be considered eligible for a new SDGG award. Satisfactory performance includes being up to date on all financial and performance reports as prescribed in the grant award and being current on tasks and timeframes for utilizing grant funds as approved in the work plan and budget. If applicants have any unspent grant funds on SDGG awards from Projects prior to September 30, 2022, the application will not be considered for funding. If an applicant's FY 2023 award has unspent funds of 50 percent or more than what the approved work plan and budget projected at the time of evaluation of the FY 2023 application, the FY 2024 application may not be considered for funding. The Agency will verify the performance status of any FY 2023 awards and make a determination after the FY 2024 application period closes.

(e) *Completeness eligibility.* Applications must provide all the information requested in Section D.2 of this notice. Applications lacking sufficient information to determine eligibility and scoring criteria will be considered ineligible.

(f) *Duplication of current services.* Applications must demonstrate that services are being provided to new customers or new services to current customers. If the work plan and budget are duplicative of an existing award, the application will not be considered for funding. If the work plan and budget are duplicative of a previous or existing Rural Cooperative Development Grant (RCDG) and/or SDGG award, the application will not be considered for funding.

(g) *Multiple grant eligibility.* Applicants may submit only one SDGG grant application each funding cycle. If two (2) applications are submitted (regardless of the applicant's name) that include the same Executive Director and/or advisory boards or committees of an existing Cooperative or Cooperative Development Center, both applications will be determined ineligible for funding.

D. Application and Submission Information

1. *Application Template.* An application template to assist applicants in applying for this funding opportunity is located at *www.rd.usda.gov/programs-services/socially-disadvantaged-groups-grant.* Use of the application template is strongly recommended to assist with the application process. Application information is also available at *www.grants.gov.* Applicants may also contact the USDA RD State Office for more information at *www.rd.usda.gov/contact-us/state-offices.*

2. *Content and Form of Application Submission.* An application must contain all the required forms and proposal elements outlined below.

(a) *Form SF–424, Application for Federal Assistance.* This form should include the applicant's Unique Entity Identifier (UEI) number. The UEI is assigned automatically to all active *SAM.gov* registered entities. If an applicant does not include the UEI number in its application, it will not be considered for funding.

(b) *Form SF–424A, Budget Information-Non-Construction Programs.* This form must be completed and submitted as part of the application package. Applicants are no longer required to complete the Form SF 424B, Assurances—Non-Construction Programs as a part of the application. This information is now collected through the applicant registration or annual recertification in *SAM.gov* through the Financial Assistance General Certifications and Representations.

(c) *Federal Debt and Judgement Certification.* Applicants must certify that there are no current outstanding Federal judgments against the applicant's property and that no grant funds will be used to pay for any judgment obtained by the United States. Applicants must also certify that they are not delinquent on the payment of Federal income taxes, or any Federal debt. There is no standard form to complete, but to satisfy the certification requirement, applicants should include this statement in the application: ''[INSERT NAME OF APPLICANT] certifies that the United States has not obtained an unsatisfied judgment against its property, is not delinquent on the payment of Federal income taxes, or any Federal debt, and will not use grant funds to pay any judgments obtained by the United States.'' A separate signature is not required.

(d) *Table of Contents (TOC).* Applications must contain a detailed TOC that includes page numbers for each part of the application. Page numbers should begin immediately following the TOC.

(e) *Executive Summary.* A summary of the proposal, not to exceed one (1) page, must briefly describe the Project, tasks to be completed, and other relevant information that provides a general overview of the Project.

(f) *Eligibility Discussion.* A detailed discussion, not to exceed four (4) pages, must describe how the applicant will meet the following requirements:

(1) *Applicant Eligibility.* Applicants must describe how they meet the definition of a Cooperative, Group of Cooperatives, or Cooperative Development Center. Applications must also show that the individual Cooperative, Group of Cooperatives or Cooperative Development Center has a majority of its Board of Directors or Governing Board comprised of individuals who are members of Socially Disadvantaged Groups, and that the applicant serves Socially Disadvantaged Groups. The application

must include a list identifying the entire Board of Directors/Governing Board by name and indicating how each member meets the definition of Socially Disadvantaged Groups.

An application will not be considered for funding if it fails to show that a majority of the Board of Directors/Governing Board (*i.e.,* greater than 50 percent rounded to the nearest tenth) is comprised of individuals who are members of Socially Disadvantaged Groups.

Applicants must verify their incorporation and status in the State in which they have applied by providing the State or Tribe's Certificate of Good Standing and Articles of Incorporation. Bylaws may also be submitted if they provide additional information not included in the Articles of Incorporation that will help verify the applicant's legal status. If applying as an institution of higher education, documentation verifying legal status is not required; however, the applicant must demonstrate that it qualifies as an institution of higher education as defined at 20 U.S.C. 1001. Each applicant can only apply as one (1) type of applicant. The requested verification documents should be included in Appendix A of the application. If the documents are not included, the application will not be considered for funding.

(2) *Use of Funds.* Applications must include a brief discussion on how the proposed Project activities meet the definition of Technical Assistance and identify the Socially Disadvantaged Groups that will be assisted.

(3) *Project Area.* Applications must provide specific information that details the location of the Project area and explain how the area meets the definition of Rural Area as defined in Section A.3 of this notice.

(4) *Grant Period.* Applications must include a time frame for the proposed Project and discuss how the Project will be completed within that time frame. See Section C.3(c) of this notice for more information.

(5) *Indirect Costs.* Applicants should indicate in the application if there is a negotiated indirect cost rate agreement (NICRA), and if so, the rate. The negotiated indirect cost rate approval does not need to be included in the application, but it will be required to be provided if a grant is awarded. Approval for indirect costs that are requested in an application without an approved indirect cost rate agreement is at the discretion of the Agency.

(g) *Scoring Criteria.* Each of the scoring criteria in Section E.1 of this notice must be addressed in narrative form, with a maximum of three (3) pages for each individual scoring criterion, unless otherwise specified. Failure to address each scoring criterion will result in the application being determined ineligible.

(h) *Annual Performance Evaluation Measures.* The Agency has established annual performance evaluation measures to evaluate the SDGG program and how the applicant met the measures. The applicant must provide estimates on the following performance evaluation measures as part of the narrative:

(1) Number of Cooperatives assisted; and

(2) Number of Socially Disadvantaged Groups assisted.

And, if applicable:

(3) Number of jobs created/saved.

(4) Number of jobs created/saved in persistent poverty area and or underserved and economically distressed areas.

(5) Number of business plans developed.

(6) Number of Cooperatives incorporated.

(7) Number of Feasibility Studies completed.

(8) Number of workshops/seminars conducted.

(9) Number of conferences held.

(10) For consumer coops (grocery, retail), number of people with access to goods or services.

3. *System for Award Management and Unique Entity Identifier.*

(a) At the time of application, applicants must have an active registration in the SAM before applying in accordance with 2 CFR part 25. To register in SAM, entities will be required to obtain a UEI. Instructions for obtaining the UEI are available at *sam.gov/content/entity-registration.*

(b) Applicants must maintain an active SAM registration, with current, accurate and complete information, at all times during which it has an active Federal award or an application under consideration by a Federal awarding agency.

(c) Applicants must complete the Financial Assistance General Certifications and Representations in SAM.

(d) Applicants must provide a valid UEI in its application, unless determined exempt under 2 CFR 25.110.

(e) The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. *Submission Dates and Times.*

(a) *Application Technical Assistance Deadline Date.* Prior to official submission of applications, applicants may request technical assistance or other application guidance from their State Office, if such requests are made prior to May 3, 2024. Agency contact information can be found in the **ADDRESSES** section of this notice.

(b) *Application Deadline Date.* Complete applications for grants must be submitted electronically no later than 11:59 p.m. ET on June 3, 2024, through *www.grants.gov* to be eligible for grant funding. Please review the *Grants.gov* website at *www.grants.gov/applicants/applicant-registration* for instructions on the process of registering your organization as soon as possible to ensure that you are able to meet the electronic application deadline. No secured/password protected documents are to be uploaded to *grants.gov.*

Applications received after the deadline are not eligible for funding under this notice and will not be evaluated. The Agency will not solicit or consider new scoring or eligibility information that is submitted after the application deadline. The Agency also reserves the right to ask applicants for clarifying information and additional verification of assertions in the application.

5. *Intergovernmental Review.* Executive Order (E.O.) 12372 applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many States have established a Single Point of Contact (SPOC), please see the White House Website: *www.whitehouse.gov/omb/management/office-federal-financial-management/.* If your State has a SPOC, you may submit a copy of the application directly for review. Any comments obtained through the SPOC must be provided to the USDA RD State Office for consideration as part of your application. If your State has not established a SPOC, you may submit your application directly to the Agency. Applications from Federally recognized Indian Tribes are not subject to this requirement.

6. *Funding Restrictions.* Grant funds must be used for Technical Assistance as defined.

(a) No funds made available under this notice shall be used to:

(1) Plan, repair, rehabilitate, acquire, or construct a building or facility, including a processing facility;

(2) Purchase, rent, or install fixed equipment, including processing equipment;

(3) Purchase vehicles, including boats;

(4) Pay for the preparation of the grant application;

(5) Pay expenses not directly related to the funded Project;

(6) Fund political or lobbying activities;

(7) Fund any activities considered unallowable by the applicable grant cost principles, including 2 CFR part 200, subpart E and the Federal Acquisition Regulation as stated in 48 CFR Chapter 1, subchapter E, part 31;

(8) Fund architectural or engineering design work for a specific physical facility;

(9) Fund any expenses dealing with production such as produce any commodity or product to which value will be added, including seed, rootstock, labor for harvesting the crop, and delivery of the commodity to a processing facility. Examples also include, but are not limited to, testing commodities, building fencing for livestock, soil amendments, soil enrichments, soil treatments, tools, equipment, soil testing supplies, laboratory fees, hoop houses, software, subscriptions, and advertising or publicity expenses for the assisted Cooperative.

(10) Fund research and development;

(11) Purchase land;

(12) Duplicate current activities or activities paid for by other Federal grant programs;

(13) Pay costs of the Project incurred prior to the date of grant approval;

(14) Pay for assistance to any private business enterprise that does not have at least fifty-one (51) percent ownership by those who are either citizens of the United States or reside in the United States after being legally admitted for permanent residence;

(15) Pay any judgment or debt owed to the United States;

(16) Pay any Operating Costs of the Cooperative, Group of Cooperatives, or Cooperative Development Center not directly related to the Project;

(17) Pay expenses for applicant employee training or professional development not directly related to the Project;

(18) Pay for any goods or services from a person or entity who has a Conflict of Interest with the grantee;

(19) Pay for Technical Assistance provided to a Cooperative that does not have a membership that consists of a majority of members from Socially Disadvantaged Groups; or

(20) Fund expenses or activities relating to production, manufacturing-based costs, cybersecurity equipment, supply chain tracing equipment, and automation costs.

(b) Applications will not be considered for funding if it does any of the following:

(1) Requests more than the maximum grant amount;

(2) Proposes ineligible costs that equal more than ten (10) percent of total grant funds requested; or

(3) Proposes Participant Support Costs that equal more than ten (10) percent of total grant funds requested.

(c) The Agency will consider an application for funding if it includes ineligible costs of ten (10) percent or less of total grant funds requested if it is determined eligible otherwise. However, if the application is successful, those ineligible costs must be removed and replaced with eligible costs before the Agency will make the grant award or the amount of the grant award will be reduced accordingly. If the Agency cannot determine the percentage of ineligible costs, the application will not be considered for funding.

(d) No assistance or funding from this grant can be provided to a hemp producer without a valid license issued from an approved State, Tribal or Federal plan in accordance with Subtitle G of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1639o *et seq.*). Verification of valid hemp licenses will occur at the time of award. The purpose of this program is to provide Technical Assistance, so funding to produce hemp or marketing hemp production is not eligible.

7. *Other Submission Requirements.* Applications will not be accepted if the text is less than an 11-point font. Applications will not be accepted through mail or courier delivery, in-person delivery, email, or fax. Applications must be submitted electronically through *www.grants.gov.* A password is not required to access the website. Applicants can locate the *Grants.gov* downloadable application package for this program by using a keyword, the program name, Assistance Listing number, or the Funding Opportunity Number for this program.

The *Grants.gov* website provides information about applying electronically through the site, as well as the hours of operation. Users of *Grants.gov* must already have a UEI number and must also be registered and maintain registration in SAM as detailed in Section D.3 of this notice. The UEI number must be associated with the correct tax identification number of the SDGG applicant. It is strongly recommended that applicants do not wait until the application deadline date to begin the application process through *Grants.gov.*

Applications must include electronic signatures. Original signatures may be required if funds are awarded. After applying electronically through *Grants.gov,* applicants will receive an automated acknowledgement from *Grants.gov* with a *Grants.gov* tracking number.

E. Application Review Information

1. *Selection Criteria.* All eligible and complete applications will be evaluated and scored based on the following selection criteria and weights. Evaluators will base scores only on the information provided or cross-referenced by page number in each individual evaluation criterion. SDGG is a competitive program, so applications will receive scores based on the quality of the responses. Simply addressing the criteria will not guarantee higher scores. The total points possible for the criteria are 105.

(a) *Technical Assistance (maximum score of 25 points).* Three-page limit. A panel of USDA employees will evaluate the applications to determine the ability to assess the needs of and provide effective Technical Assistance to Socially Disadvantaged Groups. Applicants must discuss the following:

(1) Needs of the Socially Disadvantaged Groups to be assisted and explain how those needs were determined,

(2) Proposed Technical Assistance to be provided to the Socially Disadvantaged Groups; and

(3) Expected outcomes of the proposed Technical Assistance, including how Socially Disadvantaged Groups will benefit from participating in the Project. Applicants will score higher on this criterion if examples of the entity's past Projects that demonstrate successful outcomes in identifying specific needs and providing Technical Assistance to Socially Disadvantaged Groups are provided.

(b) *Work Plan/Budget (maximum of 25 points).* Six-page limit. Work plans must provide activities to be completed, including specific and detailed descriptions of all tasks. Work plans must indicate all the Key Personnel, who will accomplish the Project's activities that align with the goals of the Project. The budget will be reviewed for completeness. Applicants must list what tasks are to be done, when the tasks will be done, who will do the tasks, and a detailed account of how much each task will cost. Reviewers must be able to understand what is being proposed and how all the grant funds will be spent.

The budget must provide a detailed breakdown of estimated costs. These costs should be allocated to each of the tasks to be undertaken. (For example: Joe Smith has committed 20 percent of his work time. Joe's salary is $60,000 × 20% (0.20) = $12,000. This Project requires travel within the United States. The distance from Joe's office to the airport is 150 miles at $0.585/mile = $175.50 Round trip. The overnight trip includes lodging expense with tax at $189/night for 3 overnights = $567.00. Supplies include 2 boxes of paper at $50 each = $100 as an example.) A panel of USDA employees will evaluate the work plan for detailed actions and an accompanying timetable for implementing the proposal. Applicants will receive a higher score to the extent that they provide a clear, detailed, logical, realistic, and efficient plan that matches and reconciles with the Form SF424A and that allocates costs to specific tasks using applicable budget object class categories (See SF 424–A, Block 6 a–c, e–h, and j). At a minimum, the following must be discussed:

(1) Specific tasks to be completed using grant funds;

(2) How customers will be identified and selected;

(3) Key Personnel and how their work and experience is tied to the work plan task (or if not yet hired, a description of new employee qualifications must be tied to the work plan task); and

(4) The evaluation methods to be used by the applicant to determine the success of specific tasks and overall Project activities and objectives. Please provide qualitative methods of evaluation. For example, evaluation methods should be measurable and go beyond quantitative measurements of completing surveys or number of evaluations. Examples include discussions of pre-test, post-test, and the evaluation of how task results will be measured.

(c) *Experience (maximum score of 25 points).* Three-page limit. A panel of USDA employees will evaluate the applicant's experience, commitment, and availability for identified staff or consultants in providing Technical Assistance, as defined in Section A.3 of this notice. Applicants must describe the Technical Assistance experience for each identified staff member or consultant, as well as years of experience in providing that assistance. Applicants must discuss the commitment and the availability of identified staff, consultants, or other professionals to be hired for the Project, especially those who may be consulting on multiple SDGG/RCDG Projects. If staff or consultants have not been selected at the time of application, the applicants must provide specific descriptions of the qualifications required for the positions to be filled. In addition, resumes for each individual staff member or consultant must be included as an attachment in Appendix B of the application. The attachments will not count toward the maximum page total. The Agency will compare the described experience in this section and in the resumes to the work plan to determine relevance of the experience. Applications that do not include the attached resumes will not be considered for funding. Applications that demonstrate strong credentials, education, capabilities, experience, and availability of Project personnel, that will contribute to a high likelihood of Project success will receive more points than those that demonstrate less potential for success in these areas. In addition, for SDGG program Key Personnel, resumes must list all Cooperatives or Boards of Directors, in which they are part of.

Points will be awarded as follows:

(1) 0 points will be awarded if you do not substantively address the criterion.

(2) 1 to 9 points will be awarded if qualifications and experience of some, but not all, staff is addressed and, if necessary, qualifications of unfilled positions are not provided.

(3) 10 to 14 points will be awarded if paragraph (2) of this section is met, plus all Project personnel are identified but do not demonstrate qualifications or experience relevant to the Project.

(4) 15 to 19 will be awarded if paragraphs (2) and (3) of this section are met, plus most, but not all, Key Personnel demonstrate strong credentials and/or experience, and availability indicating a reasonable likelihood of success.

(5) 20 to 25 points will be awarded if paragraphs (2) through (4) of this section are met, plus all personnel demonstrate strong, relevant credentials or experience and availability indicating a high likelihood of Project success.

(d) *Commitment (maximum of 10 points).* Three-page limit. A panel of USDA employees will evaluate the applicant's commitment to providing Technical Assistance to Socially Disadvantaged Groups in Rural Areas. Applicants must list the number and location (full address if known and at a minimum provide county(ies)) of Socially Disadvantaged Groups that will directly benefit from the assistance provided. Applicants must define and describe the underserved and economically distressed areas within the applicant's service area and provide current and relevant statistics that support the applicant's description of the service area. Projects located in Persistent Poverty Counties as detailed in Section A.2 of this notice, if discussed, will score higher on this criterion.

(e) *Local support (maximum of 10 points).* Three-page limit. A panel of USDA employees will evaluate applications for local support of the Technical Assistance activities. Discussion on local support should include previous and/or expected local support and plans for coordinating with other developmental organizations in the proposed service area or with Tribal, State, and local government institutions. Applications that demonstrate strong support from potential beneficiaries and other developmental organizations will score higher. A maximum of 10 letters of support may be included with the application. Points will be awarded as follows:

(1) 0 points are awarded if the applicant does not adequately address this criterion.

(2) A range of 1 to5 points are awarded if the applicant demonstrates support from potential beneficiaries and other developmental organizations in the discussion but does not provide letters of support.

(3) Additional 1 point is awarded if 2 or 3 support letters are provided and show support from potential beneficiaries and/or support from local organizations.

(4) Additional 2 points are awarded if 4 or 5 support letters are provided and show support from potential beneficiaries and/or support from local organizations.

(5) Additional 3 points are awarded if 6 or 7 support letters are provided and show support from potential beneficiaries and/or support from local organizations.

(6) Additional 4 points are awarded if 8 or 9 support letters are provided and show support from potential beneficiaries and/or support from local organizations.

(7) Additional 5 points are awarded if 10 support letters are provided and show support from potential beneficiaries and/or support from local organizations.

Support letters should be signed and dated after the publication date of this notice and should come from potential beneficiaries and other local organizations. Letters received from Congressional members, or Technical Assistance providers/contractors paid with grant funding, will not be included in the count of support letters received. Additionally, letters having the appearance of being identical in form

and signed by multiple potential beneficiaries and/or local organizations will not be included in the count of support letters received. Support letters should be included as an attachment to the application in Appendix C and will not count against the maximum page total. Additional letters from industry groups, commodity groups, Congressional members, and similar organizations should be referenced but not included in the application package. When referencing these letters, provide the name of the organization, the date of the letter, the nature of the support, and the name and title of the person signing the letter.

(f) *Administrator Discretionary Points (maximum of 10 points).* The Administrator may choose to award points to applications where:

(1) The applicant has never received a SDGG award—5 points; and/or

(2) The applicant seeks to advance one or more key priorities addressed in the Supplementary Information, Overview section of this notice—5 points. Applicants seeking these points must discuss in the application (1 page limit) if they are first time applicants and are seeking to advance one or more key priorities: (i) Assisting rural communities recover economically through more and better market opportunities and through improved infrastructure. Applicant would receive priority points if the project is located in or serving a rural community whose economic well-being ranks in the most distressed tier (distress score of 80 or higher) of the Distressed Communities Index using the Distressed Communities Look-Up Map available at *www.rd.usda.gov/priority-points.*

(ii) Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects. Using the Social Vulnerability Index (SVI) Look-Up Map (available at *www.rd.usda.gov/priority-points*), an applicant would receive priority points if the project is:

- Located in or serving a community with score 0.75 or above on the SVI;
- Is a Federally recognized Tribe, including Tribal instrumentalities and entities that are wholly owned by Tribes; or
- Is a project where at least 50 percent of the project beneficiaries are members of Federally Recognized Tribes and non-Tribal applicants include a Tribal Resolution of Consent from the Tribe or Tribes that the applicant is proposing to serve.

(iii) Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities. Using the Disadvantaged Community and Energy Community Look-Up Map (available at *www.rd.usda.gov/priority-points*), applicants will receive priority in three ways:

- If the project is located in or serves a Disadvantaged Community as defined by the Climate and Economic Justice Screening Tool (CEJST), from the White House Council on Environmental Quality;
- If the project is located in or serves an Energy Community as defined by the Inflation Reduction Act (IRA); and
- If applicants can demonstrate through a written narrative how the proposed climate-impact projects will improve the livelihoods of community residents and meet pollution mitigation or clean energy goals.

See the website, *https://www.rd.usda.gov/priority-points,* for options.

2. *Review and Selection Process.* Applications will be reviewed in the USDA RD State Offices to determine if they are eligible for assistance based on requirements in this notice, and other applicable Federal regulations. If determined eligible, applications will be scored by a panel of USDA employees in accordance with the point allocation specified in this notice. The review panel will convene to reach a consensus on the scores for each of the eligible applications. The Administrator may choose to award up to 10 Administrator priority points based on Section E.1(f) of this notice. These points will be added to the cumulative score for a total possible score of 105. Applications will be funded from highest ranking order until the funding limitation has been reached. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion. The Agency reserves the right to offer the applicant less than the grant funding requested. Applications that are ranked and not funded will not be carried forward into the next competition.

F. Federal Award Administration Information

1. *Federal Award Notices.* Applicants selected for funding will receive a signed notice of Federal award, by postal or electronic mail, containing instructions on requirements necessary to proceed with execution and performance of the award.

Applicants not selected for funding will be notified in writing via postal or electronic mail and informed of any review and appeal rights. Funding of successfully appealed applications will be limited to available FY 2024 funding.

2. *Administrative and National Policy Requirements.* Additional requirements that apply to grantees selected for this program can be found in 2 CFR parts 200, 400, 415, 417, 418, and 421. All recipients of Federal financial assistance are required to report information about first tier subawards and executive compensation in accordance with 2 CFR part 170, Appendix A. Recipients will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act reporting requirements of 2 CFR 170.200(b), unless they are exempt under 2 CFR 170.110(b).

The following additional requirements apply to grantees selected for this program:

(a) *Execution of an Agency approved Grant Agreement.*

(b) *Acceptance of a written Letter of Conditions.*

(c) *Submission of Form RD 1940–1, Request for Obligation of Funds.*

(d) *Submission of Form RD 1942–46, Letter of Intent to Meet Conditions.*

(e) *Assurance Agreement.* By signing the Financial Assistance General Certifications and Representations in SAM, grant recipients affirm that they will operate the program free from discrimination. The grant recipients will maintain the race and ethnic data on their board members and the beneficiaries of the program. The grant recipient will provide alternative forms of communication to persons with limited English proficiency. The Agency will conduct civil rights compliance reviews on grant recipients to identify the collection of racial and ethnic data on program beneficiaries. In addition, the compliance review will ensure that equal access to the program benefits and activities are provided for persons with disabilities and language barriers.

3. *Reporting.* After grant approval and through grant completion, applicants will be required to provide the following:

(a) An SF–425, Federal Financial Report, and a project performance report will be required on a semiannual basis (due 30 calendar days after the end of the semiannual period). The project performance reports shall include a comparison of actual accomplishments to the objectives established for that period;

(b) A statement providing reasons why established objectives were not met, if applicable;

(c) A statement providing reasons for any problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall Project objectives, prevent meeting time schedules or objectives, or preclude the attainment of objectives during

established time periods, and a description of the action taken or planned to resolve the situation;

(d) Objectives and timetable established for the next reporting period;

(e) A final Project and financial status report within 90 days after the expiration or termination of the grant in accordance with 2 CFR 200.344; and

(f) Outcome Project performance reports and final deliverables.

G. Agency Contacts

For general questions about this notice and for program technical assistance, please see the contact information in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

H. Other Information

1. *Paperwork Reduction Act.* In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13), the information collection requirements associated with the program, as covered in this notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0052.

2. *National Environmental Policy Act.* All recipients under this notice are subject to the requirements of 7 CFR part 1970. However, awards for Technical Assistance and training under this notice are classified as a Categorical Exclusion according to 7 CFR 1970.53(b), and usually do not require any additional documentation. RBCS will review each grant application to determine its compliance with 7 CFR part 1970. The applicant may be asked to provide additional information or documentation to assist RBCS with this determination.

3. *Federal Funding Accountability and Transparency Act.* All applicants, in accordance with 2 CFR part 25, must be registered in SAM and have a UEI number as stated in Section D.3 of this notice. All recipients of Federal financial assistance are required to report information about first-tier subawards and executive total compensation in accordance with 2 CFR part 170.

4. *Civil Rights Compliance Requirements.* All grants made under this notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA in accordance with 7 CFR part 15, subpart A and Section 504 of the Rehabilitation Act of 1973, Title VIII of the Civil Rights Act of 1968, Title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

5. *Nondiscrimination Statement.* In accordance with Federal civil rights laws and USDA civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English upon request. All requirements found in 2 CFR 200.111 must be adhered to. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; or the 711 Relay Service.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *www.usda.gov/sites/default/files/documents/ad-3027.pdf,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Kathryn E. Dirksen Londrigan,

Administrator, Rural Business-Cooperative Service, Rural Development.

[FR Doc. 2024–07005 Filed 4–2–24; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #: RBS–23–BUSINESS–0024]

Notice for the Rural Innovation Stronger Economy (RISE) Grant Program for Fiscal Year 2024

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service (RBCS, Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA), published in the **Federal Register**, a Notice of Solicitation of Applications for the Rural Innovation Stronger Economy (RISE) program for fiscal year (FY) 2024 on January 2, 2024 that invited applications for funding subject to the availability of funding. However, the Agency did not receive any funding for FY24, so it will not be accepting applications this cycle.

DATES: Completed applications were to be submitted electronically no later than 11:59 p.m. Eastern Time April 1, 2024 through *grants.gov.* Effective now, RBCS is not accepting applications and any applications submitted to date will not be funded through the RISE program.

FOR FURTHER INFORMATION CONTACT: Rachel Reister, Program Management Division, RBCS, USDA, 1400 Independence Avenue SW, Mail Stop-3226, Washington, DC 20250–3226, (202) 720–1400 or email: *rachel.reister@usda.gov.*

SUPPLEMENTARY INFORMATION: The Agency invited applications for the RISE program for FY24 on January 2, 2024, 89 FR 43, in anticipation of funding appropriations. However, the program did not receive any funding for FY24, so it will not be accepting applications this cycle.

Kathryn E. Dirksen Londrigan,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2024–06999 Filed 4–2–24; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

[Docket No.: RHS–24–MFH–0008]

Section 514 Off-Farm Labor Housing Subsequent Loans and Section 516 Off-Farm Labor Housing Subsequent Grants To Improve, Repair, or Make Modifications to Existing Off-Farm Labor Housing Properties for Fiscal Year 2024

Correction

In notice document, 2024–05505, appearing on pages 19400 through 19468 in the issue of Monday, March 18, 2024, make the following correction:

On page 19400, in the third column, in line twelve, change the phone number from ''254–757–5647'' to ''202–205–9217''.

[FR Doc. C1–2024–05505 Filed 4–2–24; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–13–2024]

Foreign-Trade Zone 21; Application for Subzone; AESC Florence LLC; Florence, South Carolina

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the South Carolina State Ports Authority, grantee of FTZ 21, requesting subzone status for the facility of AESC Florence LLC (AESC), located in Florence, South Carolina. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on March 29, 2024.

The proposed subzone (472 acres) is located at 1330 Estate Road, Florence, South Carolina. No authorization for production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is May 13, 2024. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to May 28, 2024.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov.*

Dated: March 29, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–07076 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–899]

Granular Polytetrafluoroethylene Resin From India: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that granular polytetrafluoroethylene resin (granular PTFE) from India was sold in the United States at less than normal value (NV) during the period of review (POR) September 2, 2021, through February 28, 2023. We invite interested parties to comment on these preliminary results of review.

DATES: Applicable April 3, 2024.

FOR FURTHER INFORMATION CONTACT: Katherine Johnson or David Williams, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4929 or (202) 482–4338, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 15, 2022, Commerce published in the **Federal Register** the antidumping duty order on granular PTFE from India.[1] On March 2, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order.*[2] On May 9, 2023, based on a timely request for review, in accordance with 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the *Order,* covering one producer/exporter, Gujarat Fluorochemicals Limited (GFCL).[3]

Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), on October 17, 2023, Commerce determined that it was not practicable to complete the preliminary results of this review within 245 days and extended the deadline for the preliminary results of this review until March 29, 2024.[4]

Scope of the Order

The merchandise covered by the *Order* is granular PTFE from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[5]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a) of the Act. Export price and constructed export price are calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

We preliminarily determine the following weighted-average dumping margin for the respondent for the period September 2, 2021, through February 28, 2023:

[1] *See Granular Polytetrafluoroethylene Resin from India and the Russian Federation: Antidumping Duty Orders,* 87 FR 14514 (March 15, 2022) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 13091 (March 2, 2023).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881 (May 9, 2023).

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review, dated October 17, 2023.

[5] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review; 2021–2023: Granular Polytetrafluoroethylene from Resin India,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Exporter/producer	Weighted-average dumping margin (percent)
Gujarat Fluorochemicals Limited	2.38

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed for these preliminary results to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[6] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[7] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[8] Case and rebuttal briefs should be filed using ACCESS.

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[9] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[10]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety via ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.[11]

If the weighted-average dumping margin for GFCL is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, Commerce intends to calculate an importer-specific *ad valorem* antidumping duty assessment rate based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1).[12] We intend to instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.50 percent).

Where we do not have entered values for all U.S. sales to a particular importer (or customer), we will calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[13] To determine whether a per-unit assessment rate is *de minimis,* we will calculate estimated entered values.

If the weighted-average dumping margin for GFCL or an importer-specific assessment rate is zero or *de minimis* in the final results of review, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[14] The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[15]

For entries of subject merchandise during the POR produced by GFCL for which it did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate unreviewed entries at the all-others rate (*i.e.,* 10.01) established in the less-than-fair-value (LTFV) investigation [16] if there is no rate for the intermediate company involved in the transaction.[17]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the notice of final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for GFCL will be equal to the weighed-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent, and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by a company not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific cash deposit rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, or a previous segment, but the producer is, then the cash deposit rate will be the rate established in the

[6] *See* 19 CFR 351.309(c); *see also* 19 CFR 351.303 (for general filing requirements).

[7] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[8] *See* 19 351.309(c)(2) and (d)(2).

[9] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[10] *See APO and Service Final Rule.*

[11] *See* 19 CFR 351.212(b).

[12] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012) (*Final Modification*).

[13] *See* 19 CFR 351.212(b)(1).

[14] *See* 19 CFR 351.106(c)(2); *see also Final Modification,* 77 FR at 8103.

[15] *See* section 751(a)(2)(C) of the Act.

[16] *See Order,* 87 FR at 14515.

[17] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

completed segment for the most recent period of the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 10.01 percent, the all-others rate established in the LTFV investigation.[18] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless the deadline is otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by interested parties in any case or rebuttal briefs, within 120 days after the date of publication of these preliminary results in the **Federal Register**.[19]

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: March 28, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–07073 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

[18] *See Order,* 87 FR at 14515.

[19] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–112]

Certain Collated Steel Staples From the People's Republic of China: Preliminary Determination of No Shipments and Partial Rescission of Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that Zhejiang Best Nail Industrial Co., Ltd. and its affiliated exporter Shaoxing Bohui Import & Export Co., Ltd. (Best Nail/Shaoxing Bohui) made no shipments of subject merchandise during the period of review (POR) July 1, 2022, through June 30, 2023. In addition, we are rescinding the administrative review with respect to Shanghai Yueda Nail Co., Ltd. (Shanghai Yueda); Tianjin Hweschun Fasteners Manufacturing, Co., Ltd. (Tianjin Hweschun); Vina Hardwares Joint Stock Company (Vina Hardwares); YF Technology Corporation (Thailand) Ltd.; and YF Technology Corporation Limited because the requests for review for these companies were timely withdrawn. We invite interested parties to comment on these preliminary results.

DATES: Applicable April 3, 2024.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Kate Johnson, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 11, 2023, in accordance with 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the antidumping duty order on certain collated steel staples (staples) from the People's Republic of China (China) with respect to the following companies: Best Nail/Shaoxing Bohui; Shanghai Yueda; Tianjin Hweschun; Vina Hardwares; YF Technology Corporation (Thailand) Ltd.; and YF Technology Corporation Limited.[1] In accordance with the publication of the *Initiation Notice,* Commerce released data obtained from the U.S. Customs and Border Protection (CBP) with respect to entries of staples from China for the POR and invited comments on the data for respondent selection purposes.[2]

On October 4, 2023, Vina Hardwares timely withdrew its request for an administrative review.[3] On October 11, 2023, Best Nail/Shaoxing Bohui submitted a no shipment claim for this POR segment.[4] In response to a no-shipment inquiry Commerce issued to CBP, on October 25, 2024, CBP responded that it had no record of any subject entries for Best Nail/Shaoxing Bohui.[5]

On November 6, 2023, we selected Shanghai Yueda and Tianjin Hweschun as the mandatory respondents in this administrative review.[6] We subsequently issued Commerce's antidumping duty questionnaire to these two companies.

On December 7 and 11, 2023, Shanghai Yueda and Tianjin Hweschun, respectively, withdrew their requests for administrative review.[7] On December 11, 2023, Kyocera Senco Industrial Tools, Inc. (Kyocera Senco), a domestic producer of staples, withdrew its request for an administrative review of Tianjin Hweschun.[8] On this same date, Black & Decker, a U.S. importer, withdrew its request for an administrative review of YF Technology Corporation (Thailand) Ltd. and YF Technology Corporation Limited.[9]

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 62322 (September 11, 2023) (*Initiation Notice*).

[2] *See* Memorandum, ''Release of U.S. Customs and Border Protection Data,'' dated September 15, 2023 (CBP Entry Data).

[3] *See* Vina Hardwares' Letter, ''Withdrawal of Request for Administrative Review,'' dated October 4, 2023.

[4] *See* Best Nail/Shaoxing Bohui's Letter, ''Submission of Statement of No Shipment,'' dated October 11, 2023.

[5] *See* Memorandum, ''No Shipment Inquiry for Zhejiang Best Nail Industrial Co., Ltd. and Shaoxing Bohui Import & Export Co., Ltd. during the period 07/01/2022 through 06/30/2023,'' dated November 6, 2023 (CBP No Shipment Memo). Prior to issuing our no-shipment inquiry to CBP and receiving CBP's response to that inquiry, we requested entry documentation for a certain entry in the CBP Entry Data that appeared to be associated with Best Nail/Shaoxing Bohui. We placed this entry documentation on the record of this review on January 19, 2024, and provided parties the opportunity to comment on the information. No party submitted comments.

[6] *See* Memorandum, ''Respondent Selection,'' dated November 6, 2023.

[7] *See* Shanghai Yueda's Letter, ''Withdrawal of Request for Administrative Review and Request for Suspension of Deadlines,'' dated December 7, 2023; and Tianjin Hweschun's Letter, ''Withdrawal of Request for Administrative Review,'' dated December 11, 2023.

[8] *See* Kyocera Senco's Letter, ''Withdrawal of Request for Administrative Review,'' dated December 11, 2023.

[9] *See* Black & Decker's Letter, ''Withdrawal of Request for Administrative Review, dated December 11, 2023.

Scope of the Order [10]

The merchandise covered by the scope of this *Order* is certain collated steel staples. Certain collated steel staples subject to this investigation are made from steel wire having a nominal diameter from 0.0355 inch to 0.0830 inch, inclusive, and have a nominal leg length from 0.25 inch to 3.0 inches, inclusive, and a nominal crown width from 0.187 inch to 1.125 inch, inclusive. Certain collated steel staples may be manufactured from any type of steel, and are included in the scope of this *Order* regardless of whether they are uncoated or coated, and regardless of the type or number of coatings, including but not limited to coatings to inhibit corrosion.

Certain collated steel staples may be collated using any material or combination of materials, including but not limited to adhesive, glue, and adhesive film or adhesive or paper tape.

Certain collated steel staples are generally made to American Society for Testing and Materials (ASTM) specification ASTM F1667–18a, but can also be made to other specifications.

Excluded from the scope of this *Order* are any carton-closing staples covered by the scope of the antidumping duty order on Carton-Closing Staples from the People's Republic of China. *See Carton-Closing Staples from the People's Republic of China: Antidumping Duty Order,* 83 FR 20792 (May 8, 2018).

Also excluded are collated fasteners commonly referred to as ''C-ring hog rings'' and ''D-ring hog rings'' produced from stainless or carbon steel wire having a nominal diameter of 0.050 to 0.081 inches, inclusive. C-ring hog rings are fasteners whose legs are not perpendicular to the crown, but are curved inward resulting in the fastener forming the shape of the letter ''C''. D-ring hog rings are fasteners whose legs are straight but not perpendicular to the crown, instead intersecting with the crown at an angle ranging from 30 degrees to 75 degrees. The hog rings subject to the exclusion are collated using glue, adhesive, or tape. The hog rings subject to this exclusion have either a 90 degree blunt point or 15–75 degree divergent point.

Certain collated steel staples subject to this *Order* are currently classifiable under subheading 8305.20.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). While the HTSUS subheading and ASTM specification are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Rescission of Administrative Review, in Part

As discussed above, the review requests for Shanghai Yueda, Tianjin Hweschun, Vina Hardwares, YF Technology Corporation (Thailand) Ltd., and YF Technology Corporation Limited have all been withdrawn. Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw their request within 90 days of the date of publication of the notice of initiation. Because no other parties requested a review of the above five companies, Commerce is rescinding this review, in part, with respect to these companies. As such, only Best Nail/Shaoxing Bohui remain under review.

Preliminary Determination of No Shipments

In the *Initiation Notice,* we instructed producers or exporters under review that had no exports, sales, or entries of subject merchandise during the POR to notify Commerce within 30 days of publication of the notice. As noted above, Best Nail/Shaoxing Bohui timely submitted a no-shipment certification. Based on an analysis of information from CBP, we preliminarily determine that the information on the record does not contradict Best Nail/Shaoxing Bohui's no- shipment certification.[11]

Consistent with our practice in non-market economy (NME) cases, we are not rescinding this review with respect to Best Nail/Shaoxing Bohui but, rather, we intend to complete the review and issue appropriate instructions to CBP based on the final results of the review.[12]

The China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[13] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, the entity is not under review, and the entity's rate (*i.e.,* 112.01 percent) [14] is not subject to change.

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with the preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of the preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce is rescinding the review for five companies and preliminarily finding that Best Nail/Shaoxing Bohui made no shipments of subject merchandise during the POR, there are no calculations to disclose. Given these facts, there is no decision memorandum accompanying this notice.

Public Comment

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[15] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[16] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[17]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[18] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment

[10] *See Certain Collated Steel Staples from the People's Republic of China: Antidumping Duty Order,* 85 FR 43815 (July 20, 2020) (*Order*).

[11] *See* CBP No Shipment Memo and Memorandum, ''Placing CBP Entry Documents on the Record,'' dated January 19, 2024.

[12] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011) (*NME AD Assessment*); *see also* the ''Assessment Rates'' section, below.

[13] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[14] *See Order,* 85 FR at 43816.

[15] *See* 19 CFR 351.309(c); see also 19 CFR 351.303 (for general filing requirements).

[16] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[17] *See* 19 351.309(c)(2) and (d)(2).

[18] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[19]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Assessment Rates

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period July 1, 2022, through June 30, 2023, in accordance with 19 CFR 351.212(c)(1)(i). We intend to issue assessment instructions to CBP for these companies no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

In addition, if we continue to find no POR shipments of subject merchandise for Best Nail/Shaoxing Bohui in the final results, any suspended entries of subject merchandise associated with this company will be liquidated at the China-wide rate.[20] For this company, we intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

[19] *See APO and Service Final Rule.*

[20] *See NME AD Assessment.*

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties, and/or an increase in the amount of the antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.221(b)(4).

Dated: March 26, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–07011 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–875]

Non-Malleable Cast Iron Pipe Fittings From the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Results of Scope Ruling

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 6, 2024, the U.S. Court of International Trade (CIT) issued its final judgment in *Star Pipe Products* v. *United States and ASC Engineered Solutions LLC.,* Court No. 17–00236, Slip Op. 24–28 (CIT March 6, 2024) (*Star Pipe Slip Op. 24–28*), sustaining the final remand results, of the U.S. Department of Commerce (Commerce), pertaining to the final scope ruling on certain non-malleable cast iron pipe fittings (pipe fittings) from the People's Republic of China (China). Commerce is therefore amending its Final Scope Ruling to find that ductile iron flanges exported by Star Pipe Products (Star Pipe) are not within the scope of the antidumping (AD) order on pipe fittings from China. Commerce is also notifying the public that the CIT's final judgment is not in harmony with the Final Scope Ruling.

DATES: Applicable March 16, 2024.

FOR FURTHER INFORMATION CONTACT: Maisha Cryor, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5831.

SUPPLEMENTARY INFORMATION:

Background

On August 17, 2017, Commerce issued its Final Scope Ruling on pipe fittings from China.[1] In its Final Scope Ruling, Commerce found that Star Pipe's ductile iron flanges were within the scope of the AD order[2] on pipe fittings from China.[3] Star Pipe appealed Commerce's Final Scope Ruling. During the course of litigation, the CIT issued several remand orders culminating in *Star Pipe Products* v. *United States and ASC Engineered Solutions, LLC,* Court No. 17–00236, Slip Op. 22–127 (November 18, 2022) (*Star Pipe IV*). In *Star Pipe IV,* the CIT directed Commerce to issue a new determination, in a form that would go into effect if sustained upon judicial review, determining whether Star Pipe's ductile iron flanges are within the scope of the *Order.*[4] Pursuant to the CIT's instructions, on remand, and under respectful protest, on December 16, 2022, Commerce found that Star Pipe's ductile iron flanges are outside the scope of the *Order.*[5] On March 6, 2024, the CIT sustained Commerce's *Fourth Remand Redetermination.*[6]

Timken Notice

In its decision in *Timken,*[7] as clarified by *Diamond Sawblades,*[8] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in

[1] *See* ''Final Scope Ruling on the Antidumping Duty Order on Non-Malleable Cast Iron Pipe Fittings from the People's Republic of China: Request by Star Pipe Products,'' dated August 17, 2017 (Final Scope Ruling).

[2] *See Notice of Antidumping Duty Order: Non-Malleable Cast Iron Pipe Fittings from the People's Republic of China,* 68 FR 16765 (April 7, 2003) (*Order*).

[3] *See* Final Scope Ruling.

[4] *See Star Pipe IV* at 3 and 15–18.

[5] *See Final Results of Redetermination Pursuant to Court Remand, Star Pipe Products* v. *United States and Anvil International,* Court No. 17–00236, Slip Op. 22–127, dated December 16, 2022 (*Fourth Remand Redetermination*), available at *https://access.trade.gov/Resources/remands/22-127.pdf.*

[6] *See Star Pipe Slip Op. 24–28.*

[7] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[8] *See Diamond Sawblades Mfrs. Coal.* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's March 6, 2024, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's final scope ruling. This notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Scope Ruling

There is now a final scope decision with respect to the Star Pipe Final Scope Ruling. Therefore, Commerce is amending its Final Scope Ruling and finds that the scope of the *Order* does not cover the products addressed in the Star Pipe Final Scope Ruling. The period to appeal the CIT's ruling expires on May 6, 2024. Commerce will instruct U.S. Customs and Border Protection (CBP) that, pending any appeals, the cash deposit rate will be zero percent for entries of Star Pipe's ductile iron flanges from China. In accordance with the CIT's order sustaining Commerce's *Fourth Remand Redetermination,* Commerce intends to, with the publication of this notice, issue instructions to CBP to lift suspension of liquidation of such entries, and to liquidate entries of the ductile iron flanges without regard to antidumping duties, with consideration for any potential appeal of the CIT's final judgement.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c)(1) and (e), of the Act.

Dated: March 28, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–07075 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States Investment Advisory Council

AGENCY: SelectUSA, International Trade Administration, Department of Commerce.

ACTION: Notice of deadline extension.

SUMMARY: On February 7, 2024, the Department of Commerce published in the **Federal Register** a notice soliciting applications for membership on the United States Investment Advisory Council (IAC or Council). The notice established a deadline date of March 20, 2024, for the transmittal of applications. This notice extends the deadline for transmittal of applications until May 15, 2024.

DATES: Applications for immediate consideration for membership must be received by the Office of SelectUSA by 5:00 p.m. Eastern Daylight Time (EDT) on May 15, 2024. Applications received after this date may be considered by SelectUSA as appropriate and when vacancies become available.

ADDRESSES: Please submit application information by email to *IAC@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Claire Pillsbury, SelectUSA, U.S. Department of Commerce; telephone: (202) 578–8239; email: *IAC@trade.gov.*

SUPPLEMENTARY INFORMATION: On February 7, 2024, we published a notice soliciting members for the United States Investment Advisory Council in the **Federal Register** (89 FR 8405). The notice established a deadline date of March 20, 2024, for the transmittal applications. We are extending the deadline for the transmittal of applications to allow additional time for applicants to complete and submit their applications.

All applications previously received pursuant to the February 7, 2024 **Federal Register** Notice will be duly considered during the extended solicitation period and should not be resubmitted.

Note: All requirements and conditions stated in the original notice remain the same, except for the deadline for the transmittal of applications.

Jasjit Kalra,

Executive Director, SelectUSA.

[FR Doc. 2024–06988 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–122]

Certain Corrosion Inhibitors From the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain producers and/or exporters made sales of certain corrosion inhibitors (corrosion inhibitors) at less than normal value during the period of review (POR) March 1, 2022, through February 28, 2023. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable April 3, 2024.

FOR FURTHER INFORMATION CONTACT: Hermes Pinilla and Dusten Hom, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3477, and (202) 482–5075, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 19, 2021, Commerce published in the **Federal Register** the antidumping duty (AD) order on certain corrosion inhibitors from the People's Republic of China (China).[1] On March 2, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order.*[2] On May 9, 2023, based on timely requests for an administrative review, Commerce initiated the administrative review of the *Order.*[3] The administrative review covers 21 companies, including two mandatory respondents, Anhui Trust Chem Co., Ltd., and Nantong Botao Chemical Co., Ltd.[4]

On October 30, 2023, Commerce extended the deadline for these preliminary results to March 28, 2024.[5] For a complete description of the events that occurred since the initiation of this review, see the Preliminary Decision Memorandum.[6] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A list of topics discussed in the Preliminary Decision

[1] *See Certain Corrosion Inhibitors from the People's Republic of China: Antidumping Duty Order,* 86 FR 14869 (March 19, 2021) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 88 FR 13091 (March 2, 2023).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881 (May 9, 2023) (*Initiation Notice*).

[4] *See* Memoranda, ''Respondent Selection,'' dated June 22, 2023.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated October 30, 2023.

[6] *See* Memorandum, ''Decision Memorandum for Preliminary Results of the 2022–2023 Antidumping Duty Administrative Review of Certain Corrosion Inhibitors from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Memorandum is included in appendix I to this notice. In addition, a complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by this *Order* are certain corrosion inhibitors from China. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[7]

Separate Rates

Commerce preliminarily determines that three companies, not individually examined, are eligible for separate rates in this administrative review.[8]

The Tariff Act of 1930, as amended (the Act) and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777AI(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review. Section 735(c)(5)(A) of the Act states that the all-others rate should be calculated by averaging the weighted-average dumping margins calculated for individually-examined respondents, excluding dumping margins that are zero, de minimis, or based entirely on facts available. For the preliminary results of this review, Commerce determined the estimated dumping margins for Anhui Trust Chem Co., Ltd., and affiliates, and Nantong Botao Chemical Co., Ltd to be 11.58, and 8.27 percent, respectively. For the reasons explained in the Preliminary Decision Memorandum, we are assigning the 10.49 percent rate to the three non-examined respondents, Gold Chemical Limited (Gold Chemical); Jiangyin Delian Chemical Co., Ltd. (Delian); Kanghua Chemical Co., Ltd. (Chuzhou Kanghua), which qualify for a separate rate in this review, consistent with Commerce's practice and section 735(c)(5)(A) of the Act.

China-Wide Entity

Commerce's policy regarding the conditional review of the China-wide entity applies to this administrative review.[9] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's assessment rate (*i.e.,* 241.02 percent) is not subject to change.[10] For the reasons explained in the Preliminary Decision Memorandum, Commerce considers all other companies for which a review was requested (none of which filed a separate rate application), listed in Appendix II to this notice, to be part of the China-wide entity.[11]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results of the Administrative Review

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist for the administrative review covering the period March 1, 2022, through February 28, 2023:

Exporter	Weighted-average dumping margin (percent)
Anhui Trust Chem Co., Ltd.; Jiangsu Trust Chem Co., Ltd.; Nanjing Trust Chem Co., Ltd	11.58
Nantong Botao Chemical Co., Ltd	8.27
Gold Chemical Limited	10.49
Jiangyin Delian Chemical Co., Ltd	10.49
Kanghua Chemical Co., Ltd	10.49

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after publication of this notice.[12] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[13] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs.[14] Interested parties who submit case briefs or rebuttal briefs in this proceeding are must submit: (1) table of contents listing each issue; and (2) a table of authorities.[15]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings, we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.[16] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, no including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[17]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the publication of this notice. Requests should contain the party's name, address, telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce will announce the date and time of the hearing.

[7] *Id.*

[8] *See* Appendix II; *see also* Preliminary Decision Memorandum at the ''Separate Rate Determination'' section for more details.

[9] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[10] *See Order.*

[11] *See* Appendix II for the list of companies that are subject to this administrative review that are considered to be part of the China-wide entity.

[12] *See* 19 CFR 351.224(b).

[13] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[14] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[15] *See* 19 CFR 351.309(c)(2) and (d)(2); *see also* 19 CFR 351.303 (for general filing requirements).

[16] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[17] *See APO and Service Final Rule.*

Final Results of Review

Unless the deadline is extended, Commerce intends to issue the final results of this review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuing the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[18] If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 241.02 percent to all entries of subject merchandise during the POR which were exported by the companies considered to be a part of the China-wide entity listed in Appendix II of this notice.

For each individually examined respondent in this review whose weighted-average dumping margin in the final results of review is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce intends to calculate importer/customer-specific assessment rates.[19] Where the respondent reported reliable entered values, Commerce intends to calculate importer/customer-specific *ad valorem* assessment rates by aggregating the amount of dumping calculated for all U.S. sales to the importer/customer and dividing this amount by the total entered value of the merchandise sold to the importer/customer.[20] Where the respondent did not report entered values, Commerce will calculate importer/customer-specific assessment rates by dividing the amount of dumping for reviewed sales to the importer/customer by the total quantity of those sales. Commerce will calculate an estimated *ad valorem* importer/customer-specific assessment rate to determine whether the per-unit assessment rate is *de minimis;* however, Commerce will use the per-unit assessment rate where entered values were not reported.[21] Where an importer/customer-specific *ad valorem* assessment rate is not zero or *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where either the respondent's weighted average dumping margin is zero or *de minimis,* or an importer/customer-specific *ad valorem* assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[22]

For the respondents that were not selected for individual examination in this administrative review, but which qualified for a separate rate, the assessment rate will be based on the weighted-average dumping margin(s) assigned to the respondent(s) selected for individual examination, as appropriate, in the final results of this review.[23]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for the subject merchandise exported by the company listed above that has a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during these PORs. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

Commerce is issuing and publishing these preliminary results of this review in accordance with sections 751(a)(1)(B), 751(a)(3) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(4).

Dated: March 28, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Affiliation and Collapsing
V. Discussions of the Methodology
VI. Adjustment Under Section 777A(f) of the Act
VII. Currency Conversion
VIII. Recommendation

Appendix II

Companies Considered To Be Part of the China-Wide Entity

1. Alfa Aesar China Chemical Co. Ltd.
2. Focus Chemical B.V.
3. Haruno Sangyo Kaisha Ltd.
4. Johoku Chemical Co., Ltd.
5. KD Finechem Co., Ltd.
6. New Essential Corp.
7. Sagar Speciality Chemicals Pvt., Ltd.
8. Shanghai Sunwise Chemicals Pvt., Ltd.
9. Sinochem Pharmaceutical Co., Ltd.
10. Tianjin Jinbin International Trade
11. TotalEnergies Lubrifiants
12. Vcare Medicines
13. Wuxi Base International Trade Co., Ltd.
14. Xiamen Amity Industry & Trade Co., Ltd.
15. Yasho Industries Pvt. Ltd.

[18] *See* 19 CFR 351.212(b)(1).

[19] *See Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification*).

[20] *See* 19 CFR 351.212(b)(1).

[21] *Id.*

[22] *See Final Modification,* 77 FR at 8103.

[23] *See Drawn Stainless Steel Sinks from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: 2014–2015,* 81 FR 29528 (May 12, 2016), and accompanying Issues and Decision Memorandum at 10–11, unchanged in *Drawn Stainless Steel Sinks from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; Final Determination of No Shipments; 2014–2015,* 81 FR 54042 (August 15, 2016).

16. Zaozhuang Kerui Chemicals Co., Ltd

[FR Doc. 2024–07070 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–137]

Pentafluoroethane (R–125) From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2021–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that Pentafluoroethane (R–125) from the People's Republic of China (China) was sold in the United States at prices below normal value (NV) during the period of review (POR), August 17, 2021, through February 28, 2023. Additionally, we are rescinding this administrative review in part with respect to two companies for which all review requests were withdrawn. We invite interested parties to comment on these preliminary results of review.

DATES: Applicable April 3, 2024.

FOR FURTHER INFORMATION CONTACT: Andrew Hart or Samantha Kinney, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1058 or (202) 482–2285, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 2022, Commerce published in the **Federal Register** the antidumping duty (AD) order on R–125 from China.[1] On March 2, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order,* covering the POR, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act).[2] On May 9, 2023, based on timely requests for review from Huantai Dongyue International Trade Co., Ltd. (Huantai Dongyue), Shandong Dongyue Chemical Co., Ltd. (Shandong Dongyue), Zhejiang Sanmei Chemical Ind. Co., Ltd. (Zhejiang Sanmei), and Zhejiang Yonghe Refrigerant Co., Ltd. (Zhejiang Yonghe),[3] Commerce initiated an administrative review of the *Order* covering four companies,[4] including the two mandatory respondents, Zhejiang Yonghe and Zhejiang Sanmei. On November 21, 2023, Commerce extended the deadline for the preliminary results of this review until March 29, 2024.[5]

Scope of the Order

The product covered by the *Order* is R–125 from China. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.[6]

Rescission of Review, In Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. On June 18 and July 18, 2023, Huantai Dongyue and Shandong Dongyue each timely withdrew its request for review of itself, respectively.[7] Because no other parties requested a review of these two companies, Commerce is rescinding the administrative review in part, with respect to these companies. *See* the Preliminary Decision Memorandum for further discussion.

Separate Rates

Commerce preliminarily determines that the Sanmei Companies[8] and the Yonghe Companies,[9] the two companies individually examined in this review, are eligible to receive separate rates in this review.[10]

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[11] the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 267.51 percent) is not subject to change.[12]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. We calculated export price in accordance with section 772 of the Act. Because China is a non-market economy country within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum.[13] A list of topics discussed in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized

[1] *See Pentafluoroethane (R–125) from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 87 FR 12081 (March 3, 2022) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 13091 (March 2, 2023).

[3] *See* Huantai Dongyue's Letter, ''Request for Administrative Review,'' dated March 31, 2023; Shandong Dongyue's Letter, ''Request for Administrative Review,'' dated March 31, 2023; Zhejiang Sanmei's Letter, ''Request for Administrative Review,'' dated March 31, 2023; and Zhejiang Yonghe's Letter, ''Request for Administrative Review,'' dated March 31, 2023.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29887 (May 9, 2023) (*Initiation Notice*). The *Initiation Notice* listed five companies. However, Zhejiang Sanmei Chemical Ind. Co., Ltd. is the same company as Zhejiang Sanmei Chemical Industry Co., Ltd.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated November 21, 2023.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2021–2023 Antidumping Duty Administrative Review of Pentafluoroethane (R–125) from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* Huantai Dongyue's Letter, ''Withdrawal of Request for Administrative Review,'' dated June 18, 2023; *see also* Shandong Dongyue's Letter, ''Withdrawal of Request for Administrative Review and Request Suspension of Deadlines,'' dated July 18. 2023.

[8] We preliminarily find that the following affiliated companies should be collapsed and treated as a single entity: Zhejiang Sanmei; Jiangsu Sanmei Chemical Ind. Co., Ltd.; and Fujian Qingliu Dongying Chemical Ind. Co., Ltd. (collectively, Sanmei Companies). For further discussion, *see* Memorandum, ''Affiliation and Single Entity Determination for Zhejiang Sanmei Chemical Ind. Co., Ltd.,'' dated concurrently with this notice.

[9] We preliminarily find that the following affiliated companies should be collapsed and treated as a single entity: Zhejiang Yonghe; Jinhua Yonghe Flurine Chemical Co., Ltd.; Inner Mongolia Yonghe Fluorochemical Co., Ltd.; and Shaowu Yonge Jintag new material Co., Ltd. (collectively, Yonghe Companies). For further discussion, *see* Memorandum, ''Affiliation and Single Entity Determination for Zhejiang Yonghe Refrigerant Co., Ltd.,'' dated concurrently with this notice.

[10] *See* Preliminary Decision Memorandum at ''Separate Rate Recipients'' section.

[11] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[12] *See Order.*

[13] *See* Preliminary Decision Memorandum at ''Discussion of the Methodology'' section.

Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margins exist for the period August 17, 2021, through February 28, 2023:

Exporter	Weighted-average dumping margin (percent)
Zhejiang Sanmei Chemical Ind. Co., Ltd.; Fujian Qingliu Dongying Chemical Co., Ltd.; Jiangsu Sanmei Chemical Ind. Co., Ltd	24.62
Zhejiang Yonghe Refrigerant Co., Ltd.; Jinhua Yonghe Fluorine Chemical Co., Ltd.; Inner Mongolia Yonghe Fluorochemical Co., Ltd.; Shaowu Yonghe Jintang new material Co., Ltd	281.30

Disclosure and Public Comment

Commerce intends to disclose the calculations performed for these preliminary results to interested parties within five days after public announcement, or if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**.[14]

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[15] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[16] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[17]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[18] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[19]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. If a request for a hearing is made, Commerce intends to hold a hearing at a time and date to be determined.[20] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[21] An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[22]

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review. Upon completion of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[23]

If the individually examined respondents' weighted-average dumping margins are above *de minimis* (*i.e.,* 0.50 percent) in the final results of this review, we will calculate importer-specific assessment rates for each respondent on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and, where possible, the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[24] Where a respondent did not report entered value, we will calculate importer-specific per-unit duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total quantity of those sales. To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values.

If, in the final results, a mandatory respondent's weighted-average dumping margin is zero or *de minimis* (*i.e.,* 0.50 percent), Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[25] For entries that were not reported in the U.S. sales database submitted by each mandatory respondent individually examined during this review, Commerce will instruct CBP to liquidate such entries at the China-wide rate.[26]

[14] *See* 19 CFR 351.224(b).

[15] *See* 19 CFR 351.303 (for general filing requirements).

[16] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Final Service Rule*).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

[18] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[19] *See APO and Final Service Rule.*

[20] *See* 19 CFR 351.310(d).

[21] *See* 19 CFR 351.303.

[22] *See APO and Final Service Rule.*

[23] *See* 19 CFR 351.212(b)(1).

[24] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[25] *See* 19 CFR 351.106(c)(2).

[26] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings:*

For the companies for which we have rescinded this review in part, Commerce intends to instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP for the rescinded companies no earlier than 35 days after the date of publication of the preliminary results in the **Federal Register**.

Commerce intends to issue assessment instructions, other than the assessment instructions for the rescinded companies, to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) for the subject merchandise exported by the companies listed above that have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.221(b)(4).

Dated: March 28, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rescission of Review, In Part
V. Single Entity Determinations
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2024–07069 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–105]

Carbon and Alloy Steel Threaded Rod From the People's Republic of China: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that Ningbo Zhenghai Yongding Fastener Co., Ltd. (Yongding), a producer/exporter of carbon and alloy steel threaded rod (threaded rod) from the People's Republic of China (China), received countervailable subsidies during the period of review (POR) January 1, 2022, through December 31, 2022. In addition, Commerce is rescinding this review, in part, with respect to four companies. Interested parties are invited to comment on these preliminary results.

DATES: Applicable April 3, 2024.

FOR FURTHER INFORMATION CONTACT: Bryan Hansen or Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3683 or (202) 482–0410, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 2020, Commerce published in the **Federal Register** the countervailing duty order on threaded rod from China.[1] On June 12, 2023, based on timely requests for an administrative review, Commerce published in the **Federal Register** the notice of initiation of this administrative review of the *Order* with respect to five companies.[2] On December 11, 2023, Commerce extended the deadline for the preliminary results of this review until April 26, 2024.[3]

For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed

Assessment of Antidumping Duties, 76 FR 65694 (October 24, 2011).

[1] *See Alloy and Certain Carbon Steel Threaded Rod from the People's Republic of China: Countervailing Duty Orders,* 85 FR 19927 (April 9, 2020) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021, 38031, 38034 n.13 (June 12, 2023) (*Initiation Notice*).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review, 2022,'' dated December 11, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Carbon and Alloy Steel Threaded Rod from the People's Republic of China; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise subject to the *Order* are threaded rod from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, In Part

In accordance with 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if all parties that requested the review withdraw their requests within 90 days of the date of publication of the notice of initiation of the requested review. Commerce is rescinding this administrative, in part, pursuant to 19 CFR 351.213(d)(1), for the following parties that requested an administrative review and timely withdrew their review requests: Ningbo Dingtuo Imp. & Exp. Co., Ltd.; Ningbo Dongxin High-Strength Nut Co., Ltd.; Ningbo Jinding Fastening Piece Co., Ltd.; Ningbo Zhongjiang High Strength Bolts Co., Ltd.; and Ningbo Zhongmin Metal Product Co., Ltd.[5] For further information, *see* the ''Final Rescission of Administrative Review, In Part'' section in the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our preliminary conclusions, including our reliance, in part, on adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.[7]

Preliminary Results of Review

Commerce preliminarily determines that the following net countervailable subsidy rate exists for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent *ad valorem*)
Ningbo Zhenghai Yongding Fastener Co., Ltd.[8]	17.39

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of these preliminary results of review in the **Federal Register**.[9] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the deadline for filing case briefs.[10] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[11]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[12] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[13]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via ACCESS. An electronically-filed request must be received successfully, and in its entirety, by ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[14] An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Final Results of Review

Unless the deadline is extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.221(b)(4)(i), we preliminarily determined subsidy rates in the amount for Yongding. Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a

[5] Commerce previously found Ningbo Zhongmin Metal Product Co., Ltd. to be a cross-owned affiliate of Ningbo Zhongjiang High Strength Bolts Co., Ltd. *See Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019), and accompanying Preliminary Decision Memorandum at 2 and 27–28, unchanged in *Carbon and Alloy Steel Threaded Rod From the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 85 FR 8833 (February 18, 2020) (*Final Determination*), and accompanying Issues and Decision Memorandum at Comment 7. Accordingly, we initiated this review with respect to Ningbo Zhongjiang High Strength Bolts Co., Ltd. and its cross-owned entity, Ningbo Zhongmin Metal Product Co., Ltd. *See Initiation Notice.*

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See* Preliminary Decision Memorandum at 8–38.

[8] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds Ningbo Yongzan Machinery Parts Co., Ltd. to be cross-owned with Ningbo Zhenghai Yongding Fastener Co., Ltd.

[9] *See* 19 CFR 351.309(c)(1)(ii).

[10] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[11] *See* 19 CFR 351.309(c)(2) and (d)(2)

[12] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[13] *See APO and Service Final Rule.*

[14] *See* 19 CFR 351.303.

timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of the estimated countervailing duties in the amount calculated in the final results of this administrative review for Yongding with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. If the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate (*i.e.,* 41.17 percent) [15] for the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, 19 CFR 351.213(d)(4) and (h)(2), and 19 CFR 351.221(b)(4).

Dated: March 27, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–07013 Filed 4–2–24; 8:45 am]

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[15] *See Final Determination.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–123]

Certain Corrosion Inhibitors From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Review, in Part; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that countervailable subsidies were provided to producers and exporters of corrosion inhibitors from the People's Republic of China (China), during the period of review (POR) from January 1, 2022, through December 31, 2022. In addition, Commerce is rescinding the review, in part, with respect to 16 companies. Interested parties are invited to comment on these preliminary results.

DATES: Applicable April 3, 2024.

FOR FURTHER INFORMATION CONTACT: Ted Pearson or Suresh Maniam, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2631 and (202) 482–1603, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 19, 2021, Commerce published in the **Federal Register** the countervailing duty order on corrosion inhibitors from China.[1] On May 9, 2023, Commerce published in the **Federal Register** the notice of initiation of an administrative review of the *Order*.[2] On June 23, 2023, Commerce selected Anhui Trust Chem Co., Ltd. (ATC) and Nantong Botao Chemical Co., Ltd. (Botao) for individual examination as the mandatory respondents in this administrative review.[3] On October 30, 2023, Commerce extended the deadline for the preliminary results of review until March 28, 2024.[4]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by the *Order* are corrosion inhibitors. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[6]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each subsidy program found countervailable, we preliminarily find that there is a subsidy, (*i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific).[7] For a full description of the methodology underlying our conclusions, including our reliance, in part, on adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

[1] *See Certain Corrosion Inhibitors from the People's Republic of China: Antidumping Duty and Countervailing Duty Orders,* 86 FR 14869 (March 19, 2021) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 29881 (May 9, 2023).

[3] *See* Memorandum, ''Respondent Selection,'' dated June 23, 2023.

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated October 30, 2023.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Countervailing Duty Administrative Review and Recission of Review in Part; 2022: Corrosion Inhibitors from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *Id.*

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received timely-filed withdrawal requests with respect to 16 companies, pursuant to 19 CFR 351.213(d)(1).[8] Because the withdrawal requests were timely filed, and no other parties requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to these 16 companies. For a complete list of companies, *see* Appendix II to this notice.

Preliminary Rate for Non-Selected Companies Under Review

There are three companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or based entirely on facts available. In this review, the preliminary rates calculated for ATC and Botao were above *de minimis* and not based entirely on facts available. Therefore, we are applying to the non-selected companies the average of the net subsidy rates calculated for ATC and Botao, which we calculated using the publicly-ranged sales data submitted by ATC and Botao.[9] This methodology to establish the rate for the non-selected companies uses section 705(c)(5)(A) of the Act, which governs the calculation of the ''all-others'' rate in an investigation, as guidance. For further information on the calculation of the non-selected respondent rate, refer to the section in the Preliminary Decision Memorandum entitled ''Non-Selected Companies Under Review.''

Preliminary Results of Review

Commerce preliminarily determines that the following net countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent *ad valorem*)
Anhui Trust Chem Co., Ltd.[10] ..	19.64
Nantong Botao Chemical Co., Ltd.[11]	17.02
Gold Chemical Limited	18.90
Jiangyin Delian Chemical Co., Ltd.	18.90
Kanghua Chemical Co., Ltd.[12]	18.90

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days after the date of publication of this notice.[13] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of these preliminary results of review.[14] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[15] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[16]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[17] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

[8] *See* Preliminary Decision Memorandum at ''Partial Rescission of Administrative Review.''

[9] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[10] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds the following companies to be cross-owned with ATC: Nanjing Trust Chem Co., Ltd. and Jiangsu Trust Chem Co., Ltd.

[11] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds the following companies to be cross-owned with Botao: Rugao Connect Chemical Co., Ltd.; Rugao Jinling Chemical Co., Ltd.; and Nantong Yutu Group Co., Ltd.

[12] Formerly known as Nantong Kanghua Chemical Co., Ltd. *See Certain Corrosion Inhibitors from the People's Republic of China: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 88 FR 1357 (January 10, 2023).

[13] *See* 19 CFR 351.224(b).

[14] *See* 19 CFR 351.309(c)(1)(ii).

[15] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[16] *See* 19 351.309(c)(2) and (d)(2).

[17] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[18] *See APO and Service Final Rule.*

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.221(b)(4)(i), we preliminarily determined subsidy rates in the amounts shown above for the producers/exporters shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review.

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2021, through December 31, 2021, in accordance with 19 CFR 351.212(c)(l)(i). For the companies remaining in the review, we intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce also intends upon publication of the final results, to instruct U.S. Customs and Border Protection (CBP) to collect cash deposits of the estimated countervailing duties in the amounts calculated in the final results of this review for the respective companies listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. If the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: March 28, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

Companies Rescinded From Review

1. Alfa Aesar China Chemical Co., Ltd.
2. Focus Chemical B.V.
3. Haruno Sangyo Kaisha, Ltd.
4. Johoku Chemical Co., Ltd.
5. KD Finechem Co., Ltd.
6. New Essential Corp.
7. Sagar Speciality Chemicals Pvt., Ltd.
8. Shanghai Sunwise Chemical Co., Ltd.
9. Sinochem Pharmaceutical Co., Ltd.
10. Tianjin Jinbin International Trade
11. TotalEnergies Lubrifiants
12. Vcare Medicines
13. Wuxi Base International Trade Co., Ltd.
14. Xiamen Amity Industry & Trade Co., Ltd.
15. Yasho Industries Pvt. Ltd.
16. Zaozhuang Kerui Chemicals Co., Ltd.

[FR Doc. 2024–07071 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Department of Defense Federal Advisory Committee Meeting—Defense Innovation Board

AGENCY: Office of the Under Secretary of Defense for Research and Engineering (USD(R&E)), Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Innovation Board (DIB) will take place.

DATES: Open to the public Wednesday, April 17, 2024, from 12:30 p.m. to 2:00 p.m. Eastern Standard Time.

ADDRESSES: The open meeting will take place virtually, via the Defense Visual Information Distribution Service.

FOR FURTHER INFORMATION CONTACT: Dr. Marina Theodotou, the Designated Federal Officer (DFO) at (571) 372–7344 (voice) or *osd.innovation@mail.mil.* Mailing address is Defense Innovation Board, 4800 Mark Center Drive, Suite 15D08, Alexandria, VA 22350–3600. Website: *https://innovation.defense.gov.* The most up-to-date changes to the meeting agenda and link to the virtual meeting can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA'') and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Due to circumstances beyond the control of the DFO and the DoD, the DIB was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its April 17, 2024 meeting. Accordingly, the Advisory Committee Management Officer for the DoD, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Purpose of Meeting: The mission of the DIB is to provide the Secretary of Defense, the Deputy Secretary of Defense, and the USD(R&E) independent advice and strategic insights on emerging and disruptive technologies and their impact on national security, adoption of commercial sector innovation best practices, and ways to leverage the U.S. innovation ecosystem to align structures, processes, and human capital practices to accelerate and scale innovation adoption, foster a culture of innovation and an experimentation mindset, and enable the DoD to build enduring advantages. The DIB focuses on innovation-related issues and topics raised by the Secretary of Defense, the Deputy Secretary of Defense, or the USD(R&E). The objective of this DIB meeting is to provide the public with an update on the current studies as well as obtain, review, and evaluate information related to the DIB's mission and studies.

Agenda: The DIB's open meeting will take place on April 17, 2024, from 12:30 p.m. to 2:00 p.m. The DIB DFO, Dr. Marina Theodotou, will open the meeting and introduce the DIB Chair,

Michael Bloomberg for his welcome and opening remarks. The DIB Chair and members will discuss relevant innovation topics through conversation and Q&A, share updates on the status of current studies, and continue gathering data and insights to inform the DIB's current studies through an open discussion with diverse speakers. Guest speakers have been confirmed to inform current studies, as follows:

''Optimizing How We Innovate with Our Allies and Partners''—

1. Chief Master Sergeant Ron Lerch—Senior Enlisted Leader Space Systems Command
2. Mr. Sander Oude Hengel—Defense Attaché for Cooperation, Embassy of the Netherlands in Washington, DC speaking in his capacity as chair of the Defense Memorandum of Understanding Attaches Group

''Aligning Incentives to Drive Faster Tech Adoption''—

1. Colonel Kristi Saling—Chief Talent Officer, U.S. Army
2. Captain Chris Aliperti—Mechanical Engineering Instructor, U.S. Military Academy; Co-Founder and Director, Marne Innovation Center

The DFO will read written public comments into the meeting record, and the Chair to provide closing remarks. The DFO will adjourn the public meeting.

Meeting Accessibility: Pursuant to Federal statutes and regulations (the FACA and 41 CFR 102–3.140 and 102–3.150), the open meeting will be accessible to the public virtually on April 17, 2024, from 12:30 p.m. to 2:00 p.m. Members of the public wishing to attend the meeting virtually will be able to access a link published on the DIB website the morning of the meeting.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 1009(a)(3) of the FACA, the public or interested organizations may submit written comments or statements to the DIB in response to the stated agenda of the meeting or regarding the DIB's mission in general. Written comments or statements should be submitted to Dr. Marina Theodotou, the DFO, via email to *osd.innovation@mail.mil.* Comments or statements must include the author's name, title or affiliation, address, and daytime phone number. The DFO must receive written comments or statements being submitted in response to the agenda set forth in this notice by 12:00 p.m. on April 14th, 2024 to be considered by the DIB. The DFO will review all timely submitted written comments or statements with the DIB Chair and ensure the comments are provided to all members before the meeting. Written comments or statements received after this date may not be provided to the DIB until its next scheduled meeting. Please note that all submitted comments and statements will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the DIB's website.

Dated: March 28, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–07053 Filed 4–2–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee for the Prevention of Sexual Misconduct; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee for the Prevention of Sexual Misconduct (DAC–PSM) will take place.

DATES: DAC–PSM will hold a meeting open to the public on Wednesday, April 10, 2024, from 9 a.m. to 3 p.m. (EST).

ADDRESSES: The meeting may be accessed by videoconference. Information for accessing the videoconference will be provided after registering. (Pre-meeting registration is required. See guidance in **SUPPLEMENTARY INFORMATION,** ''Meeting Accessibility''.)

FOR FURTHER INFORMATION CONTACT: Dr. Suzanne Holroyd, Designated Federal Officer (DFO), (571) 372–2652 (voice), *osd.mc-alex.ousd-p-r.mbx.DAC-PSM@mail.mil* (email). Website: *www.sapr.mil/DAC–PSM.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Defense Advisory Committee for the Prevention of Sexual Misconduct was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its April 10, 2024 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of chapter 10 of title 5 United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available on the DAC–PSM website (*www.sapr.mil/DAC–PSM*). Materials presented in the meeting may also be obtained on the DAC–PSM website.

Purpose of the Meeting: The purpose of the meeting is for the DAC–PSM to receive briefings and have discussions on topics related to the prevention of sexual misconduct within the Armed Forces of the United States.

Agenda: Wednesday, April 10, 2024, from 9 a.m. to 3 p.m. Eastern Standard Time (EST)—9:00 a.m. Meeting Open (Roll Call and Opening Remarks); 9:15 a.m. Brief: Office of People Analytics on Measurement of Risk and Protective Factors for Harmful Behaviors; 10:45 a.m. Brief: DoD Violence Prevention Cell on Prevention Research Agenda; 12:45 p.m. Panel: Service Representatives on Professional Military Education Instructor Preparation.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public from 9:00 a.m. to 3:00 p.m. EST on April 10, 2024. The meeting will be held by videoconference. All members of the public who wish to attend must register by contacting DAC–PSM at *osd.mc-alex.ousd-p-r.mbx.DAC-PSM@mail.mil* or by contacting Dr. Suzanne Holroyd at (571) 372–2652 no later than Friday, April 5, 2024 (by 5:00 p.m. EST). Once registered, the web address and/or audio number will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Dr. Suzanne Holroyd at *osd.mc-alex.ousd-p-r.mbx.DAC-PSM@mail.mil* or (571) 372–2652 no later than Friday, April 5, 2024 (by 5:00 p.m. EST) so that appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140, and 5 U.S.C. 1009(a)(3), interested persons may submit a written statement to the DAC–PSM. Individuals submitting a statement must submit their statement no later than 5 p.m. EST, Friday, April 5, 2024 to Dr. Suzanne

Holroyd at (571) 372–2652 (voice) or to *osd.mc-alex.ousd-p-r.mbx.DAC-PSM@mail.mil* (email). If a statement pertaining to a specific topic being discussed at the planned meeting is not received by Friday, April 5, 2024, then it may not be provided to, or considered by, the DAC–PSM during the April 10, 2024, meeting. The DFO will review all timely submissions with the DAC–PSM Chair and ensure such submissions are provided to the members of the DAC–PSM before the meeting. Any comments received by the DAC–PSM will be posted on the DAC–PSM website (*www.sapr.mil/DAC–PSM*).

Dated: March 27, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–07084 Filed 4–2–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF ENERGY

DOE/NSF Nuclear Science Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual meeting of the DOE/NSF Nuclear Science Advisory Committee (NSAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Friday, April 26, 2024; 9:00 a.m. to 5:00 p.m. EST.

ADDRESSES: Hilton Arlington National Landing, 2399 Richmond Highway, Arlington, VA 22202, 703–418–6800. Information to participate virtually can be found on the NSAC website closer to the meeting at: *https://science.osti.gov/np/nsac/meetings.*

FOR FURTHER INFORMATION CONTACT: Brenda L. May, Committee Manager, NSAC, 301–903–0536, Email: *Brenda.May@science.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of the Committee is to provide advice and guidance on a continuing basis to the Department of Energy and the National Science Foundation on scientific priorities within the field of basic nuclear science research.

Tentative Agenda:

- Call to Order, Introductions, Review of the Agenda
- Update from the Department of Energy and National Science Foundation's Nuclear Physics Office's
- Presentation of the Report on Facilities
- Discussion of the Facilities Report
- Supporting the Workforce Proposals in the LRP from DOE & NSF
- NSAC Business/Discussions
- Public Comment

Public Participation: The meeting is open to the public in-person and virtually. Please check *https://science.osti.gov/np/nsac* for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact Brenda L. May at *Brenda.May@science.doe.gov.* You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. If you have any questions or need a reasonable accommodation under the Americans with Disabilities Act for this event, please send your request to Brenda L. May at *Brenda.May@science.doe.gov,* two weeks but no later than 48 hours, prior to the event. Closed captions will be enabled.

Minutes: The minutes of the meeting will be available for review on the U.S. Department of Energy's Office of Nuclear Physics website at *https://science.osti.gov/np/nsac/meetings.*

Signing Authority: This document of the Department of Energy was signed March 28, 2024, by David Borak, Deputy Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 29, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–07074 Filed 4–2–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3211–010]

Power Authority of the State of New York; Notice of Availability of Final Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a new license to continue to operate and maintain the Hinckley (Gregory B. Jarvis) Hydroelectric Project (Jarvis Project). The Jarvis Project is located on West Canada Creek, near the Hamlet of Hinckley in the counties of Oneida and Herkimer, New York.

The final EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the final EA via the internet through the Commission's Home Page (*http://www.ferc.gov/*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

For further information, contact Andy Bernick at (202) 502–8660 or by email at *andrew.bernick@ferc.gov*.

Dated: March 28, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–07043 Filed 4–2–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Numbers: RP24–582–000]

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Applicants: El Paso Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco Apr 2024) to be effective 4/1/2024.

Filed Date: 3/27/24.

Accession Number: 20240327–5230.

Comment Date: 5 p.m. ET 4/8/24.

Docket Numbers: RP24–583–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreements Update (Hartree 614700 615843 610670 Apr 2024) to be effective 4/1/2024.

Filed Date: 3/27/24.

Accession Number: 20240327–5251.

Comment Date: 5 p.m. ET 4/8/24.

Docket Numbers: RP24–584–000.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Compliance filing: Flow Through of Penalty Revenues Report filed on 3–28–24 to be effective N/A.

Filed Date: 3/28/24.

Accession Number: 20240328–5007.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–585–000.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Compliance filing: Flow Through of Cash-Out Revenues filed on 3–28–24 to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5010.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–586–000.

Applicants: Enable Gas Transmission, LLC.

Description: Compliance filing: 2024 Annual IT Revenue Crediting Filing to be effective N/A.

Filed Date: 3/28/24.

Accession Number: 20240328–5016.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–587–000.

Applicants: Enable Gas Transmission, LLC.

Description: 4(d) Rate Filing: Fuel Tracker Filing—Effective May 1, 2024 to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5020.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–588–000.

Applicants: Enable Mississippi River Transmission, LLC.

Description: Compliance filing: 2024 Annual SCT Revenue Crediting Filing to be effective N/A.

Filed Date: 3/28/24.

Accession Number: 20240328–5023.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–589–000.

Applicants: ETC Tiger Pipeline, LLC.

Description: 4(d) Rate Filing: Negotiated Rate Filing—CIMA to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5081.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–590–000.

Applicants: Equitrans, L.P.

Description: 4(d) Rate Filing: OVCX Nonconforming and Negotiated Rate Agreements to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5091.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–591–000.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: 4(d) Rate Filing: Negotiated Rates Filing—Citizens to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5094.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–592–000.

Applicants: Equitrans, L.P.

Description: 4(d) Rate Filing: Negotiated Rate Agreements—4–1–2024 to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5095.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–593–000.

Applicants: Kern River Gas Transmission Company.

Description: Annual Gas Compressor Fuel & LAUF Report of Kern River Gas Transmission Company.

Filed Date: 3/28/24.

Accession Number: 20240328–5127.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–594–000.

Applicants: WBI Energy Transmission, Inc.

Description: 4(d) Rate Filing: 2024 Non-Conforming Negotiated SA—Kentex IT–839 to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5125.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–595–000.

Applicants: Columbia Gas Transmission, LLC.

Description: 4(d) Rate Filing: OTRA Summer 2024 to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5132.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–596–000.

Applicants: Southwest Gas Storage Company.

Description: 4(d) Rate Filing: Baseline Original Volume No. 1–A Filing to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5144.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–597–000.

Applicants: Southwest Gas Storage Company.

Description: 4(d) Rate Filing: Add GT&C Section 20—Non-Conforming Agreements to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5147.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–598–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreements Filing (TMV_EcoEnergy Apr 24) to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5152.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–599–000.

Applicants: Gulf Run Transmission, LLC.

Description: 4(d) Rate Filing: Amendment No. 2—NRA with TGC to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5153.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–600–000.

Applicants: Hardy Storage Company, LLC.

Description: 4(d) Rate Filing: RAM 2024 to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5160.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–601–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: 4(d) Rate Filing: Negotiated Rates—FTP—LLOG Permt Rls to KUSA to be effective 4/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5161.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–602–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: 4(d) Rate Filing: Non-Conforming Agreement Update (Anadarko 33666000) to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5171.

Comment Date: 5 p.m. ET 4/9/24.

Docket Numbers: RP24–603–000.

Applicants: Northern Border Pipeline Company.

Description: 4(d) Rate Filing: Electric Compressor Surcharge 2024 to be effective 5/1/2024.

Filed Date: 3/28/24.

Accession Number: 20240328–5173.

Comment Date: 5 p.m. ET 4/9/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: March 28, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–07046 Filed 4–2–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15340–001]

Pembroke Tidal Power Project, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On March 1, 2024, Pembroke Tidal Power Project, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Pembroke Tidal Power Plant Project No. 15340 (project), to be located at the mouth of Cobscook Bay near the Town of Pembroke, Washington County, Maine. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following new features: (1) a 9.8-foot-wide, 1,640-foot-long concrete tidal diversion dam; (2) a 118-foot-long, 141-foot-wide concrete powerhouse caisson located inline of the tidal diversion dam near the midpoint, housing four turbine-generators each with a generating capacity of 5.3 megawatts; (3) a 40-ton traveling gantry boat lift; (4) two impervious core, sand and crushed rock embankments (one 689-foot-long embankment from Leighton Neck, a peninsula south of the proposed project site, and one 164-foot-long embankment from Hershey Neck, a peninsula north of the proposed site); (5) a 2.5-mile-long, 35-kilovolt transmission line connecting the turbine-generator units to the regional grid; and (6) appurtenant facilities. The proposed project would have an estimated annual generation of 87,000-megawatt-hours.

Applicant Contact: Brad Fletcher, Pembroke Tidal Power Project, LLC, 62 Portland Rd., Ste. 25A, Kennebunk, ME 04043; phone: (612) 315–9053; email: *brad@nestarenergy.com.*

FERC Contact: Nathan Tatum; phone: (202) 502–7313, or by email at *Nathan.Tatum@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15340–001.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

More information about this project, including a copy of the application, can be viewed on the Commission's website (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number, excluding the last three digits (P–15340), in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: March 28, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–07042 Filed 4–2–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24–153–000.
Applicants: Furry Creek Power Ltd.
Description: Furry Creek Power Ltd. submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 3/28/24.
Accession Number: 20240328–5110.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: EG24–154–000.
Applicants: McNair Creek Hydro Limited Partnership.
Description: McNair Creek Hydro Limited Partnership submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 3/28/24.
Accession Number: 20240328–5117.
Comment Date: 5 p.m. ET 4/18/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24–1071–001.
Applicants: Consumers Energy Company.
Description: Tariff Amendment: Amended Contract-RS with Alpena Pwr. Co. & Notice of Cancellation (ER24–1071–) to be effective 4/1/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5083.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1164–001.
Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.
Description: Tariff Amendment: American Electric Power Service Corporation submits tariff filing per 35.17(b): Amendment to ILDSA, SA No. 5120 to be effective 4/1/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5241.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1616–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: AMD of Notice of Cancellation WMPA, SA No. 6847; AF2–102 to be effective 5/27/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5192.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1631–000.
Applicants: Duquesne Light Company, PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Duquesne Light Company submits tariff filing per 35.13(a)(2)(iii: Duquesne submits Interconnection Agreement, Service Agreement No. 6648 to be effective 5/31/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5075.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1632–000.
Applicants: PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Ministerial Revisions to PJM Tariff, Attachment Q to be effective 10/28/2023.
Filed Date: 3/28/24.
Accession Number: 20240328–5077.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1633–000.
Applicants: Mississippi Power Company.
Description: 205(d) Rate Filing: Modifications to the Gulf States TFA to be effective 5/28/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5085.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1634–000.
Applicants: Midcontinent Independent System Operator, Inc., Entergy Services, LLC.
Description: 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2024–03–28_Entergy Companies Attachment O Clean Up to be effective 6/1/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5089.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1635–000.
Applicants: Southern California Edison Company.
Description: 205(d) Rate Filing: LGIA, Sapphire Solar (TOT976/SA No. 309) to be effective 3/29/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5111.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1636–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 205(d) Rate Filing: 2024–03–28_Attachment MM True-up for ATC, MRES, & OTP to be effective 6/1/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5141.
Comment Date: 5 p.m. ET 4/18/24.

Docket Numbers: ER24–1637–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: 205(d) Rate Filing: Amendment to Rate Schedule FERC No. 29 to be effective 5/28/2024.
Filed Date: 3/28/24.
Accession Number: 20240328–5157.
Comment Date: 5 p.m. ET 4/18/24.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES24–27–000.

Applicants: NextEra Energy Transmission MidAtlantic, Inc.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of NextEra Energy Transmission MidAtlantic, Inc.

Filed Date: 3/27/24.

Accession Number: 20240327–5300.

Comment Date: 5 p.m. ET 4/17/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: March 28, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–07047 Filed 4–2–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 2322–069; 2322–071; and 2325–100; Project No. 2574–092; Project No. 2611–091]

Brookfield White Pine Hydro, LLC; Merimil Limited Partnership; Hydro-Kennebec, LLC; Notice of Availability of the Draft Environmental Impact Statement for the Shawmut Hydroelectric Project, Lockwood Hydroelectric Project, Hydro-Kennebec Hydroelectric Project, and Weston Hydroelectric Project

In accordance with the National Environmental Policy Act of 1969 [1] and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Shawmut Hydroelectric Project (FERC No. 2322), the proposed Interim Species Protection Plan for the Shawmut Project, and the Final Species Protection Plan for the Lockwood Hydroelectric Project (FERC No. 2574), Hydro-Kennebec Hydroelectric Project (FERC No. 2611), and Weston Hydroelectric Project (FERC No. 2325) and has prepared a draft environmental impact statement (EIS) for the projects. All four projects are located on the Kennebec River, in Kennebec and Somerset Counties, Maine.

The draft EIS contains staff's analysis of the applicant's proposal and the alternatives for licensing the Shawmut Project, and amending the licenses for the Shawmut, Lockwood, Hydro-Kennebec, and Weston projects. The draft EIS documents the views of governmental agencies, non-governmental organizations, affected Native-American tribes, the public, the license applicant, and Commission staff.

The Commission provides all interested persons with an opportunity to view and/or print the EIS via the internet through the Commission's Home Page (*http://www.ferc.gov/*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595, or *OPP@ferc.gov.*

All comments must be filed by June 4, 2024.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket numbers P–2322–069; P–2322–071; P–2325–100; P–2574–092; and P–2611–091.

Anyone may intervene in this proceeding based on this draft EIS (18 CFR 380.10). You must file your request to intervene as specified above.[2] You do not need intervenor status to have your comments considered.

In addition to or in lieu of sending written comments, you are invited to attend a public meeting that will be held to receive comments on the draft EIS. Commission staff will hold two public meetings for the purpose of receiving comments on the draft EIS. At the meetings, resource agency personnel and other interested persons will have the opportunity to provide oral and written comments and recommendations regarding the draft EIS. The meetings will be recorded by a court reporter, and all statements (verbal and written) will become part of the Commission's public record for the projects. All interested individuals and entities will be invited to attend one or both of the public meetings. A notice detailing the exact date, time, and location of the public meetings will be forthcoming.

For further information, contact Marybeth Gay at *Marybeth.gay@ferc.gov* or 202–502–6125, or Matt Cutlip at *Matt.Cutlip@ferc.gov* or 503–552–2762.

Dated: March 28, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–07044 Filed 4–2–24; 8:45 am]

BILLING CODE 6717–01–P

[1] National Environmental Policy Act of 1969, amended (Pub. L. 91–190. 42 U.S.C. 4321–4347, as amended by Pub. L. 94–52, July 3, 1975, Pub. L. 94–83, August 9, 1975, Pub. L. 97–258, 4(b), September 13, 1982, Pub. L. 118–5, June 3, 2023).

[2] Interventions may also be filed electronically via the internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2153–066]

United Water Conservation District; Notice of Intent To Prepare an Environmental Assessment

On May 26, 2020, as supplemented on September 7, 2021, February 2, 2022, September 8, 2022, and January 3, 2024, United Water Conservation District (UWCD) filed a non-capacity amendment application for the Santa Felicia Project No. 2153 (project). The project is located on Piru Creek in Ventura County, California. The project occupies federal lands administered by the U.S. Forest Service.

The purpose of the amendment application is to implement the Santa Felicia Dam Safety Improvement Project. The Dam Safety Project proposes to replace the existing outlet works and modify the existing spillway and dam to address the potential for failure under seismic loading conditions and increase the conveyance capacity to sufficiently pass the inflow design flood. On June 1, 2020, the Commission issued a public notice of UWCD's request for a license amendment soliciting comments, motions to intervene, and protests. No comments, motions to intervene, or protests were received.

This notice identifies Commission staff's intention to prepare an

environmental assessment (EA) for the project and the planned schedule for the completion of the environmental review. The target date for staff to issue the EA is July 2024.[1] Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties and all comments filed on the EA will be analyzed by staff and considered in the Commission's final decision on the proceeding.

With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal to cooperate in the preparation of the EA planned to be issued July 2024. Agencies wishing to cooperate, or further discuss the benefits, responsibilities, and obligations of the cooperating agency role, should contact staff listed at the bottom of this notice by April 18, 2024. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Any questions regarding this notice may be directed to David Rudisail at (202) 502–6376 or *David.rudisail@ferc.gov*.

Dated: March 28, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–07045 Filed 4–2–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 42 U.S.C. 4336a(g)(1)(B) requires lead federal agencies to complete EAs within 1 year of the agency's decision to prepare an EA. This notice establishes the Commission's intent to prepare an EA for the project; therefore, the EA must be issued within 1 year of the issuance date of this notice.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0492; FRL–11842–01–OCSPP]

Existing Stocks Order for Dicamba Products Previously Registered for Over-the-Top Use on Dicamba-Tolerant Cotton and Soybean

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On February 14, 2024, EPA issued its Existing Stocks Order for Dicamba Products Previously Registered for Over-the-Top Use on Dicamba-Tolerant Cotton and Soybean. EPA hereby provides notice of the existing stocks order. EPA issued the existing stocks order following the February 6, 2024, order and judgement by the District of Arizona vacating the registrations for three products, XtendiMax® with VaporGrip® Technology (''XtendiMax''), Engenia® Herbicide (''Engenia''), and A21472 Plus VaporGrip® Technology (Tavium® Plus VaporGrip® Technology) (''Tavium''). As of February 6, 2024, these products are no longer registered, and it is unlawful under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to sell or distribute them except to the extent otherwise authorized by EPA.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPP–2020–0492, is available online at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

II. What action did the Agency take?

On February 6, 2024, the District of Arizona issued an order and judgment vacating the registrations of three dicamba products (XtendiMax® with VaporGrip® Technology (EPA Reg. No. 264–1210) (''XtendiMax''), Engenia® Herbicide (EPA Reg. No. 7969–472) (''Engenia''), and A21472 Plus VaporGrip® Technology (Tavium® Plus VaporGrip® Technology) (EPA Reg. No. 100–1623) (''Tavium'')) previously registered for over-the-top use on dicamba-tolerant cotton and soybean. These products are no longer registered, and it is unlawful under FIFRA to sell or distribute them except to the extent otherwise authorized by EPA. To allow for the legal and orderly disposition of those products, EPA issued an existing stocks order for the three products on February 14, 2024, and revised the order on March 12, 2024.

III. Provisions for Disposition of Existing Stocks

Pursuant to FIFRA Section 6(a)(1), on February 14, 2024, EPA issued an existing stocks order for XtendiMax® with VaporGrip® Technology (EPA Reg. No. 264–1210), Engenia® Herbicide (EPA Reg. No. 7969–472), and A21472 Plus VaporGrip® Technology (Tavium® Plus VaporGrip® Technology) (EPA Reg. No. 100–1623). EPA revised the order on March 12, 2024. The order will remain in effect unless or until subsequent action is taken. The issuance of the order did not follow a public hearing. EPA's issuance of the order is a final agency action, judicially reviewable under FIFRA § 16(a) (7 U.S.C. 136n). Any sale, distribution, or use of existing stocks of these products inconsistent with the order is prohibited.

For purposes of the order, ''existing stocks'' is defined as those stocks of previously registered pesticide products that are currently in the United States and were packaged, labeled, and released for shipment prior to February 6, 2024 (the effective date of the District of Arizona's vacatur of the dicamba registrations). Pursuant to FIFRA section 6(a)(1), the order issued on February 14, 2024 (and revised on March 12, 2024) includes the following existing stocks provisions:

1. *Sale or Distribution by the Registrants.* As of February 6, 2024, sale or distribution by the registrants of these products is prohibited, except for the purposes of proper disposal or to facilitate lawful export.

2. *Sale or Distribution by Persons other than the Registrants.* Persons other than the registrants, including but not limited to co-ops and commercial distributors, who are already in possession of these products as of February 6, 2024, may sell or distribute these products until the end date for sale and distribution of existing stocks identified in Tables 1 or 2 (depending on your state); except that such persons may distribute these products after the date identified in Tables 1 or 2 solely for purposes of proper disposal, lawful export, or to facilitate return to the manufacturer.

3. *Distribution or Sale by Commercial Applicators.* Notwithstanding paragraph 2, for the purpose of facilitating use no later than the relevant end date for use of existing stocks identified in Tables 1 or 2, distribution or sale of existing stocks of these dicamba products that are in the possession of commercial applicators is permitted until the relevant end date for use in Tables 1 or 2.

4. *Use of Existing Stocks.* As of the date of the order, use of XtendiMax, Engenia, and Tavium is permitted until the relevant date identified in Tables 1 or 2, provided that such use of existing stocks is consistent in all respects with the previously approved labeling accompanying the product.

TABLE 1—END DATES FOR SALE, DISTRIBUTION, AND USE OF EXISTING STOCKS

State(s)	End date for sale & distribution of existing stocks for use (para. 2)	End date for use of existing stocks (paras. 3 & 4)*
IA, IL, IN	Sale & Distribution of XtendiMax, Engenia, or Tavium: May 13, 2024.	Use of XtendiMax, Engenia, or Tavium: June 12, 2024, or V4 growth stage (soybean) or 1st square growth stage (cotton) in 2024, whichever comes first.
MN	Sale & Distribution of XtendiMax, Engenia, or Tavium to Purchasers South of I–94: May 13, 2024.	Use of XtendiMax, Engenia, or Tavium south of I–94: June 12, 2024.
	Sale & Distribution of XtendiMax, Engenia, or Tavium to Purchasers North of I–94: May 31, 2024.	Use of XtendiMax, Engenia, or Tavium north of I–94: June 30, 2024.
SD	Sale & Distribution of XtendiMax, Engenia, or Tavium: May 21, 2024.	Use of XtendiMax, Engenia, or Tavium: June 20, 2024.
AL, AZ, CO, DE, FL (excluding Palm Beach County), GA, KS, KY, LA, MD, MI, MS, MO, NE, NJ, NM, NY, NC, ND, OH, OK, PA, SC, TN (excluding Wilson County), TX, VA, WV, WI.	Sale & Distribution of XtendiMax, Engenia, or Tavium for Use on Dicamba-Tolerant Soybean: May 31, 2024.	Use of XtendiMax, Engenia, or Tavium on Dicamba-Tolerant Soybean: June 30, 2024.
	Sale & Distribution of XtendiMax, Engenia, or Tavium for Use on Dicamba-Tolerant Cotton: June 30, 2024.	Use of XtendiMax, Engenia, or Tavium on Dicamba-Tolerant Cotton: July 30, 2024.

*The end dates for the use of existing stocks outlined in this Table are consistent with the application cut-off dates on the previously approved labeling of the formerly registered dicamba products at the time of vacatur. EPA believes these cut-off dates are appropriate because they will minimize confusion amongst the grower community. Furthermore, establishing cut-off dates in the existing stocks order consistent with those on the previously approved labeling is expected to encourage lawful use.

TABLE 2—END DATES FOR SALE, DISTRIBUTION, AND USE OF EXISTING STOCKS IN ARKANSAS

State	End date for sale & distribution of existing stocks for use (para. 2)	End date for use of existing stocks (paras. 3 & 4)
AR	Sale & Distribution of XtendiMax, Engenia, or Tavium: May 31, 2024.	Use of XtendiMax, Engenia, or Tavium: June 30, 2024.

*The end date for the use of existing stocks outlined in this Table is consistent with the application cut-off date under Ark. Admin. Code 209.02.4–XIII. EPA did not intend its February 14, 2024, order to allow use of these dicamba products beyond any state-imposed application cutoff dates. Nevertheless, EPA added this cut-off date to the order to provide clarity to users in Arkansas.

Additional information regarding the existing stocks order may be found in *https://www.regulations.gov/docket/EPA-HQ-OPP-2020-0492.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 26, 2024.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2024–06979 Filed 4–2–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0223; FRL–11828–01–OCSPP]

Chlorpyrifos; Notice of Receipt of Request To Cancel Certain Pesticide Registrations and Amend Registrations To Terminate/Amend Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of request by the registrants in Table 3 of Unit II to voluntarily cancel registrations of certain products containing the pesticide chlorpyrifos or to amend their chlorpyrifos registrations to terminate/delete one or more uses. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests or if the registrants withdraw their request to cancel these uses or products. If these requests are granted, any sale, distribution, or use of the products listed in this notice after the registrations have been cancelled or the uses have been terminated would need to be consistent with the terms as described in the final cancellation order.

DATES: Comments must be received on or before May 3, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0223, is available at *https://*

*www.regulations.*gov. Additional instructions on visiting the docket, along with more information about dockets generally, are available at *https://www.epa.gov/dockets.* For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Patricia Biggio, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI, and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What action is the Agency taking?

This notice announces receipt by the Agency of requests from the registrants in Table 3 of Unit II to cancel certain pesticide products or amend registrations by terminating certain uses registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). These registrations are listed in sequence by registration number in Table 1 and Table 2 of this Unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the **Federal Register** canceling registrations and terminating uses as requested.

TABLE 1—CHLORPYRIFOS PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR TERMINATION OF SPECIFIC USES

Registration No.	Product name	Company	Uses to be terminated
81964–21	Chlorpyrifos 61.5% MUP.	Chemstarr, LLC	Food processing plants (food and non-food areas).
84229–20	Chlorpyrifos 4 EC	Tide International	Food uses: Alfalfa, apple tree trunk, asparagus. *Brassica* (Cole) leafy vegetables: Radish, rutabaga, turnip; cauliflower; broccoli, Brussels sprout, cabbage, Chinese cabbage, collards, kale, kohlrabi; citrus; calamondin, chironja, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin (tangerine), pummelo, Satsuma mandarin, sour orange, sweet orange, tangelo, tangor; corn (field and sweet); cotton; cranberry; legume vegetable: Adzuki bean, bean, blackeyed pea, broad bean (dry and succulent), catjang, chickpea, cowpea, crowder pea, English pea, field bean, field pea, garden pea, grain lupin, green pea, guar, lima bean (dry and green), kidney bean, lablab bean, lentil, moth bean, mung bean, navy bean, pea, pigeon pea, pinto bean, rice bean, southern pea, sweet lupin, tepary bean, urd bean, white lupin, white sweet lupin; onion (dry bulb); peanut; peppermint; sorghum (grain sorghum (milo)); soybean; spearmint; sugarbeet; sunflower; sweet potato; tree fruits: cherry, nectarine, peach, pear, plum, and prune; tree nuts: almonds, filbert, pecan and walnut; and wheat.

TABLE 2—CHLORPYRIFOS PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

EPA Registration No.	Product name	Company	Active ingredients
89459–72	Equil Chlorpyrifos ULV 1	Central Garden & Pet	Chlorpyrifos.
89459–73	Equil Chlorpyrifos ULV 2	Central Garden & Pet	Chlorpyrifos.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION OR TERMINATION OF USES

EPA Company No.	Company name and address
81964	Chemstarr, LLC, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
84229	Tide International USA, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
89459	Central Garden & Pet, 1501 E Woodfield Rd., Suite 200W, Schaumburg, IL 60173.

III. What is the Agency's authority for taking these actions?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or to cancel registered uses for a pesticide. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrant requests a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 3 of Unit II have requested that EPA waive the 180-day comment period. Accordingly, EPA is providing a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action.

If the requests for voluntary cancellation and amendments to terminate uses are granted, the Agency intends to publish a final cancellation order in the **Federal Register**. In that order, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Tables 1 and 2 of Unit II.

Upon cancellation of the products identified in Table 2 of Unit II, the sale and distribution of these products will be prohibited, except for export consistent with FIFRA section 17 or for proper disposal. Use of existing stocks would be permitted until exhausted.

EPA is proposing to allow use of existing stocks of chlorpyrifos products identified in Table 1 of Unit II as follows: The sale and distribution of existing stocks would be permitted through April 30, 2025. After that date, products identified in Table 1 would not be allowed to be sold or distributed, unless none of the terminated uses appears on the product's labeling.

Use of existing stocks would be permitted through June 30, 2025. After that date, products identified in Table 1 would be allowed to be used only for non-food uses to the extent permitted by the label.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 29, 2024.

Timothy Kiely,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2024–07078 Filed 4–2–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11874–01–OAR]

Renewable Fuel Standard (RFS) Program Compliance; Rescheduled Webinar on Biogas Regulatory Reform Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of rescheduled webinar.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that it is rescheduling the date of the public webinar on the Biogas Regulatory Reform Rule (BRRR) provisions of the Renewable Fuel Standard (RFS) program from April 4, 2024, to April 12, 2024.

DATES: The webinar will be held on April 12, 2024, from 11 a.m.–3:30 p.m., Eastern Time. Additional information regarding the workshop appears below under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: All attendees must pre-register for the webinar by notifying the contact person listed under **FOR FURTHER INFORMATION CONTACT** by April 8, 2024. If you had already registered for the original webinar date, then you do not need to register again if you are able to attend on the rescheduled date. Additional information related to the webinar will be posted at: *https://www.epa.gov/renewable-fuel-standard-program/rfs-set-rule-implementation-webinars.* Interested parties should check the website for any updated information.

FOR FURTHER INFORMATION CONTACT: Nick Parsons, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency; telephone number: (734) 214–4479; email address: *RFS-Hearing@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is hosting a public webinar to discuss the implementation of the Biogas Regulatory Reform Rule (BRRR) provisions promulgated as part of the Renewable Fuel Standard (RFS) final rule for 2023–2025 (the ''Set Rule'').[1] These regulatory provisions include registration and reporting, and updated regulatory provisions for the production, distribution, and use of biogas as a renewable fuel.

The webinar was originally scheduled for April 4, 2024, and was announced by a **Federal Register** notice dated March 6, 2024.[2] The webinar is being rescheduled and will be held on April 12, 2024. Those who have already registered for the original webinar date do not need to re-register if they are able to attend on the rescheduled date.

During the webinar, EPA intends to discuss various aspects of the BRRR program, including:

- The implementation timeline for BRRR.
- An implementation overview of the BRRR program.
- EPA Central Data Exchange (CDX) registration for biogas producers, renewable natural gas (RNG) producers, RNG RIN separators, and performing required associations.
- Alternative measurement protocols.
- A curated question and answer session.

EPA will post an agenda approximately one week before the webinar at: *https://www.epa.gov/renewable-fuel-standard-program/rfs-set-rule-implementation-webinars.* Interested parties should check this website for any updated information.

If you require the services of an interpreter or special accommodations such as audio description, please pre-register for the webinar and describe your needs by April 8, 2024. EPA may not be able to arrange accommodations without advance notice. If you had already registered and informed us of the need for an interpreter or special accommodations, then you do not need

[1] 88 FR 44468 (July 12, 2023).

[2] 89 FR 15988 (March 6, 2024).

to notify us again if you are able to attend on the rescheduled date.

Byron Bunker,

Director, Compliance Division, Office of Transportation and Air Quality.

[FR Doc. 2024–07052 Filed 4–2–24; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Board of Directors Meeting

SUMMARY: Notice of the forthcoming regular meeting of the Board of Directors of the Farm Credit System Insurance Corporation (FCSIC), is hereby given in accordance with the provisions of the Bylaws of the FCSIC.

DATES: 10 a.m., Wednesday, April 10, 2024.

ADDRESSES: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to virtually attend, at least 24 hours in advance, visit *FCSIC.gov,* select ''News & Events,'' then select ''Board Meetings.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

FOR FURTHER INFORMATION CONTACT: If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

SUPPLEMENTARY INFORMATION: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public. The following matters will be considered:

Portions Open to the Public

- Approval of Minutes for February 7, 2024
- Quarterly FCSIC Financial Reports
- Quarterly Report on Insured Obligations
- Quarterly Report on Annual Performance Plan
- Annual Report on Investment Portfolio
- Payment from Allocated Insurance Reserves Accounts

Portions Closed to the Public

- Quarterly Report on Insurance Risk
- Presentation of 2023 Audit Results
- Executive Session of the FCSIC Board Audit Committee with the External Auditor

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2024–07062 Filed 4–2–24; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL ELECTION COMMISSION

[Notice 2024–10]

Filing Dates for the Colorado Special Election in the 4th Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: Colorado has scheduled a special election on June 25, 2024, to fill the U.S. House of Representatives seat in the 4th Congressional District vacated by Representative Ken Buck.

Committees required to file reports in connection with the Special General Election on June 25, 2024, shall file a 12-day Pre-General and a 30-Day Post-General Report.

ADDRESSES: 1050 First Street NE, Washington, DC 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, (202) 694–1100 or (800) 424–9530, *info@fec.gov.*

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

All principal campaign committees of candidates who participate in the Colorado Special General Election shall file a 12-day Pre-General Report on June 13, 2024, and a 30-day Post-General Report on July 25, 2024. (See chart below for the closing date for each report.)

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See chart below for the closing date for each report).

Unauthorized Committees (PACs and Party Committees)

Political committees not filing monthly are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Colorado Special General Election by the close of books for the applicable report(s). (See chart below for the closing date for each report.)

Committees filing monthly that make contributions or expenditures in connection with the Colorado Special General Election will continue to file according to the monthly reporting schedule.

Additional disclosure information for the Colorado special election may be found on the FEC website at *https://www.fec.gov/help-candidates-and-committees/dates-and-deadlines/.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and leadership PACs that are otherwise required to file reports in connection with the special election must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of $22,700 during the special election reporting periods. (See chart below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b), 110.17(e)(2), (f).

CALENDAR OF REPORTING DATES FOR COLORADO SPECIAL ELECTION

Report	Close of books [1]	Reg./cert. & overnight mailing deadline	Filing deadline
Political Committees Involved in the Special General (06/25/2024) Must File:			
Pre-General	06/05/2024	06/10/2024	06/13/2024
July Quarterly	—WAIVED—		
Post-General	07/15/2024	07/25/2024	07/25/2024

[1] The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.

CALENDAR OF REPORTING DATES FOR COLORADO SPECIAL ELECTION—Continued

Report	Close of books [1]	Reg./cert. & overnight mailing deadline	Filing deadline
October Quarterly	09/30/2024	10/15/2024	10/15/2024

Dated: March 29, 2024

On behalf of the Commission,

Sean J. Cooksey,

Chairman, Federal Election Commission.

[FR Doc. 2024–07051 Filed 4–2–24; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 201422.

Agreement Name: CMA CGM/COSCO Shipping/ONE Vessel Sharing Agreement.

Parties: CMA CGM S.A.; COSCO Shipping Lines Co., Ltd.; Ocean Network Express Pte. Ltd.

Filing Party: Draughn Arbona; CMA CGM.

Synopsis: This Agreement authorizes share liner shipping services operated by CMA CGM, COSCO SHIPPING and ONE in the trade between the East Coast of the United States, on one hand, and ports in Colombia, Ecuador, Peru, and Chile, on the other hand, utilizing vessels contributed, and independently operated, by each Party.

Proposed Effective Date: 03/26/2024.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/86555.

Dated: March 29, 2024.

Alanna Beck,

Federal Register Alternate Liaison Officer.

[FR Doc. 2024–07061 Filed 4–2–24; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Applications for Employment with the Board of Governors of the Federal Reserve System (FR 28; OMB No. 7100–0181).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Applications for Employment with the Board of Governors of the Federal Reserve System.

Collection identifier: FR 28.

OMB control number: 7100–0181.

General description of collection: The FR 28 is comprised of the Application for Employment (FR 28a), Applicant's Voluntary Self-Identification (FR 28s), Research Assistant Candidate Survey of Interests and Computer Experience (FR 28i), and Pre-Hire Conflict of Interest Screening Form (FR 28c).

The Application for Employment (FR 28a) collects information to determine the qualifications of applicants for employment with the Board (such as education and training, employment record, and other information since the time the applicant left high school). Among other things, the FR 28a is used to examine, rate, or assess the applicant's qualifications, and to contact the applicant to arrange an interview. The Applicant's Voluntary Self-Identification (FR 28s) is an optional form that collects information on the applicant's gender, race, and ethnicity. The Research Assistant Candidate Survey of Interests and Computer Experience (FR 28i) collects information on a Research Assistant (RA) applicant's level of interest in various economic topics and experience in different data analytics/programs. The Pre-Hire Conflict of Interest Screening Form (FR 28c) collects information from external applicants after they have been selected for an interview at the Board regarding certain financial interests that could pose a conflict of interest based on the duties of the position for which they are applying.

The information collected through the FR 28 is used to assist the Board in recruiting and hiring individuals for Board employment, retaining qualified employees, and periodically reviewing its hiring practices.

Frequency: Event-generated.

Respondents: Individuals seeking employment with the Board.

Total estimated number of respondents: 17,150.

Total estimated annual burden hours: 8,109.[1]

Current actions: On November 15, 2023, the Board published a notice in the **Federal Register** (88 FR 78363) requesting public comment for 60 days on the extension, without revision, of the FR 28. The comment period for this notice expired on January 16, 2024. The Board did not receive any comments.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024–07088 Filed 4–2–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Board Public Website Usability Surveys (FR 3076; OMB No. 7100–0366).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Board Public Website Usability Surveys.

Collection identifier: FR 3076.

OMB control number: 7100–0366.

General description of collection: The Board uses the ad hoc FR 3076 to seek input (1) from users or potential users of the Board's public website and social media tools, (2) about the Board's outreach, and (3) about other communication tools used by Board. The FR 3076 is offered to a diverse audience of individuals including consumers, bankers, media, government employees, educators, and others. Responses to the FR 3076 are used to help improve the usability and offerings on the Board's public website and other online public communications. The FR 3076 comprises two parts: surveys and focus groups. The frequency of the surveys and content of the questions varies as needs arise for feedback on different Board resources and from different audiences. The FR 3076 surveys may be conducted up to 12 times per year. In addition, the Board may conduct up to four focus group sessions per year.

Frequency: As needed.

Respondents: Individual users and potential users of the Board's public website.

Total estimated number of respondents: 120.

Total estimated annual burden hours: 420.[1]

Current actions: On November 14, 2023, the Board published a notice in the **Federal Register** (88 FR 78021) requesting public comment for 60 days on the extension, without revision, of the FR 3076. The comment period for this notice expired on January 16, 2024. The Board did not receive any comments.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024–07093 Filed 4–2–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Government-Administered, General-Use Prepaid Card Survey (FR 3063; OMB No. 7100–0343).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 28.

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 3076.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Government-Administered, General-Use Prepaid Card Survey.

Collection identifier: FR 3063.

OMB control number: 7100–0343.

General description of collection: The FR 3063 survey collects data from issuers of government-administered, general-use prepaid cards, including information on the prepaid card program, the number of cards outstanding, card funding, purchase transactions, interchange fees, and cardholder fees. The FR 3063 survey is mandatory. The Board uses data from the FR 3063 survey to support an annual report to Congress on the prevalence of use of general-use prepaid cards in federal, state, and local government-administered payment programs and on the interchange and cardholder fees charged with respect to the use of such cards.

Frequency: Annually.

Respondents: Issuers of Government-Administered, General-Use Prepaid Cards.

Total estimated number of respondents: 22.

Total estimated annual burden hours: 220.[1]

Current actions: On November 14, 2023, the Board published a notice in the **Federal Register** (88 FR 78023) requesting public comment for 60 days on the extension, without revision, of the FR 3063. The comment period for this notice expired on January 16, 2024. The Board did not receive any comments.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024–07092 Filed 4–2–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Senior Loan Officer Opinion Survey on Bank Lending Practices (FR 2018; OMB No. 7100–0058).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Senior Loan Officer Opinion Survey on Bank Lending Practices.

Collection identifier: FR 2018.

OMB control number: 7100–0058.

General description of collection: A senior loan officer at each respondent bank completes this voluntary survey through an electronic submission up to six times a year. Senior staff at the Reserve Banks with knowledge of bank lending practices serve as the main contacts for the survey respondents in their district and help administer the survey. The current reporting panel consists of up to 80 large domestically chartered commercial banks and up to 24 large U.S. branches and agencies of foreign banks. The purpose of the survey is to provide qualitative and limited quantitative information on credit availability and demand, as well as on evolving developments and lending practices in the U.S. loan markets. A portion of each survey typically covers special topics of timely interest.

Frequency: Quarterly.

Respondents: Domestically chartered commercial banks and U.S. branches and agencies of foreign banks. Other types of respondents (such as other depository institutions, bank holding companies, or other financial entities) may also be surveyed if appropriate.

Total estimated number of respondents: 104.

Total estimated annual burden hours: 1,248.[1]

Current actions: On November 14, 2023, the Board published a notice in the **Federal Register** (88 FR 78024) requesting public comment for 60 days on the extension, without revision, of the FR 2018. The comment period for this notice expired on January 16, 2024. The Board did not receive any comments.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024–07089 Filed 4–2–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Domestic Finance Company Report of Consolidated Assets and Liabilities (FR 2248; OMB No. 7100–0005).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 3063.

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 2018.

Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Domestic Finance Company Report of Consolidated Assets and Liabilities.

Collection identifier: FR 2248.

OMB control number: 7100–0005.

General description of collection: The voluntary FR 2248 is collected monthly as of the last calendar day of the month from a stratified sample of finance companies. Each monthly report collects balance sheet data on major categories of consumer and business credit receivables and on major short-term liabilities. For quarter-end months, additional asset and liability items are collected to provide a full balance sheet. A supplemental section collects data on securitized assets. Board staff may ask either quantitative or qualitative questions through the use of a special addendum section no more than twice per year. The data are used to construct universe estimates of finance company holdings, which are published in several statistical releases.

Frequency: Monthly.

Respondents: Sample of 150 finance companies.

Total estimated number of respondents: 150.

Total estimated annual burden hours: 750.[1]

Current actions: On November 14, 2023, the Board published a notice in the **Federal Register** (88 FR 78022) requesting public comment for 60 days on the extension, without revision, of the FR 2248. The comment period for this notice expired on January 16, 2024. The Board did not receive any comments.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024–07090 Filed 4–2–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Quarterly Report of Interest Rates on Selected Direct Consumer Installment Loans and the Quarterly Report of Credit Card Plans (FR 2835 and FR 2835a; OMB No. 7100–0085).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Collection title: Quarterly Report of Interest Rates on Selected Direct Consumer Installment Loans and the Quarterly Report of Credit Card Plans.

Collection identifier: FR 2835 and FR 2835a.

OMB control number: 7100–0085.

General description of collection: The FR 2835 collects information on interest rates on loans for new vehicles and loans for other consumer goods and personal expenses from a sample of commercial banks. The FR 2835a collects information on interest rates, finance charges, and loan balances for credit card accounts from a sample of commercial banks. The data from these reports help the Board analyze current household financial conditions and the implications of these conditions for household spending and, as such, these data provide valuable input to the monetary policymaking process. The data are also used to create aggregate statistics on consumer loan terms that are published in the some of the Federal Reserve's monthly statistical releases.

Frequency: Quarterly.

Respondents: The FR 2835 panel comprises a sample of commercial banks. The FR 2835a panel comprises a sample of commercial banks with $1 billion or more in credit card receivables and a representative group of smaller issuers.

Total estimated number of respondents: 200.

Total estimated annual burden hours: 274.[1]

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 2248.

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting

Current actions: On November 14, 2023, the Board published a notice in the **Federal Register** (88 FR 78025) requesting public comment for 60 days on the extension, without revision, of the FR 2835 and FR 2835a. The comment period for this notice expired on January 16, 2024. The Board received one comment.

Detailed Discussion of Public Comments

The Board received one comment on the FR 2835 and FR 2835a from the U.S. Department of Commerce Bureau of Economic Analysis (BEA). BEA was in strong support of the continued collection of the FR 2835 and FR 2835a data. The Board will adopt the extension, without revision of the FR 2835 and FR 2835a as originally proposed.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024–07091 Filed 4–2–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; 2024 National Survey of Early Care and Education Longitudinal Follow-Ups (Office of Management and Budget #: 0970–0391)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity to be conducted September 2024 through May 2025 as a follow-up of the 2024 National Survey of Early Care and Education (NSECE). The objectives of the 2024 NSECE Longitudinal Follow-ups are to build on the design and implementation of the 2024 NSECE to collect urgently needed information on the following two topics relevant to early care and education (ECE) policy: (1) how households learn about and make use of financial assistance in seeking and selecting ECE, with additional focus on paid individual care arrangements; and (2) patterns of retention and attrition among individuals in the center-based ECE workforce.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The 2024 NSECE Longitudinal Follow-ups will consist of two nationally representative surveys:

1. a survey of households (1) with incomes under 300 percent of the federal poverty level (FPL) and with at least one resident child under the age of 9 years and/or (2) who had used paid care by an individual in the spring of 2024 (2024 NSECE Household Follow-up)

2. a survey of individuals who were employed in early 2024 in center-based ECE programs working directly with children in classrooms serving children age 5 years and under, not yet in kindergarten (2024 NSECE Workforce Follow-up).

Participants will be drawn from respondents to the 2024 NSECE Household and Workforce surveys.

The 2024 NSECE Longitudinal Follow-up data collection efforts will provide urgently needed information that will expand the potential of the 2024 NSECE data to describe: (1) households' search for and use of financial assistance for ECE (including assistance for paid individual care arrangements); and (2) employment experiences of individuals who have recently worked in center-based ECE classrooms. The household follow-up in Fall 2024 will re-interview households participating in the 2024 NSECE who (1) report using paid individual ECE or (2) report incomes below 300 percent of the FPL and have at least one resident child under age 9 years. The workforce follow-up in early 2025 will re-interview individuals who participated in the 2024 NSECE workforce survey (*i.e.,* served as center-based classroom-assigned instructional staff between January and July 2024). Both follow-up surveys are designed to collect in-depth information that was not feasible to collect in the 2024 NSECE and which can be uniquely collected through re-interviews of selected 2024 NSECE participants. The household follow-up will include information about households' awareness of and experience with publicly funded ECE programs, how households selected ECE arrangements for Fall 2024, and who provided paid individual care to the households' children in early 2024. The workforce follow-up will include information about the experiences of ECE instructional staff over time, where workers who leave ECE employers or the ECE sector go and why they leave, and workers' experiences in various ECE settings throughout their ECE careers. Accurate data on families with young children and the experiences of ECE workers are essential to assess the current landscape of ECE, and to provide insights to advance ECE policy and initiatives. The household follow-up will be fielded using multi-mode survey methodologies in Fall 2024, and the workforce follow-up will be fielded using multi-mode survey methodologies in the first half of 2025. Both follow-ups will enhance the value of the 2024 NSECE by expanding the potential utility of those data to describe household and worker experiences over time and to address additional information needs.

Respondents: 1. Households participating in the 2024 NSECE and either a. reporting a paid individual ECE arrangement in the 2024 NSECE, or b. having at least one resident child under age 9 and who reported incomes under the 300 percent Federal poverty level in the 2024 NSECE. 2. Individuals who participated in the 2024 NSECE survey of center-based classroom-assigned instructional staff (workforce).

Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 2835 and FR 2835a.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
2024 NSECE Household Follow-up Questionnaire	3,750	1	.36	1,350
2024 NSECE Workforce Follow-up Questionnaire (Classroom Staff)	5,550	1	.33	1,832

Estimated Total Annual Burden Hours: 3,182.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Child Care and Development Block Grant Act of 1990, as amended by the CCDBG Act of 2014 (Pub. L. 113–186). Social Security Act, section 418 as extended by the Continuing Appropriations Act of 2017 and the TANF Extension Act of 2019. Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–06982 Filed 4–2–24; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1245]

Data Integrity for In Vivo Bioavailability and Bioequivalence Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Data Integrity for In Vivo Bioavailability and Bioequivalence Studies.'' The purpose of this guidance is to provide recommendations to applicants and testing site management on achieving and maintaining data integrity for the clinical and bioanalytical portions of bioavailability (BA) and bioequivalence (BE) studies submitted in support of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and the bioanalytical portion of clinical pharmacologic studies supporting Center for Drug Evaluation and Research-regulated biologic license applications (BLAs) as well as amendments and supplements to these applications. In addition, the recommendations in this guidance apply to the bioanalytical portion of nonclinical studies. FDA also encourages applicants and testing sites to consider these recommendations when conducting other studies, including in vitro and pharmacology and toxicology studies.

DATES: Submit either electronic or written comments on the draft guidance by June 3, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1245 for ''Data Integrity for Bioavailability and Bioequivalence Studies at Testing Sites.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Coppersmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Silver Spring, MD 20993, 301–796–9193.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Data Integrity for In Vivo Bioavailability and Bioequivalence Studies.''

Requirements for submitting BA and BE data in INDs, NDAs, ANDAs, and amendments and supplements to these applications, the definitions of BA and BE, and the types of in vitro and in vivo studies that are appropriate to measure BA and establish BE are set forth in parts 312, 314, and 320 (21 CFR parts 312, 314, and 320). Requirements for BLAs and amendments and supplements to these applications are included in part 601 (21 CFR part 601). FDA expects that all data submitted to the Agency, including data from BA and BE studies submitted in support of INDs, NDAs, and ANDAs and clinical pharmacologic studies submitted in support of BLAs, are accurate, complete, and reliable, and that industry maintain data integrity throughout the data lifecycle of the product(s) or biologic therapeutic(s). In recent years, however, FDA has observed data integrity concerns during the inspection of testing sites, clinical testing sites, and analytical testing sites, and during the assessment of the BA and BE study data submitted in support of applications. Data integrity concerns can impact application acceptance for filing, assessment, regulatory actions, and approval as well as post-approval actions, such as therapeutic equivalence ratings.

This guidance provides recommendations to achieve and maintain data integrity with respect to (1) applicants, (2) testing site management, and (3) implementation and management of a quality management system. This guidance does not include a comprehensive list of all best practices that applicants and testing sites should use to achieve and maintain data integrity. It is each applicant's responsibility to achieve and maintain data integrity for their studies, which includes identifying and implementing the most effective and efficient risk-based controls. FDA encourages applicants and testing site management to review FDA regulations and all applicable guidance for industry to understand FDA's current thinking on a topic.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Data Integrity for In Vivo Bioavailability and Bioequivalence Studies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in part 314 for new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in part 601 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information found in 21 CFR part 11 pertaining to electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information found in 21 CFR parts 50 and 56 pertaining to protection of human subjects, institutional review boards and informed consent have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 58 for good laboratory practices for have been approved under OMB control number 0910–0119. The collections of information found in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice (CGMP) and the recordkeeping requirement for CGMP sample retention have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07080 Filed 4–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance for Oxymetazoline Hydrochloride; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Draft Guidance on Oxymetazoline Hydrochloride.'' The draft guidance,

when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for oxymetazoline hydrochloride ophthalmic solution.

DATES: Submit either electronic or written comments on the draft guidance by June 3, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance on Oxymetazoline Hydrochloride.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. This notice announces the availability of a draft product-specific guidance on generic oxymetazoline hydrochloride ophthalmic solution.

FDA initially approved new drug application 212520 UPNEEQ (oxymetazoline hydrochloride) in July 2020. We are now issuing a draft guidance for industry on, among other things, BE recommendations for generic oxymetazoline hydrochloride ophthalmic solution (''Draft Guidance on Oxymetazoline Hydrochloride'').

In June 2021, RVL Pharmaceuticals, Inc. (RVL) submitted a citizen petition requesting, among other things, that FDA withhold approval of any ANDA or section 505(b)(2) application that references or relies upon UPNEEQ (oxymetazoline hydrochloride ophthalmic solution), unless certain conditions are satisfied, including conditions related to demonstrating BE (Docket No. FDA–2021–P–0533). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the draft guidance entitled ''Draft Guidance on Oxymetazoline Hydrochloride'' before responding to RVL's citizen petition. FDA's issuance of the draft guidance on oxymetazoline hydrochloride ophthalmic solution does not represent a final decision on the issues raised in the petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Draft Guidance on Oxymetazoline Hydrochloride.'' It does not establish

any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06985 Filed 4–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Assessing Strategies To Promote Children's Engagement and Active Participation in Virtual Visits

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing Strategies to Promote Children's Engagement and Active Participation in Virtual Home Visits OMB No. 0915–xxxx—[NEW]

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, title V, section 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies to provide home visiting services to eligible families in at-risk communities.

This information collection is part of the Assessing and Describing Practice Transitions Among Evidence-Based Home Visiting Programs in Response to the COVID–19 Public Health Emergency Study, which aims to identify and study practices implemented in response to the COVID–19 public health emergency that support evidence-based practice and have the potential to enhance home visiting programming. One of the practices the study identified is strategies home visitors use to engage children and promote their active engagement during virtual visits. The purpose of this information collection is to better understand, through rapid cycle learning, how MIECHV-funded home visiting programs can implement virtual strategies improve child engagement and how home visitors can apply these strategies during in-person service delivery.

Information will be collected in four phases designed to (1) identify virtual child engagement strategies (co-definition phase); (2) pilot test and identify refinements to improve the implementation of strategies (installation phase); (3) iteratively test the strategies with refinements to their implementation (refinement phase); and (4) assess the potential of these child engagement strategies to improve service delivery and promote family engagement and family satisfaction with home visiting programs in both virtual and in-person settings (summary phase). Data collection activities include focus groups, online questionnaires, and review of documents and administrative data.

A 60-day notice published in the **Federal Register** on December 5, 2023, 88 FR 84340–41. There were no public comments. One home visiting model developer requested copies of the information collection forms.

Need and Proposed Use of the Information: With the end of the COVID–19 public health emergency, most MIECHV-funded home visiting programs have transitioned back to some level of in-person service delivery. However, many continue to offer occasional virtual home visits if warranted and appropriate, such as during inclement weather or due to family and staff health concerns. Understanding the virtual strategies that home visitors used or are using to address the challenges of engaging children during virtual home visits, how these strategies can be implemented, how these strategies and learned lessons can be applied to in-person settings, and how children and families respond to these strategies will be valuable to the field. HRSA intends to use collected information to share evidence-informed resources and strategies that MIECHV awardees can use to optimize children's engagement and active participation and strengthen their home visiting services.

Likely Respondents: Respondents include (1) families who receive home visiting services and (2) MIECHV-funded home visiting program staff, which may include program directors, managers, supervisors, and home visitors.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to

transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Program Eligibility Protocol	16	1	16	1.00	16.0
Program Staff Focus Group Protocol 1 (Co-definition Phase)	24	1	24	1.50	36.0
Program Staff Focus Group Protocol 2 (Co-definition Phase)	24	1	24	1.50	36.0
Program Staff Focus Group Protocol (Installation & Refinement Phases)	24	3	72	1.00	72.0
Program Staff Focus Group Protocol (Summary Phase)	24	1	24	1.00	24.0
Family Focus Group Protocol (Co-definition & Summary Phases)	48	1	48	1.00	48.0
Home Visitor Questionnaire (Installation & Refinement Phases)	40	9	360	0.17	61.2
Family Post-Visit Questionnaire (Refinement Phase)	48	6	288	0.08	23.0
Focus Group Participant Characteristics Form (All Phases)	120	1	120	0.08	9.6
Total	368		976		325.8

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–07066 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Alliance for Innovation on Maternal Health Biannual Survey

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Alliance for Innovation on Maternal Health Biannual Survey, OMB No. 0915–xxxx—New.

Abstract: The Alliance for Innovation on Maternal Health (AIM) program is administered by HRSA and authorized by 42 U.S.C. 254c–21 (Public Health Service Act, Title III Section 330O), as added by the Consolidated Appropriations Act, 2022 (Pub. L. 117–103).

The AIM program supports the identification, development, implementation, and dissemination of maternal (patient) safety bundles to promote safe care for every U.S. birth and assist with addressing the complex problem of high maternal mortality and severe maternal morbidity rates within the U.S. The mission of AIM is to support best practices that make birth safer, improve the quality of maternal health care and outcomes, and save lives. Maternal patient safety bundles address topics commonly associated with health complications or risks related to prenatal, labor and delivery, and postpartum care.

The AIM program consists of two components: The AIM Capacity program and the AIM Technical Assistance (TA) Center. The AIM Capacity awards began in fiscal year 2023 and directly fund 28 states and jurisdictions (including U.S. territories and the District of Columbia) to implement AIM maternal patient safety bundles. The second component, the AIM TA Center, is funded through a cooperative agreement to provide TA to all 50 states, the District of Columbia, jurisdictions, U.S. territories, tribal communities, and birthing facilities who participate in the AIM program. The TA Center builds data capacity for participating entities to track progress on bundle implementation and support improvement of data collection.

The funding amount for the AIM program was increased in fiscal year 2023, which allowed HRSA to directly fund states and territories to support AIM bundle implementation. Previously, HRSA supported AIM through one cooperative agreement to develop maternal patient safety bundles, provide TA on bundle implementation, and enroll states and territories in the program. The shift to directly fund

states and jurisdictions for the work makes the collection of information about the reach of the program, participation by birthing facilities, and TA needs necessary. The AIM Biannual Survey will be administered to AIM State Teams (the state-or jurisdiction-level entity leading AIM implementation) twice a year in all states and jurisdictions enrolled in AIM. Respondents will include AIM State Teams that receive HRSA funding through the AIM Capacity program, as well as AIM State Teams that do not receive HRSA funding to implement AIM, to gauge the full reach of the program.

A 60-day notice published in the **Federal Register** on December 7, 2023, vol. 88, No. 234; pp. 85298–85299. There were four public comments received. Two comments suggested changes that were incorporated into the instrument, one comment was a request for materials, and one comment was out-of-scope and no changes to the proposed data collection were made.

Need and Proposed Use of the Information: The information will be used by the HRSA program team to understand and report on AIM program reach and potential growth regarding participating birthing facilities and patient safety bundles implemented, inform development of resources and types of TA offered, and develop program targets. In addition, information on the number of participating birthing facilities and patient safety bundles being implemented is shared on the HRSA and American College of Obstetricians and Gynecologists AIM websites. The biannual survey is the only place this information is collected.

Likely Respondents: Respondents are AIM State Teams in all states and jurisdictions enrolled in AIM, including AIM Capacity award recipients and AIM State Teams that do not receive direct funding from HRSA.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
AIM Biannual Survey	52	1 per survey; 2 surveys per year.	104	1	104
Total	52	1 per survey; 2 surveys per year.	104	1	104

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–06992 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Home Visiting Assessment of Implementation Quality Study: Exploring Family Voice and Leadership in Home Visiting

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Home Visiting Assessment of Implementation Quality Study: Exploring Family Voice and Leadership in Home Visiting, OMB No. 0915–xxxx–[NEW].

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program, authorized by Social Security Act, Title V, § 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) to provide home visiting services to eligible families in at-risk communities.

Through the Home Visiting Assessment of Implementation Quality Study, HRSA aims to examine specific components of the Home Visiting Implementation Quality Conceptual Framework to inform strategies for implementing high quality home

visiting programs. One of the three quality components the study will focus on is family voice and leadership (FVL), which involves including families in decisions related to program implementation. The requested information collection will provide a better understanding of how MIECHV-funded home visiting programs currently engage families and will provide preliminary information on how FVL may influence home visiting implementation and program quality. Information collection activities include two online surveys, focus groups, and interviews.

A 60-day notice was published in the **Federal Register** on December 5, 2023, 88 FR 84339–84340. There was one response to public comment from a home visiting model developer. The commentor expressed concerns about the estimated burden for focus group and made suggestions for language changes including use of plain language, clarifying instructions, and providing questions in advance. In response to these comments, the burden hours for focus groups and interviews were increased, and the number of items on the MIECHV Program FVL Online Survey was reduced. Recommendations for language revisions were incorporated into the revised information collection tools. An additional information collection tool was added to this ICR to facilitate the recruitment of families for participation in a focus group (Family Focus Group Recruitment Survey). Two form names were also modified slightly: the Tribal and State MIECHV Administrators Interview Guide was renamed the MIECHV Lead Interview Guide, and the LIA Program Staff Focus Group Protocol was renamed the Home Visiting Program Staff Focus Group Protocol.

Need and Proposed Use of the Information: HRSA is seeking additional information about how the MIECHV program engages and supports families in leadership opportunities to inform and improve programs. HRSA intends to use this information to identify actionable strategies that MIECHV awardees and LIAs could take to engage families meaningfully and effectively in program decisions and to ensure that families' unique strengths, needs, cultures, and preferences drive service delivery.

Likely Respondents: MIECHV awardees that are states, nonprofit organizations, and tribes, LIA staff (program directors, coordinators, supervisors, and home visitors); and families who have been engaged in FVL activities by MIECHV-funded home visiting programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. Compared to the versions submitted for the 60-day approval process in December, estimated burden hours have increased as a result of adding an additional information collection activity and implementing the feedback provided in public comments during the 60-day comment period and pre-testing data collection protocols. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
MIECHV Program FVL Online Survey	1000	1	1000	0.33	330
Family Focus Group Protocol	48	1	48	1.50	72
MIECHV Lead Interview Guide	12	1	12	1.50	18
Home Visiting Program Staff Focus Group Protocol	48	1	48	1.50	72
Family Focus Group Recruitment Survey	100	1	100	0.08	8
Total	1,208		1,208		500

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–07008 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities Title: Assessing the Use of Coaching To Promote Positive Caregiver-Child Interactions in Home Visiting

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing the Use of Coaching to Promote Positive Caregiver-Child

Interactions in Home Visiting OMB No. 0906–xxxx[NEW].

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, Title V, § 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies to provide home visiting services to eligible families in at-risk communities.

This information collection is part of the Assessing and Describing Practice Transitions Among Evidence-Based Home Visiting Programs in Response to the COVID–19 Public Health Emergency Study, which aims to identify and study practices implemented in response to the COVID–19 public health emergency that support evidence-based practice and have the potential to enhance home visiting programming. One of the practices the study identified is the use of coaching to promote caregiver-child interactions and positive caregiving skills. Coaching involves a home visitor providing instructions to the parent or caregiver as they carry out the skill and differs from a common home visiting strategy, modeling, in which home visitors first demonstrate a skill themselves before asking the parent or caregiver to try it. The purpose of this information collection is to better understand, through rapid cycle learning, how MIECHV-funded home visiting programs can implement coaching strategies during home visits.

Information will be collected in four phases designed to: (1) define coaching strategies (co-definition phase), (2) identify potential refinements to improve coaching strategies (installation phase), (3) iteratively test the refinements (refinement phase), and (4) assess the potential of coaching strategies to improve service delivery and promote family engagement and family satisfaction with home visiting programs (summary phase). Data collection activities include focus groups, online questionnaires, and review of documents and administrative data.

A 60-day notice published in the **Federal Register** on December 5, 2023, vol. 88, No. 232; pp. 84342–43. There were no public comments. One home visiting model developer requested copies of the information collection instruments.

Need and Proposed Use of the Information: The COVID–19 public health emergency led the MIECHV Program to rapidly adjust practices, within the bounds of evidence-based home visiting model guidance, to reduce service delivery disruptions while protecting the health and safety of home visiting participants and the home visiting workforce. Largely prompted by the shift to virtual home visits, one of these practice changes was to use coaching to promote positive caregiving skills and family-child interactions. Home visitors suggested that using coaching strategies enhanced the way that home visitors worked with families, particularly in virtual settings when home visitors were unable to use modeling strategies (*e.g.,* in-person demonstrations by home visitors). Some findings indicate that home visitors who used coaching perceived that it led to improved family engagement and caregiver confidence in interacting with their child. However, other findings suggest that some families may not prefer coaching over modeling, and that coaching may create burden on home visitors. As home visitors transition back to primarily in-person home visits, there is a need for more information about strategies to support the implementation of coaching to effectively promote positive caregiver-child interactions in virtual and in-person settings, while reducing home visitor burden and increasing family acceptance of this strategy. HRSA intends to use collected information to provide evidence-informed resources and strategies that MIECHV awardees can use to inform their use of coaching strategies to strengthen their home visiting services.

Likely Respondents: Respondents include families who receive home visiting services and MIECHV-funded home visiting program staff, which may include program directors, managers, supervisors, and home visitors.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Program Eligibility Protocol	16	1	16	1.00	16.0
Program Staff Focus Group Protocol 1 (Co definition Phase)	24	1	24	1.50	36.0
Program Staff Focus Group Protocol 2 (Co-definition Phase)	24	1	24	1.50	36.0
Program Staff Focus Group Protocol (Installation & Refinement Phases)	24	3	72	1.00	72.0
Program Staff Focus Group Protocol (Summary Phase)	24	1	24	1.00	24.0
Family Focus Group Protocol (Co-definition & Summary Phases)	48	1	48	1.00	48.0
Home Visitor Learning Cycle Form (Installation & Refinement Phases)	40	9	360	0.17	61.2
Family Post-Visit Form (Refinement Phase)	48	6	288	0.08	23.0
Focus Group Participant Characteristics Form (All Phases)	120	1	120	0.08	9.6

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Total	368		976		325.8

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–07009 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 3, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906–0017, Revision.

Abstract: This request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System. The MIECHV Program is administered by the Maternal and Child Health Bureau within HRSA in partnership with the Administration for Children and Families and provides support to all 56 states and jurisdictions, as well as tribes and tribal organizations. Through a needs assessment, states, jurisdictions, tribes, and tribal organizations identify target populations and select the home visiting service delivery model(s) that best meet their needs. There is no proposed change to the previously approved information collection instruments. Over the next 3 years, as part of efforts to implement new statutory provisions enacted as part of reauthorization of the MIECHV program, HRSA intends to engage with MIECHV awardees, home visiting model developers, and federal partners to identify opportunities to reduce administrative burden related to performance reporting, to enhance performance measures to measure disparities, and to align performance measures with other programs administered by HRSA's Maternal and Child Health Bureau.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to continue collecting information on demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services and a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas. This information will be used to demonstrate awardees' compliance with statutory and programmatic requirements. It will also be used to monitor and provide continued oversight for awardee performance and to target technical assistance resources to awardees.

Likely Respondents: MIECHV Program awardees that are states, jurisdictions, and, where applicable, nonprofit organizations providing home visiting services within states.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 1: Demographic, Service Utilization, and Select Clinical Indicators	56	1	56	560	31,360

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 2: Performance Indicators and Systems Outcome Measures	56	1	56	221	12,376
Total	56		56		43,736

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–06998 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request Title: Assessing the Use of Informal Contacts To Promote Caregivers' Engagement and Satisfaction With Home Visiting

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Assessing the Use of Informal Contacts to Promote Caregivers' Engagement and Satisfaction with Home Visiting OMB No. 0915–xxxx—NEW

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, Title V, § 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies to provide home visiting services to eligible families in at-risk communities.

This information collection is part of the Assessing and Describing Practice Transitions Among Evidence-Based Home Visiting Programs in Response to the COVID–19 Public Health Emergency Study, which aims to identify and study practices implemented in response to the COVID–19 public health emergency that support evidence-based practice and have the potential to enhance home visiting programming. One of the practices the study identified is the use of informal contacts. Informal contacts are any contacts between a home visitor and family that occur between formal home visits (*e.g.,* text messages, emails). The purpose of this information collection is to better understand, through rapid cycle learning, how MIECHV-funded home visiting programs can use informal contacts to improve service delivery and promote caregiver's engagement and satisfaction.

Information will be collected in four phases designed to (1) identify informal contact strategies (co-definition phase); (2) pilot test and identify refinements to improve the implementation of strategies (installation phase); (3) iteratively test the strategies with refinements to their implementation (refinement phase); and (4) assess the potential of informal contact strategies to improve service delivery and promote family engagement and family satisfaction with home visiting programs (summary phase). Data collection activities include focus groups, online questionnaires, and review of documents and administrative data.

A 60-day notice published in the **Federal Register** on December 5, 2023, vol. 88, No. 232; pp. 84343–45. There were no public comments. One home visiting model developer requested copies of the information collection forms.

Need and Proposed Use of the Information: The onset of the COVID–19 public health emergency prompted home visitors to use telephone, text, and social media direct messaging to informally contact families on a more frequent basis—in some instances, daily. This practice has continued for some programs even after the end of the public health emergency and the transition back to in-person service delivery. Current evidence suggests considerable variation in strategies used by home visiting programs with regards to context, type, frequency, and purpose of informal contacts. While increasing contacts helped home visitors to build rapport and further address family needs, other findings suggest that informal contacts can place pressure on families to engage with home visitors beyond what they have the capacity for and increase the workloads of home

visitors. Given these initial findings and the increased use of informal contacts since the public health emergency, there is a need for more information about how home visitors contact families outside of home visits, variations in strategies, how families perceive the strategies, and how to address challenges around informal contacts. HRSA intends to use collected information to provide evidence-informed resources and strategies that MIECHV awardees can use to effectively engage and communicate with families between scheduled home visits.

Likely Respondents: Respondents include families who receive home visiting services and MIECHV-funded home visiting program staff, which may include program directors, managers, supervisors, and home visitors.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Program Eligibility Protocol	16	1	16	1.00	16.00
Program Staff Focus Group Protocol 1 (Co-definition Phase)	24	1	24	1.50	36.00
Program Staff Focus Group Protocol 2 (Co-definition Phase)	24	1	24	1.50	36.00
Program Staff Focus Group Protocol (Installation & Refinement Phases)	24	3	72	1.00	72.00
Program Staff Focus Group Protocol (Summary Phase)	24	1	24	1.00	24.00
Family Focus Group Protocol (Co-definition & Summary Phases)	48	1	48	1.00	48.00
Home Visitor Questionnaire (Installation & Refinement Phases)	40	9	360	0.17	61.20
Family Post-Visit Form (Refinement Phase)	48	6	288	0.08	23.00
Focus Group Participant Characteristics Form (All Phases)	120	1	120	0.08	9.60
Total	368	.....	976	.....	325.80

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–06987 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Home Visiting Assessment of Implementation Quality Study: Better Addressing Disparities Through Home Visiting

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Home Visiting Assessment of Implementation Quality Study: Better Addressing Disparities Through Home Visiting, OMB No. 0915-xxxx—NEW.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program, authorized by

Social Security Act, Title V, § 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) to provide home visiting services to eligible families in at-risk communities.

HRSA aims to explore how families that experience disparities in outcomes targeted by the MIECHV program experience home visiting services. This study is an initial step in understanding those experiences and will provide a better understanding of how MIECHV-funded home visiting programs currently address disparities and promote equity. Data collection activities include interviews, focus groups, online surveys, program observations, and review of documents and management information systems data.

A 60-day notice was published in the **Federal Register** on December 5, 2023, vol. 88, No. 84339; pp. 84341–42. HRSA received one response to the request for public comment from a home visiting model developer. The commentor expressed concerns about the estimated burden for focus groups and the request for information from programs and over surveying families, suggesting using previously collected data, and made suggestions for language changes including use of plain language, clarifying instructions, and providing questions in advance. In response to these comments, the burden hours were increased for focus groups, clarifying instructions were added to the LIA Leadership Interview Protocol and edits were made to plain language. The burden estimate was not increased for the information form for LIAs as it did not fall under the definition for public burden. The suggestion of using information already collected from families was not taken as there is not currently existing data of this nature. In addition, Family Focus Group Protocol and Family Case Study Focus Group Protocol have been combined to one form as the protocols were similar.

Need and Proposed Use of the Information: HRSA is seeking additional information about families' experiences within home visiting and strategies the MIECHV program has used to address disparities in their work with families. This information collection is part of the Home Visiting Assessment of Implementation Quality Study, which will examine specific components of the Home Visiting Implementation Quality Conceptual Framework, to inform strategies for implementing high quality home visiting programs. HRSA intends to use this information to identify actionable strategies that MIECHV awardees and LIAs could take to remove potential obstacles to family enrollment in home visiting services and to help address health disparities.

Likely Respondents: MIECHV awardees that are states, nonprofit organizations, and tribes; LIA staff (program directors, coordinators, supervisors, and home visitors); and families that experience greater disparities in maternal and newborn health (families participating in MIECHV-funded home visiting services).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS [1]

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Request for Information about LIAs	56	1	56	0.25	14.0
LIA and Family Nomination Form	70	1	70	2.00	140.0
Family Online Survey	210	1	210	0.33	69.3
Family Focus Group Protocol	64	1	64	1.00	64.0
Home Visitor Group Interview Protocol	10	1	10	1.50	15.0
LIA Leadership Interview Protocol	6	1	6	1.50	9.0
Total	416	.....	416	.....	311.3

[1] There may be variation in the number of study participants (*e.g.,* some programs may have fewer home visitors). The total burden hours presented here provide information assuming the maximum number of respondents in each community.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–06991 Filed 4–2–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0482]

Agency Information Collection Request 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@hhs.gov.* When submitting comments or requesting information, please include the document identifier 0990–0482–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Continued Evaluation of the National Hypertension Control Initiative.

Type of Collection: Revision; OMB No. 0990–0482–OS/Office of Assistant Secretary for Health (OASH)/Office of Minority Health (OMH).

Abstract: As part of the Federal response to COVID–19, the U.S. Department of Health and Human Services (HHS)/Office of Secretary (OS)/Office of Assistant Secretary for Health (OASH)/Office of Minority Health (OMH) has funded a new initiative involving two cooperative agreements with the American Heart Association (AHA) to improve COVID–19-related health outcomes by addressing hypertension (high blood pressure) among racial and ethnic minority populations.

The $32 million project from the HHS Office of Minority Health (OMH) and the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care will support the implementation of the National Hypertension Control Initiative (NHCI), a national initiative to improve blood pressure control among the most at-risk populations, including racial and ethnic minorities.

The NHCI will support 350 participating HRSA-funded health centers by providing patient and provider education and training for effective hypertension control and integration of remote blood pressure monitoring technology into treating hypertension for patients served by participating health centers. The project will also utilize the American Heart Association's targeted media campaigns and existing partnerships with community-based organizations (CBOs) to help reach Black, Latino, and other impacted communities with (i) culturally and linguistically appropriate messages, (ii) access to blood pressure screenings, and (iii) connection to health centers to encourage proper treatment and management of hypertension of screened individuals. This initiative serves to increase the number of adult patients with controlled hypertension and reduce the potential risk of COVID-related health outcomes.

AHA aims to conduct an evaluation to assess the feasibility of the implementation of each of the three NHCI strategies. The findings of this evaluation will inform the improvement and tailoring of AHA's communication approaches about the importance of and techniques for improving blood pressure control, including the benefits of accurately measuring, rapidly acting, and having a patient-focused approach to blood pressure control.

Methodology

The current proposed evaluation of the NHCI project will use a mixed methods design, integrating both quantitative and qualitative data collection and analyses. Three main goals of data collection will be to: (1) track and monitor Community Health Workers' (CHW) progress on activities related to knowledge and practices for blood pressure control and general health quarterly, (2) assess the reach and success of NHCI project strategies implemented by CHC partners.

Specifically, the AHA will engage in:

1. *Primary Data Collection.*

a. *CHW Application.* Collecting information on participating Community Health Workers (CHWs) at a single point in time to assist with placement in workforce activities related to blood pressure control.

b. *CHW Assessment Form.* Monitoring the placement and community-based goals of CHWs participating in the NHCI at a single point in time.

c. *CHW Program Modules.* Administering health lessons and quizzes to Community Health Workers (CHWs) working with Community-based Organizations and Community Health Centers to assess knowledge, skills, and practices both before (pre) and after (post) completion of the modules.

d. *CHC Surveys.* Conducting online data collection on participation and use of NHCI services and supports with CHC staff, with a single collection for each survey.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
CHW: Application	300	1	30/60	150
CHW: Assessment	300	1	1	300
CHW: Program Modules (Pre-test and Post-test)	300	14	10/60	700
CHCs: Use of Azara/Population Health Tool	40	1	1	40
CHCs: JumpStart Modules	350	1	1	350
CHCs: Uniti Health	350	1	1	350
Total	.....	.....	.....	1,890.0

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–07039 Filed 4–2–24; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors Chairs Meeting, Office of the Director, National Institutes of Health.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Board of Scientific Counselors Chairs Meeting, National Institutes of Health.

Date: May 10, 2024.

Time: 1:00 p.m. to 4:00 p.m., EST.

Agenda: The meeting will include a discussion of policies and procedures that apply to the regular review of NIH intramural scientists and their work.

Place: National Institutes of Health, 1 Center Drive, Building 1, Room 160, Bethesda, MD 20892 (Zoom Meeting).

This meeting is a virtual meeting via Zoom and can be accessed at: *https://nih.zoomgov.com/j/1609046129?pwd=SVo5djRrbTdicE5oMDcrTFBJejFOZz09*.

Meeting ID: 160 904 6129.

Passcode: 611826.

One tap mobile:

+16692545252,,1609046129#,,,,*611826# US (San Jose)

+16469641167,,1609046129#,,,,*611826# US (US Spanish Line)

Dial by your location:

+1 669 254 5252 US (San Jose)
+1 646 964 1167 US (US Spanish Line)
+1 646 828 7666 US (New York)
+1 551 285 1373 US (New Jersey)
+1 669 216 1590 US (San Jose)
+1 415 449 4000 US (US Spanish Line)

Meeting ID: 160 904 6129.

Passcode: 611826.

Find your local number: https://nih.zoomgov.com/u/aBCa9yw2p.

Contact Person: Margaret McBurney, Management Analyst, Office of the Deputy Director for Intramural Research, National Institutes of Health, 1 Center Drive, Room 160, Bethesda, MD 20892–0140, (301) 496–1921, *mmcburney@od.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Office of Intramural Research home page: *http://sourcebook.od.nih.gov/*.

Dated: March 28, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–06978 Filed 4–2–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute On Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA Board of Scientific Council, NIA.

Date: May 29–31, 2024.

Closed: May 29, 2024, 8:00 a.m. to 8:45 a.m.

Agenda: To review and evaluate executive Session; Opening Remarks, (Richard J. Hodes, M.D., NIA Director, and Luigi Ferrucci, M.D., Ph.D., Scientific Director, NIA); Board Business, (Andrea LaCroix, Ph.D., Chairperson, and Holly M. Brown-Borg, Ph.D., Incoming Chairperson).

Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 8:45 a.m. to 9:45 a.m.

Agenda: Bias in the Review Process Presentation (Marie Bernard, M.D., Chief Officer for Scientific Workforce Diversity, NIH).

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 9:45 a.m. to 10:00 a.m.

Agenda: Break.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 10:00 a.m. to 10:15 a.m.

Agenda: LBN Overview (Susan Resnick, Ph.D., Laboratory Chief, Senior Investigator, LBN).

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 10:15 a.m. to 10:30 a.m.

Agenda: Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 10:30 a.m. to 11:00 a.m.

Agenda: A historical perspective on BABS brain and cognitive aging studies: Setting the stage for the future (Susan Resnick, Ph.D., Laboratory Chief, Senior Investigator, LBN).

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 11:00 a.m. to 11:30 a.m.

Agenda: Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Closed: May 29, 2024, 11:30 a.m. to 11:45 a.m.

Agenda: To review and evaluate Dr. Resnick meets individually and privately with BSC members.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 11:45 a.m. to 12:00 p.m.

Agenda: Break.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Closed: May 29, 2024, 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate executive Session Luncheon.

Place: National Institute on Aging, Biomedical Research Center, 3A519/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 1:30 p.m. to 2:00 p.m.

Agenda: Integrating omics and neuroimaging to identify ADRD risk factors, biomarkers, and therapeutic targets (Keenan Walker, Ph.D., NIH Distinguished Scholar, Tenure-Track Investigator, LBN).

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 2:00 p.m. to 2:30 p.m.

Agenda: Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Open: May 29, 2024, 2:30 p.m. to 3:00 p.m.
Agenda: Target discovery, preclinical validation, and clinical translation of novel Alzheimer's therapies (Madhav Thambisetty, M.D., Ph.D., Senior Investigator (Clinical), LBN).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 29, 2024, 3:00 p.m. to 3:30 p.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 29, 2024, 3:30 p.m. to 3:45 p.m.
Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 29, 2024, 3:45 p.m. to 4:00 p.m.
Agenda: Drs. Walker and Thambisetty meet individually and privately with BSC members.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 29, 2024, 4:00 p.m. to 5:30 p.m.
Agenda: To review and evaluate executive Session (Biomedical Research Center, 3rd Floor, Room 3C211/Virtual).
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 29, 2024, 5:30 p.m. to 5:30 p.m.
Agenda: To review and evaluate adjourn.
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 8:00 a.m. to 8:30 a.m.
Agenda: To review and evaluate executive Session—Opening Remarks, (Richard J. Hodes, M.D., NIA Director, and Luigi Ferrucci, M.D., Ph.D., Scientific Director, NIA), Board Business, (Andrea LaCroix, Ph.D., Chairperson, and Holly M. Brown-Borg, Ph.D., Incoming Chairperson).
Place: National Institute on Aging, Biomedical Research Center, 3C227/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 8:30 a.m. to 9:00 a.m.
Agenda: Imaging meso- and microscopic neuropathology in aging using MRI (Dan Benjamini, Ph.D., Earl Stadtman-Tenure Track Investigator, LBN).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 9:00 a.m. to 9:30 a.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 9:30 a.m. to 9:45 a.m.
Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 9:45 a.m. to 10:15 a.m.
Agenda: Neurocognitive aging and resilience: Systems and circuits in preclinical animal models (Peter Rapp, Ph.D., Senior Investigator, LBN).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 10:15 a.m. to 10:45 a.m.
Agenda: To review and evaluate Drs. Benjamini and Rapp meet individually and privately with BSC members.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 11:00 a.m. to 11:15 a.m.
Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 11:15 a.m. to 12:30 p.m.
Agenda: To review and evaluate executive Session Luncheon.
Place: National Institute on Aging, Biomedical Research Center, 3A519/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 12:30 p.m. to 12:45 p.m.
Agenda: To review and evaluate laboratory/Branch Chief Leadership Overview (Susan Resnick, Ph.D., Laboratory Chief, Senior Investigator, LBN).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 12:45 p.m. to 1:00 p.m.
Agenda: To review and evaluate discussion with the Laboratory/Branch Chief.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 1:00 p.m. to 1:15 p.m.
Agenda: To review and evaluate leadership Review Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 1:15 p.m. to 2:00 p.m.
Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 2:00 p.m. to 2:45 p.m.
Agenda: To review and evaluate BSC members to meet with Fellows from LBN.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 2:45 p.m. to 3:15 p.m.
Agenda: Novel insights into neurodegeneration through long-read sequencing—(Cornelis Blauwendraat, Ph.D., Earl Stadtman Tenure-Track Investigator, Laboratory of Neurogenetics (LNG)).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 30, 2024, 3:15 p.m. to 3:45 p.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 4:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate executive Session.
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 30, 2024, 5:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate adjourn.
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 8:00 a.m. to 8:30 a.m.
Agenda: To review and evaluate executive Session—Opening Remarks, (Richard J. Hodes, M.D., NIA Director, and Luigi Ferrucci, M.D., Ph.D., Scientific Director, NIA); Board Business, (Andrea LaCroix, Ph.D., Chairperson, and Holly M. Brown-Borg, Ph.D., Incoming Chairperson).
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 8:30 a.m. to 8:45 a.m.
Agenda: LEPS Overview (Lenore Launer, Ph.D., Laboratory Chief, Senior Investigator, LBN).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 8:45 a.m. to 9:00 a.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 9:00 a.m. to 9:30 a.m.
Agenda: Creating conditions for dementia (Lenore Launer, Ph.D., Laboratory Chief, Senior Investigator, LEPS).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 9:30 a.m. to 10:00 a.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 10:00 a.m. to 10:15 a.m.
Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 10:15 a.m. to 10:45 a.m.
Agenda: The biological influences of social determinants of health: challenges, surprises, and complexities (Michele K. Evans, M.D., Senior Investigator (Clinical), LEPS).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 10:45 a.m. to 11:15 a.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 11:30 a.m. to 11:45 a.m.

Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 11:45 a.m. to 1:00 p.m.
Agenda: To review and evaluate executive Session Luncheon.
Place: National Institute on Aging, Biomedical Research Center, 3A519/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 1:00 p.m. to 1:15 p.m.
Agenda: To review and evaluate laboratory/Branch Chief Leadership Overview (Lenore Launer, Ph.D., Laboratory Chief, Senior Investigator, LEPS).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 1:15 p.m. to 1:30 p.m.
Agenda: To review and evaluate discussion with the Laboratory/Branch Chief.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 1:30 p.m. to 1:45 p.m.
Agenda: To review and evaluate leadership Review Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 1:45 p.m. to 2:30 p.m.
Agenda: To review and evaluate BSC members to meet with Fellows from LEPS.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 2:30 p.m. to 2:45 p.m.
Agenda: Break.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 2:45 p.m. to 3:00 p.m.
Agenda: Whole-genome sequencing in non-Alzheimer dementias: Progress, opportunities, and request for cloud resources (Concept) (Bryan J. Traynor, M.D., Ph.D., Senior Investigator, LNG).
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Open: May 31, 2024, 3:00 p.m. to 3:15 p.m.
Agenda: Discussion.
Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 3:15 p.m. to 4:30 p.m.
Agenda: To review and evaluate executive Session (Final discussion of all Principal Investigators reviewed on all days.).
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).
Closed: May 31, 2024, 4:30 p.m. to 4:30 p.m.
Agenda: To review and evaluate adjourn.
Place: National Institute on Aging, Biomedical Research Center, 3C211/Virtual, 251 Bayview Blvd., Baltimore, MD 21224 (Hybrid).

Contact Person: Luigi Ferrucci, M.D., Ph.D., Scientific Director, National Institute on Aging, 251 Bayview Boulevard, Suite 100, Room 4C225, Baltimore, MD 21224, 410–558–8110, *LF27Z@NIH.GOV*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 20, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–06980 Filed 4–2–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Human Genome Research, NHGRI.

This is a hybrid meeting held in-person and virtually and is open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from *https://www.genome.gov/event-calendar/102nd-Meeting-of-National-Advisory-Council-for-Human-Genome-Research.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the intramural programs and projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.
Date: May 20–21, 2024.
Closed: May 20, 2024, 9:00 a.m. to 10:00 a.m.
Agenda: To review and evaluate grant applications.
Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).
Open: May 20, 2024, 10:30 a.m. to 6:00 p.m.
Agenda: Report of Institute Director and Institute Staff.
Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).
Closed: May 21, 2024, 9:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).
Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 6700B Rockledge Drive, Suite 3100, Rockville, MD 20892, (301) 402–0838, *pozzattr@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: March 29, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–07054 Filed 4–2–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0240]

National Chemical Transportation Safety Advisory Committee; Vacancies

AGENCY: United States Coast Guard, Department of Homeland Security.

ACTION: Notice; request for applications.

SUMMARY: The U.S. Coast Guard is accepting applications to fill six vacancies on the National Chemical Transportation Safety Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard on matters relating to the safe and secure marine transportation of hazardous materials.

DATES: Completed applications must reach the U.S. Coast Guard on or before June 3, 2024.

ADDRESSES: Applications must include: (a) a cover letter expressing interest in an appointment to the National Chemical Transportation Safety Advisory Committee, (b) a resume

detailing the applicant's relevant experience for the position applied for, and (c) a brief biography. Applications should be submitted via email with subject line ''NCTSAC Vacancy Application'' to *Ethan.T.Beard@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: Lieutenant Ethan Beard, Assistant Designated Federal Officer of the National Chemical Transportation Safety Advisory Committee; telephone 571–607–8905 or email at *Ethan.T.Beard@uscg.mil.*

SUPPLEMENTARY INFORMATION: The National Chemical Transportation Safety Advisory Committee is a Federal advisory committee. The National Chemical Transportation Safety Advisory Committee was established by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018* (Pub. L. 115–282, 132 Stat. 4192), and is codified in 46 U.S.C. 15101. The Committee operates under the provisions of the *Federal Advisory Committee Act* (5 U.S.C. ch. 10) and 46 U.S.C. 15109. The Committee provides advice and recommendations to the Secretary of Homeland Security on matters relating to the safe and secure marine transportation of hazardous materials.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a)(1). We expect the Committee to meet at least twice a year, but it may meet more frequently. The meetings are generally held in Washington, DC and Houston, Texas.

Under 46 U.S.C. 15109(f)(6)(A), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. In accordance with 46 U.S.C. 15109(f)(4), applicants for membership may be required to pass an appropriate security background examination before their appointment to the Committee.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. If you are appointed as member of the Committee, you will be required to sign a Non-Disclosure Agreement and a Gratuitous Services Agreement.

In this solicitation for Committee Members, we will consider applications from members representing the following:

- Chemical manufacturing entities
- Entities related to marine handling or transportation of chemicals
- Marine safety or security entities
- Marine environmental protection entities

The members who will fill the positions described above will be appointed to represent the interest of their respective groups and viewpoints and are not ''special Government employees,'' as defined in 18 U.S.C. 202(a).

In order for the Department to fully leverage broad-ranging experience and education, the National Chemical Transportation Safety Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the Nation's people.

If you are interested in applying to become a member of the Committee, email your application to *Ethan.T.Beard@uscg.mil* as provided in the **ADDRESSES** section of this notice. Applications must include: (a) a cover letter expressing interest in an appointment to the National Chemical Transportation Safety Advisory Committee, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief biography of the applicant by the deadline in the **DATES** section of this notice.

The U.S. Coast Guard will not consider incomplete or late applications.

Privacy Act Statement

Purpose: To obtain qualified applicants to fill six vacancies on the National Chemical Transportation Advisory Committee. When you apply for appointment to the National Chemical Transportation Advisory Committee, Department of Homeland Security (DHS) will collect your name, contact information, and any other personal information that you submit in conjunction with your application. DHS will use this information to evaluate your candidacy for Committee membership. If you are chosen to serve as a Committee member, your name will appear in publicly available Committee documents, membership lists, and Committee reports.

Authorities: 14 U.S.C. 504; 46 U.S.C. 15101 and 15109; and 18 U.S.C. 202(a), and Department of Homeland Security Delegation No. 00915.

Routine Uses: Authorized U.S. Coast Guard personnel will use this information to consider and obtain qualified candidates to serve on the Committee. Any external disclosures of information within this record will be made in accordance with DHS/ALL–009, Department of Homeland Security Advisory Committee (73 FR 57642, October 3, 2008).

Consequences of Failure to Provide Information: Furnishing this information is voluntary. However, failure to furnish the requested information may result in your application not being considered for the Committee.

Dated: March 28, 2024.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2024–07050 Filed 4–2–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Omega-3-Acid Ethyl Esters Capsules

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (CBP) has issued a final determination concerning the country of origin of Omega-3-Acid Ethyl Esters Capsules. Based upon the facts presented, CBP has concluded that the Norwegian-origin Omega-3-Acid Ethyl Esters do not undergo a substantial transformation in China when combined with certain inactive ingredients and encapsulated into dosage form.

DATES: The final determination was issued on March 28, 2024. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than May 3, 2024.

FOR FURTHER INFORMATION CONTACT: Mitchell Emery, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0321.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on March 28, 2024, U.S. Customs and Border Protection (CBP) issued a final determination concerning the country of origin of Omega-3-Acid Ethyl Esters Capsules for purposes of title III of the Trade Agreements Act of 1979. This final determination, Headquarters Ruling (HQ) H331488, was issued at the request of Epic Pharma LLC, under procedures set forth at 19 CFR part 177, subpart B,

which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP has concluded that, based upon the facts presented, the Omega-3-Acid Ethyl Esters are not substantially transformed in China when combined with certain inactive ingredients and encapsulated into dosage form.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H331488

OT:RR:CTF: VS H331488 MLE
CATEGORY: Origin
Mr. Pei Zhang, Ph.D., Associate Director, Regulatory Affairs, Epic Pharma, LLC, 227–15 N Conduit Avenue, Laurelton, NY 11413

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. 2511); Subpart B, Part 177, CBP Regulations; Country of Origin of Omega-3-Acid Ethyl Esters Capsules.

Dear Mr. Zhang:

This is in response to your March 29, 2023 request, on behalf of Epic Pharma, LLC, for a final determination concerning the country of origin of certain Omega-3-Acid Ethyl Esters capsules pursuant to Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. 2511 *et seq.*), and subpart B of Part 177, U.S. Customs and Border Protection (''CBP'') Regulations (19 CFR 177.21, *et seq.*). Epic Pharma, LLC, is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and 177.23(a) and is therefore entitled to request this final determination.

FACTS

Epic Pharma is a New York-based company specializing in the production of generic pharmaceuticals. At issue in this case are Omega-3-Acid Ethyl Esters capsules, which you describe are intended as an ''adjunct to diet to reduce triglyceride ('TG') levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.'' You state that Omega-3-Acid Ethyl Esters, which are the sole Active Pharmaceutical Ingredient (''API'') in the final product, are produced in Norway. You state that in China the API is combined with inactive ingredients of various origins to produce the finished capsules.

The manufacturing processes in China include the following: first, inactive ingredients including gelatin glycerin, and purified water are combined to create an encapsulating gel. Second, the API is encapsulated into dosage form. Third, imprinting ink is applied for any trademark or content information.

You state that ''[n]o change in name occurs in China because the product is referred to as 'Omega-3-Acid Ethyl Esters' both before and after encapsulation.'' You also state that the processes performed to produce the final product do not result in any changes to the chemical characteristics of the Omega 3-Acid Ethyl Esters, or to any other ingredients. Finally, you claim that no change in use occurs, as the product retains the same predetermined medicinal use. In short, you characterize the operations in China as purely mechanical, intended to process the Omega-3-Acid Ethyl Esters into dosage form.

ISSUE

What is the country of origin of the Omega-3-Acid Ethyl Esters capsules for the purposes of U.S. Government procurement?

LAW AND ANALYSIS

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 CFR 177.21–177.31, which implements Title III of the TAA, as amended (19 U.S.C. 2511–2518).

CBP's authority to issue advisory rulings and final determinations is set forth in 19 U.S.C. 2515(b)(1), which states:

For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title. Emphasis added.

The Secretary of the Treasury's authority mentioned above, along with other customs revenue functions, are delegated to CBP in the Appendix to 19 CFR Part 0—Treasury Department Order No. 100–16, 68 Fed. Reg. 28, 322 (May 23, 2003).

The rule of origin set forth under 19 U.S.C. 2518(4)(B) states:

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 CFR 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Procurement Regulation (''FAR''). *See* 19 CFR 177.21. In this regard, CBP recognizes that the FAR restricts the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 CFR 25.403(c)(1).

The FAR, 48 CFR 25.003, defines ''designated country end product'' as: a WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

Section 25.003 defines ''WTO GPA country end product'' as an article that:

(1) Is wholly the growth, product, or manufacture of a WTO GPA country; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

As indicated above, the Omega-3-Acid Ethyl Esters are produced in Norway, which is a WTO GPA country. *See* FAR, 48 CFR 25.003. The encapsulation process takes place in China, which is not a designated country for the purpose of government procurement.

In order to determine whether a substantial transformation occurs, CBP

considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, CBP considers factors such as the resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process when determining whether a substantial transformation has occurred. No one factor is determinative.

In deciding whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product, even when the API is combined with other inactive ingredients. *See, e.g.,* Headquarters Ruling (''HQ'') 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; HQ H284694, dated August 22, 2017, and New York Ruling (''NY'') C85112, dated March 27, 1998.

For instance, in HQ 561975, CBP held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute a substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

More recently, in HQ H284694, CBP reviewed the country of origin of quinine sulfate capsules. In that case, the German-manufactured API quinine sulfate was exported to India in bulk form, where it was combined with several inactive ingredients, granulated, sieved and placed into gelatin capsules. No change in its name occurred because the product was referred to as ''quinine sulfate'' both before and after processing. Additionally, no change in character occurred because the product maintained the same chemical and physical properties in its processed form. Finally, because the product had a predetermined medical use as an antimalarial drug, no change in use occurred after processing. Therefore, the county of origin of the final product remained Germany.

Similar to the encapsulation here, in NY C85112, CBP reviewed the country of origin of leuprolide acetate, sold under the trade name Lupron Depot 7.5 mg. In that case, U.S.-manufactured leuprolide acetate powder was exported to Japan where it was combined with certain excipients and encapsulated into sterile microspheres. The purpose of microencapsulating the leuprolide acetate was to modify its delivery rate from daily into a form that would be released in the human body over a period of one to four months. CBP determined that the fundamental character of the leuprolide acetate was unchanged by the encapsulation processing and that the foreign processing did not result in a substantial transformation of the U.S.-manufactured leuprolide acetate.

The facts here closely follow the cases cited above, as does our decision. The processing of bulk imported pharmaceuticals into dosage form, even with the addition of inactive ingredients, will not result in a substantial transformation. In this case, the processing begins with the Norwegian-origin bulk Omega-3-Acid Ethyl Esters, and after the product is processed and combined with inactive ingredients in China, it results in Omega-3-Acid Ethyl Esters capsules. There is no change in name after processing. Furthermore, no change in character occurs in China, as the Omega-3-Acid Ethyl Esters maintain the same chemical and physical properties both before and after processing. Finally, because the Omega-3-Acid Ethyl Esters have a predetermined medical use to ''reduce TG levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia,'' no change in use occurs after it is processed in China. Under these circumstances, and consistent with previous CBP rulings, we find that the county of origin of the final product is Norway, where the active pharmaceutical ingredient was produced.

HOLDING

Based on the information outlined above, we determine that the Omega-3-Acid Ethyl Esters made in Norway, do not undergo a substantial transformation when encapsulated into individual doses and combined with inactive ingredients in China. Therefore, the country of origin of the Omega-3-Acid Ethyl Esters capsules for purposes of U.S. Government procurement is Norway.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the U.S. Court of International Trade.

Sincerely,

Alice A. Kipel,

Executive Director,

Regulations and Rulings,

Office of Trade.

[FR Doc. 2024–07065 Filed 4–2–24; 8:45 am]

BILLING CODE 3314–88–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–FAC–2024–N014; FXFR13360900000–FF09F14000–245]

Aquatic Nuisance Species Task Force Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The U.S. Fish and Wildlife Service gives notice of a public meeting of the Aquatic Nuisance Species (ANS) Task Force, in accordance with the Federal Advisory Committee Act. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

DATES: The ANS Task Force will meet Wednesday and Thursday on May 8–9, 2024, from 8 a.m. to 5 p.m. each day (eastern time). On Wednesday, May 8, 2024, there will be a site visit from 1 p.m. to 5 p.m. The site visit will include presentations on, and viewing of,

aquatic invasive species control projects.

Registration: Registration is required. The deadline for registration is May 3, 2024. Also see ''Public Input,'' below.

Accessibility: The deadline for accessibility accommodation requests is May 3, 2024. Please see ''Accessibility Information,'' below.

ADDRESSES: The meeting will take place at the Gideon Putnam Room, Saratoga Spa State Park, 19 Roosevelt Drive, Saratoga Springs, NY 12866. Virtual participation will also be available via teleconference and broadcast over the internet. To register and receive the web address and telephone number for virtual participation, contact the Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) or visit the ANS Task Force website at *https://www.fws.gov/program/aquatic-nuisance-species-task-force*.

FOR FURTHER INFORMATION CONTACT: Susan Pasko, Executive Secretary, ANS Task Force, by telephone at (571) 623–0608, or by email at *Susan_Pasko@fws.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Introduction

The Aquatic Nuisance Species (ANS) Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as amended (16 U.S.C. 4721–4728), and is composed of Federal and ex-officio members. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

Meeting Information

This meeting is open to the public. The meeting agenda will include reports from ANS Task Force members, regional panels, and subcommittees; discussion on priority outputs to advance the goals identified in the ANS Task Force Strategic Plan for 2020–2025; presentations highlighting regional invasive species challenges and innovative measures for ANS management and control; recommendations by the ANS Task Force regional panels; and public comment. The site visit will include presentations on, and viewing of, aquatic invasive species control projects within the area, including marine rapid assessment surveys conducted at local marinas and *Hydrilla* control and containment efforts in the Connecticut River. The final agenda and other related meeting information will be posted on the ANS Task Force website, *https://www.fws.gov/program/aquatic-nuisance-species-task-force*.

Public Input

If you wish to provide oral public comment or provide a written comment for the ANS Task Force to consider, contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than May 1, 2024.

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Interested parties should contact the ANS Task Force Executive Secretary, in writing (see **FOR FURTHER INFORMATION CONTACT**), for placement on the public speaker list for this meeting. Requests to address the ANS Task Force during the meeting will be accommodated in the order the requests are received. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the Executive Secretary up to 30 days following the meeting.

Accessibility Information

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. Please contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than May 3, 2024, to give the U.S. Fish and Wildlife Service sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

David A. Miko,

Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 2024–07057 Filed 4–2–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–FAC–2024–N017; FF09F42300 FVWF97920900000 XXX]

Sport Fishing and Boating Partnership Council; Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The U.S. Fish and Wildlife Service gives notice of a public meeting of the Sport Fishing and Boating Partnership Council (Council), in accordance with the Federal Advisory Committee Act.

DATES: The Council will meet on Tuesday, May 14, 2024, from 8:30 a.m. to 4:45 p.m. and Wednesday, May 15, 2024, from 8:30 a.m. to 12:30 p.m. eastern time.

Registration: Registration is required. The deadline for registration is May 10, 2024.

Accessibility: The deadline for accessibility accommodation requests is May 7, 2024. Please see *Accessibility Information,* below.

ADDRESSES: The meeting will take place at the Department of the Interior, 1849 C Street NW, Washington, DC 20240. Virtual participation will also be available via teleconference and broadcast over the internet. To register and receive the web address and telephone number for virtual participation, contact the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Tom McCann, Designated Federal Officer, by email at *thomas_mccann@fws.gov,* or by telephone at 571–329–3206. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Established in 1993, the Sport Fishing and Boating Partnership Council (Council) advises the Secretary of the

Interior, through the Director of the U.S. Fish and Wildlife Service (Service), and the Secretary of Commerce, through the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration (NOAA), on aquatic conservation endeavors that benefit recreational fishery resources and recreational boating and that encourage partnerships among industry, the public, and government.

Meeting Agenda

- Opening remarks from ex officio members
- Member introductions
- Overview of Council history and current program priorities
- Agency updates from the Service and NOAA
- Recreational Boating and Fishing Foundation updates
- National outreach and communications assessment review
- Wildlife and Sport Fish Restoration program updates
- Council business; open discussion
- Subcommittee discussion and assignment
- Public comment period

The final agenda and other related meeting information will be posted on the Council's website at *https://www.fws.gov/sfbpc/.*

Public Input

If you wish to provide oral public comment or provide a written comment for the Council to consider, contact the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). Written comments should be received no later than Friday, May 10, 2024, to be considered by the Council during the meeting.

Requests to address the Council during the meeting will be accommodated in the order the requests are received. Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Interested parties should contact the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**) for placement on the public speaker list for this meeting. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the Designated Federal Officer up to 30 days following the meeting.

Accessibility Information

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. Please contact the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**) no later than May 7, 2024, to give the Service sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

David A. Miko,

Assistant Director, Fish and Aquatic Conservation Program.

[FR Doc. 2024–07056 Filed 4–2–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/A0A501010.999900]

Final Environmental Impact Statement for the Redding Rancheria Win-River Casino Relocation Project

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of availability.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), as lead agency, with the Redding Rancheria (Tribe), City of Redding (City), Shasta County (County), the California Department of Transportation, District 2 and the U.S. Environmental Protection Agency, Region 9 serving as cooperating agencies, intends to file a Final Environmental Impact Statement (FEIS) with the U.S. Environmental Protection Agency (EPA) in connection with the Tribe's application to transfer into trust approximately 232 acres for gaming purposes in Shasta County, California (Strawberry Fields Site).

DATES: The Record of Decision for the proposed action will be issued on or after 30 days from the date the EPA publishes its Notice of Availability in the **Federal Register**. The BIA must receive any comments on the FEIS before that date.

ADDRESSES: By mail or hand delivery to: Amy Dutschke, Regional Director, Bureau of Indian Affairs, Pacific Region, 2800 Cottage Way, Sacramento, California 95825. Please include your name, return address, and ''FEIS Comments, Redding Rancheria Project'' on the first page of your written comments. You may also submit comments through email to Chad Broussard, Environmental Protection Specialist, Bureau of Indian Affairs, at *chad.broussard@bia.gov.* If emailing comments, please use ''FEIS Comments, Redding Rancheria Project'' as the subject of your email.

FOR FURTHER INFORMATION CONTACT: Chad Broussard, Environmental Protection Specialist, Bureau of Indian Affairs, Pacific Regional Office, 2800 Cottage Way, Room W–2820, Sacramento, California 95825; telephone: (916) 978–6165; email: *chad.broussard@bia.gov.* Information is also available online at *http://www.reddingeis.com.*

SUPPLEMENTARY INFORMATION: The Notice of Availability (NOA) of the Draft EIS was published by the BIA (84 FR 14391) on April 10, 2019, and EPA (84 FR 16485) in the **Federal Register** on April 19, 2019. The Draft EIS was originally made available for public comment for a 45-day period. However, the BIA extended the public comment period for an additional two weeks that concluded on June 17, 2019. A public hearing was held on May 20, 2019, to collect verbal comments on the Draft EIS. On May 14, 2020, the BIA published a notice to suspend preparation of the EIS (85 FR 28973). On September 23, 2021, the BIA published a notice of resumption of the EIS (85 FR 52922).

Background

The following alternatives are considered in the FEIS: (1) Proposed Project; (2) Proposed Project with No Retail Alternative; (3) Reduced Intensity Alternative; (4) Non-Gaming Alternative; (5) Anderson Site Alternative; (6) Expansion of Existing Casino Alternative and (7) and No Action/No Development Alternative. The BIA has selected Alternative 1, the Proposed Project, as the Preferred Alternative as discussed in the FEIS.

Environmental issues addressed in the FEIS include geology and soils, water resources, air quality, biological resources, cultural and paleontological resources, socioeconomic conditions (including environmental justice), transportation and circulation, land use, public services, noise, hazardous materials, aesthetics, cumulative effects,

and indirect and growth inducing effects.

The information and analysis contained in the FEIS, as well as its evaluation and assessment of the Preferred Alternative, will assist the Department in its review of the issues presented in the Tribe's application. Selection of the Preferred Alternative does not indicate the Department's final decision because the Department must complete its review process. The Department's review process consists of (1) issuing the notice of availability of the FEIS; (2) issuing a Record of Decision no sooner than 30 days following publication of a Notice of Availability of the FEIS by the EPA in the **Federal Register**; and (3) transfer of the Strawberry Fields Site in to trust.

Locations where the FEIS is Available for Review: The FEIS is available for review at *https://reddingeis.com.* Contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Public Comment Availability: Comments, including names and addresses of respondents, will be included as part of the administrative record and responses to comments on the Final EIS. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment that your personal identifying information be withheld from public review, the BIA cannot guarantee that this will occur.

Authority

This notice is published pursuant to section 1503.1 of the Council of Environmental Quality Regulations (40 CFR part 1500 through 1508) and section 46.305 of the Department of the Interior Regulations (43 CFR part 46), implementing the procedural requirements of the NEPA of 1969, as amended (42 U.S.C. 4371, *et seq.*), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8. This notice is also published in accordance with 40 CFR 93.155, which provides reporting requirements for conformity determinations.

Wizipan Garriott,

Principal Deputy Assistant Secretary—Indian Affairs, Exercising by delegation the authority of the Assistant Secretary—Indian Affairs.

[FR Doc. 2024–07048 Filed 4–2–24; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/A0A501010.999900]

Notice of Intent To Prepare an Environmental Impact Statement for the Confederated Tribes of the Colville Reservation's Proposed Fee-to-Trust and Casino Project, Franklin County, Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), as lead agency, intends to gather information necessary for preparing an Environmental Impact Statement (EIS) pursuant to the National Environmental Policy Act (NEPA) in connection with the Confederated Tribes of the Colville Reservation (Colville Tribes) proposed Fee-to-Trust and Casino Project in the City of Pasco, Franklin County, Washington. This notice also opens public scoping to identify potential issues, concerns, and alternatives to be considered in the EIS.

DATES: To ensure consideration during the development of the EIS, written comments on the scope of the EIS should be sent as soon as possible and no later than 30 days after publication of this Notice of Intent (NOI) in the **Federal Register**. The time and date of the public scoping meeting will be announced at least 15 days in advance through a notice to be published in the local newspaper (*The Tri-City Herald*) and online at *http://www.colvilleeis.com.*

ADDRESSES: You may mail written comments to Bryan Mercier, Regional Director, Bureau of Indian Affairs, Northwest Region, 911 NE 11th Avenue, Portland, Oregon 97232. Please include your name, return address, and ''NOI Comments, Colville Tribes Fee-to-Trust and Casino Project'' on the first page of your written comments. You may also submit comments through email to Tobiah Mogavero, NEPA Coordinator, Bureau of Indian Affairs, at: *tobiah.mogavero@bia.gov,* using ''NOI Comments, Colville Tribes Fee-to-Trust and Casino Project'' as the subject of your email.

FOR FURTHER INFORMATION CONTACT: Mr. Tobiah Mogavero, NEPA Coordinator, Bureau of Indian Affairs, Northwest Region, (435) 210–0509, *tobiah.mogavero@bia.gov*. Information is also available online at *http://www.colvilleeis.com.*

SUPPLEMENTARY INFORMATION: The Colville Tribes submitted a Fee-to-Trust application to the Bureau of Indian Affairs (BIA) requesting the placement of approximately 164.63 acres of fee land in trust by the United States upon which the Colville Tribes would construct a casino resort. The facility would include an approximately 184,200-square-foot casino, 200-room hotel, an event center, eateries, and supporting facilities. The proposed Fee-to-Trust property is located within the boundaries of the City of Pasco, Franklin County, Washington. The proposed trust property is comprised of one parcel (Assessor Parcel No. 113–130–068) bound by N. Capitol Avenue to the west, commercial and industrial development to the west and south, and agricultural parcels to the north and east. The purpose of the proposed action is to improve the economic status of the Tribal government so that it can provide comprehensive services and ensure the continued social and economic independence and well-being of its Tribal members.

The proposed action encompasses the various federal approvals that may be required to implement the Colville Tribes' proposed project, including approval of the Colville Tribes' Fee-to-Trust application and Secretarial Determination pursuant to section 20(b)(1)(A) of the Indian Gaming Regulatory Act (25 U.S.C. 2719(b)(1)(A)). The EIS will identify and evaluate issues related to these approvals and will also evaluate a range of reasonable alternatives. Possible alternatives currently under consideration include: (1) a reduced-intensity casino alternative, and (2) an alternate-use (non-gaming) alternative. The range of alternatives evaluated in the EIS may be expanded based on comments received during the scoping process.

Areas of environmental concern preliminarily identified for analysis in the EIS include land resources; water resources; air quality; noise; biological resources; cultural/historic/archaeological resources; resource use patterns; traffic and transportation; public health and safety; hazardous materials and hazardous wastes; public services and utilities; socioeconomics; environmental justice; visual resources/aesthetics; and cumulative, indirect, and growth-inducing effects. The range of issues to be addressed in the EIS may be expanded or reduced based on comments received in response to this notice and at the public scoping meeting. Additional information, including a map of the proposed trust property, is available by contacting the

person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice or online at *http://www.colvilleeis.com*.

Public Comment Availability

Comments, including names and addresses of respondents, will be included as part of the administrative record and Scoping Report for the EIS. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment that your personal identifying information be withheld from public review, the BIA cannot guarantee that this will occur.

Authority

This notice is published in accordance with sections 1503.1 and 1506.6 of the Council on Environmental Quality regulations (40 CFR 1500 *et seq.*) and the Department of the Interior regulations (43 CFR part 46) implementing the procedural requirements of the NEPA (42 U.S.C. 4321 *et seq.*), and in accordance with the exercise of authority delegated to the Assistant Secretary—Indian Affairs by part 209 of the Department Manual.

Wizipan Garriott,

Principal Deputy Assistant Secretary—Indian Affairs, Exercising by delegation the authority of the Assistant Secretary—Indian Affairs.

[FR Doc. 2024–07049 Filed 4–2–24; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2024–0009]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Vineyard Northeast Project on the U.S. Outer Continental Shelf Offshore Massachusetts; Corrections

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of intent to prepare an environmental impact statement; corrections.

SUMMARY: On March 25, 2024, the Bureau of Ocean Energy Management (BOEM) published the ''Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Vineyard Northeast Project on the U.S. Outer Continental Shelf Offshore Massachusetts'' in the **Federal Register** (89 FR 20691). That document contained incorrect in-person meeting addresses for both venues. The correct addresses are:

- Wednesday, April 17, 2024, 5 p.m.–9 p.m., Clarke Center Auditorium, Mitchell College, 682 Montauk Avenue, New London, Connecticut 06320; and
- Thursday, April 18, 2024, 5 p.m.–9 p.m., Westport High School Cafeteria, 400 Old County Road, Westport, Massachusetts 02790.

FOR FURTHER INFORMATION CONTACT: Heather Schultz, Office of Renewable Energy Programs, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166, (571) 396–1458 or *heather.schultz@boem.gov.*

SUPPLEMENTARY INFORMATION:

Technical Corrections

In the **Federal Register** dated March 25, 2024, in the third column of page 20691 and first column of page 20692, under the **DATES** caption, correct the information under the ''In Person'' heading to read:

In Person:

- Wednesday, April 17, 2024, 5 p.m.–9 p.m., Clarke Center Auditorium, Mitchell College, 682 Montauk Avenue, New London, Connecticut 06320; and
- Thursday, April 18, 2024, 5 p.m.–9 p.m., Westport High School Cafeteria, 400 Old County Road, Westport, Massachusetts 02790.

Karen Baker,

Chief, Office of Renewable Energy Programs, Bureau of Ocean Energy Management.

[FR Doc. 2024–07000 Filed 4–2–24; 8:45 am]

BILLING CODE 4340–98–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–712–715 and 731–TA–1679–1682 (Preliminary)]

Ferrosilicon From Brazil, Kazakhstan, Malaysia, and Russia; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigations Nos. 701–TA–712–715 and 731–TA–1679–1682 (Preliminary) pursuant to the Tariff Act of 1930, as amended (''the Act''), to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia, provided for in subheadings 7202.21.10, 7202.21.50, 7202.21.75, 7202.21.90, and 7202.29.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Governments of Brazil, Kazakhstan, Malaysia, and Russia. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by May 13, 2024. The Commission's views must be transmitted to Commerce within five business days thereafter, or by May 20, 2024.

DATES: March 28, 2024.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones ((202) 205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on March 28, 2024, by CC Metals and Alloy, LLC, Calvert City, Kentucky, and Ferroglobe USA, Inc., Beverly, Ohio.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary

to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on Thursday, April 18, 2024. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before Tuesday, April 16, 2024. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on April 23, 2024, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on April 17, 2024. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: March 29, 2024.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2024–07067 Filed 4–2–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1396]

Certain Medical Programmers With Printed Circuit Boards, Components Thereof, and Products and Systems for Use With the Same; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 28, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of Medtronic, Inc., Medtronic Logistics, LLC, and Medtronic USA, Inc., of Minneapolis, Minnesota, and Medtronic Puerto Rico Operations Co. of Juncos, Puerto Rico. A supplement was filed on March 1, 2024. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain medical programmers with printed circuit boards, components thereof, and products and systems for use with the same by reason of the infringement of certain claims of U.S. Patent No. 8,712,540 (''the '540 patent'') and U.S. Patent No. 9,174,059 (''the '059 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning

the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2023).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on March 29, 2024, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–5, 7, 11, 12, 14, 15, 17, 18, 20, 39, and 40 of the '540 patent and claims 1–5, 7, 11, 12, 14, 15, 17, 18, and 20 of the '059 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''sacral neuromodulation systems to control neurostimulators surgically implanted into a human patient, incorporating medical programmers and printed circuit boards used in same'';

(3) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432
Medtronic Logistics, LLC, 710 Medtronic Parkway, Minneapolis, MN 55432
Medtronic USA, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432
Medtronic Puerto Rico Operations Co., Ceiba Norte Industrial Park, 50 Road 31, Km. 24.4, Juncos, Puerto Rico 00777

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:

Axonics, Inc., 26 Technology Drive, Irvine, CA 92618

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: March 29, 2024.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2024–07068 Filed 4–2–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1347]

Importer of Controlled Substances Application: Research Triangle Institute

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Research Triangle Institute has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 3, 2024. Such persons may also file a written request for a hearing on the application on or before May 3, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 11, 2024, Research Triangle Institute, 3040 East Cornwallis Road, Hermann Building, Room 106, Research Triangle Park, North Carolina 27709–2194, applied to

be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amineptine (7-[(10,11-dihydro-5Hdibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)	1219	I
Mesocarb (N-phenyl-N′-(3-(1-phenylpropan-2-yl)-1,2,3- oxadiazol-3-ium-5-yl)carbamimidate)	1227	I
3-Fluoro-N-methylcathinone (3-FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4-FMC) 1238 I N	1238	I
Para-Methoxymethamphetamine (PMMA), 1-(4- methoxyphenyl)-N-methylpropan-2-amine	1245	I
Pentedrone (α-methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4-MEC)	1249	I
Naphyrone	1258	I
3-methylmethcathinone (2-(methylamino)-1-(3- methylphenyl)propan-1-one)	1259	I
N-Ethylamphetamine	1475	I
Methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2- amine) 1478 I N	1478	I
N,N-Dimethylamphetamine	1480	I
Fenethylline	1503	I
Aminorex	1585	I
4-Methylaminorex (cis isomer)	1590	I
4,4′-Dimethylaminorex (4,4′-DMAR; 4,5-dihydro-4- 1595 I N methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5- (4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine).	1595	I
Gamma Hydroxybutyric Acid	2010	I
Methaqualone	2565	I
Mecloqualone	2572	I
Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6Hthieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine	2780	I
Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4Hbenzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine)	2785	I
Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4Hbenzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2786	I
Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2788	I
Diclazepam (7-chloro-5-(2-chloro-5-(2-chlorophenyl)-1- methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one	2789	I
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
SR-18 (Also known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7010	I
5-Fluoro-UR-144 and XLR11 [1-(5-Fluoro-pentyl)1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	7011	I
AB-FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I
FUB-144 (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone)	7014	I
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	7019	I
MDMB-FUBINACA (Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7020	I
FUB-AMB, MMB- FUBINACA, AMB-FUBINACA (2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3-methylbutanoate)	7021	I
AB-PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7023	I
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	7024	I
5F-AB-PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluropentyl)-1H-indazole-3-carboximide)	7025	I
ADB-BUTINACA (N-(1-amino-3,3-dimethyl-1-oxobutan 2-yl)-1-butyl-1H-indazole-3-carboxamide)	7027	I
AB-CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7031	I
MAB-CHMINACA (N-(1-amino-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7032	I
5F-AMB (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	7033	I
5F-ADB, 5F-MDMB-PINACA (Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7034	I
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
5F-EDMB-PINACA (ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	7036	I
5F-MDMB-PICA (methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	7041	I
MDMB-CHMICA, MMB-CHMINACA (Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	7042	I
4F-MDMB-BINACA (4F-MDMB-BUTINACA or methyl 2- (1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate) 7043 I N.	7043	I
MMB-CHMICA, AMB-CHMICA (methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate)	7044	I
FUB-AKB48, FUB-APINACA, AKB48 N-(4-FLUOROBENZYL) (N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboximide).	7047	I
APINACA and AKB48 (N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	7048	I
5F-APINACA, 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	7049	I
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I
5F-CUMYL-PINACA, 5GT-25 (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide)	7083	I
5F-CUMYL-P7AICA (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide)	7085	I
4-CN-CUML-BUTINACA, 4-cyano-CUMYL-BUTINACA, 4-CN-CUMYL BINACA, CUMYL-4CN-BINACA, SGT-78 (1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide).	7089	I
MDMB-4en-PINACA (methyl 3,3-dimethyl-2-(1-(pent-4- en-1-yl)-1H-indazole-3-carboxamido)butanoate) 7090 I N MDMB-4en-PINACA.	7090	I
4F-MDMB-BUTICA (methyl 2-[[1-(4-fluorobutyl)indole-3- carbonyl]amino]-3,3-dimethyl-butanoate	7091	I
ADB-4en-PINACA (N-(1-amino-3,3-dimethyl-1- oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3- carboxamide)	7092	I
CUMYL-PEGACLONE (5-pentyl-2-(2-phenylpropan-2- yl)pyrido[4,3-b]indol-1-one)	7093	I
5F-EDMB-PICA (ethyl 2-[[1-(5-fluorophentyl)indole-3- carbonyl]amino]-3,3-dimethyl-butanoate	7094	I
MMB-FUBICA (methyl 2-(1-(4-fluorobenzyl)-1H-indole3-carboxamido)-3-methyl butanoate	7095	I
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I

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UR-144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
NM2201, CBL2201 (Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	7221	I
PB-22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate)	7222	I
5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I
4-methyl-alpha-ethylaminopentiophenone (4-MEAP) 7245 I N 4-MEAP	7245	I
N-ethylhexedrone 7246 I N	7246	I
Alpha-ethyltryptamine	7249	I
Ibogaine	7260	I
2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine)	7286	I
CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol)	7297	I
CP-47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol)	7298	I
Lysergic acid diethylamide	7315	I
2C-T-7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine	7348	I
Marihuana Extract	7350	I
Parahexyl	7374	I
Mescaline	7381	I
2C-T-2 (2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine)	7385	I
3,4,5-Trimethoxyamphetamine	7390	I
4-Bromo-2,5-dimethoxyamphetamine	7391	I
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
2,5-Dimethoxyamphetamine	7396	I
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I
2,5-Dimethoxy-4-ethylamphetamine	7399	I
3,4-Methylenedioxyamphetamine	7400	I
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I
3,4-Methylenedioxy-N-ethylamphetamine	7404	I
3,4-Methylenedioxymethamphetamine	7405	I
4-Methoxyamphetamine	7411	I
Peyote	7415	I
5-Methoxy-N-N-dimethyltryptamine	7431	I
Alpha-methyltryptamine	7432	I
Bufotenine	7433	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
4-chloro-alpha-pyrrolidinovalerophenone (4-chloro-aPV	7443	I
4′-methyl-alpha-pyrrolidinohexiophenone (MPHP	7446	I
N-Ethyl-1-phenylcyclohexylamine	7455	I
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	7473	I
N-Ethyl-3-piperidyl benzilate	7482	I
N-Methyl-3-piperidyl benzilate	7484	I
N-Benzylpiperazine	7493	I
4-MePPP (4-Methyl-alphapyrrolidinopropiophenone)	7498	I
2C-D (2-(2,5-Dimethoxy-4-methylphenyl) ethanamine)	7508	I
2C-E (2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine)	7509	I
2C-H 2-(2,5-Dimethoxyphenyl) ethanamine)	7517	I
2C-I 2-(4-iodo-2,5-dimethoxyphenyl) ethanamine)	7518	I
2C-C 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine)	7519	I
2C-N (2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine)	7521	I
2C-P (2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine)	7524	I
2C-T-4 (2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine)	7532	I
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I
25B-NBOMe (2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7536	I
25C-NBOMe (2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7537	I
25I-NBOMe (2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7538	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I
N-Ethypentylone, ephylone (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one)	7543	I
alpha-pyrrolidinohexanophenone (a-PHP)	7544	I
alpha-pyrrolidinopentiophenone (α-PVP)	7545	I
alpha-pyrrolidinobutiophenone (α-PBP)	7546	I
Ethylone	7547	I
alpha-pyrrolidinoheptaphenone (PV8)	7548	I

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Eutylone	7549	I
α-PiHP (4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1- one)	7551	I
AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I
Acetyldihydrocodeine	9051	I
Benzylmorphine	9052	I
Codeine-N-oxide	9053	I
Cyprenorphine	9054	I
Desomorphine	9055	I
Etorphine (except HCl)	9056	I
Codeine methylbromide	9070	I
Brorphine (1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-4l)1,3-dihydro-2H-benzo[d]imidazol-2-one)	9098	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Heroin	9200	I
Hydromorphinol	9301	I
Methyldesorphine	9302	I
Methyldihydromorphine	9304	I
Morphine methylbromide	9305	I
Morphine methylsulfonate	9306	I
Morphine-N-oxide	9307	I
Myrophine	9308	I
Nicocodeine	9309	I
Nicomorphine	9312	I
Normorphine	9313	I
Pholcodine	9314	I
Thebacon	9315	I
Acetorphine	9319	I
Drotebanol	9335	I
U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I
AH-7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine))	9560	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Benzethidine	9606	I
Betacetylmethadol	9607	I
Betameprodine	9608	I
Betamethadol	9609	I
Betaprodine	9611	I
Clonitazene	9612	I
Dextromoramide	9613	I
Isotonotazene (N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine)	9614	I
Diampromide	9615	I
Diethylthiambutene	9616	I
Dimenoxadol	9617	I
Dimepheptanol	9618	I
Dimethylthiambutene	9619	I
Dioxaphetyl butyrate	9621	I
Dipipanone	9622	I
Ethylmethylthiambutene	9623	I
Etonitazene	9624	I
Etoxeridine	9625	I
Furethidine	9626	I
Hydroxypethidine	9627	I
Ketobemidone	9628	I
Levomoramide	9629	I
Levophenacylmorphan	9631	I
Morpheridine	9632	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Norpipanone	9636	I
Phenadoxone	9637	I
Phenampromide	9638	I
Phenoperidine	9641	I
Piritramide	9642	I
Proheptazine	9643	I
Properidine	9644	I
Racemoramide	9645	I
Trimeperidine	9646	I
Phenomorphan	9647	I
Propiram	9649	I

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1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	9663	I
Tilidine	9750	I
Butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1-amine)	9751	I
lunitazene (N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro1H-benzimidazol-1-yl)ethan-1- amine)	9756	I
Metonitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)-5- nitro-1Hbenzimidazol-1-yl)ethan-1-amine	9757	I
N-pyrrolidino etonitazene; etonitazepyne (2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)- 1Hbenzimidazole)	9758	I
Protonitazene (N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine)	9759	I
Metodesnitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)- 1H-benzimidazol-1- yl)ethan-1-amine)	9764	I
Etodesnitazene; etazene (2-(2-(4-ethoxybenzyl)- 1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine)	9765	I
Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide)	9811	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide	9816	I
Para-Methylfentanyl (N-(4-methylphenyl)-N-(1- phenethylpiperidin-4-yl)propionamide; also known as 4- methylfentanyl)	9817	I
4′-Methyl acetyl fentanyl (N-(1-(4- methylphenethyl)piperidin-4-yl)-N-phenylacetamide)	9819	I
ortho-Methyl methoxyacetyl fentanyl (2-methoxy-N-(2- methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide)	9820	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Para-fluorobutyryl fentanyl	9823	I
4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)	9824	I
2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide	9825	I
Para-chloroisobutyryl fentanyl	9826	I
Isobutyryl fentanyl	9827	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide)	9834	I
Thiofentanyl	9835	I
Beta-hydroxythiofentanyl	9836	I
Para-methoxybutyryl fentanyl	9837	I
Ocfentanil	9838	I
Thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylthiophene-2-carboxamide; also known as 2- thiofuranyl fentanyl; thiophene fentanyl).	9839	I
Valeryl fentanyl	9840	I
Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylbenzamide; also known as benzoyl fentanyl)	9841	I
beta′-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3- diphenylpropanamide; also known as β′-phenyl fentanyl; 3-phenylpropanoyl fentanyl).	9842	I
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide	9843	I
Crotonyl fentanyl ((E-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide)	9844	I
Cyclopropyl Fentanyl	9845	I
ortho-Fluorobutyryl fentanyl (N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)butyramide; also known as 2- fluorobutyryl fentanyl).	9846	I
Cyclopentyl fentanyl	9847	I
ortho-Methyl acetylfentanyl (N-(2-methylphenyl)-N-(1- phenethylpiperidin-4-yl)acetamide; also known as 2- methyl acetylfentanyl).	9848	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
Fentanyl carbamate (ethyl (1-phenethylpiperidin-4- yl)(phenyl)carbamate)	9851	I
ortho-Fluoroacryl fentanyl (N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)acrylamide)	9852	I
ortho-Fluoroisobutyryl fentanyl (N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)isobutyramide)	9853	I
Para-Fluoro furanyl fentanyl (N-(4-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)furan-2-carboxamide)	9854	I
2′-Fluoro ortho-fluorofentanyl (N-(1-(2- fluorophenethyl)piperidin-4-yl)-N-(2- fluorophenyl)propionamide; also known as 2′-fluoro 2- fluorofentanyl).	9855	I
beta-Methyl fentanyl (N-phenyl-N-(1-(2- phenylpropyl)piperidin-4-yl)propionamide; also known as β-methyl fentanyl)	9856	I
meta-Fluorofentanyl (N-(3-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)propionamide)	9857	I
meta-Fluoroisobutylryl fentanyl (N-(3-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)isobutyramide)	9858	I
para-Methoxyfuranyl fentanyl (N-(4-methoxyphenyl)-N- (1-phenethylpiperidin-4-yl)furan-2-carboxamide)	9859	I
3-Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-Nphenylfuran-3-carboxamide)	9860	I
2′,5′-Dimethoxyfentanyl (N-(1-(2,5- dimethoxyphenethyl)piperidin-4-yl)-N-phenylpropionamide)	9861	I
Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4- yl)-N-phenylbutanamide)	9862	I
ortho-Fluorofuranyl fentanyl (N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4-yl)furan-2-carboxamide)	9863	I
alpha′Methyl butyryl fentanyl (2-methyl-N-(1- phenethylpiperidin-4-yl)-N-phenylbutanamide)	9864	I
para-Methylcyclopropylfentanyl (N-(4-methylphenyl)-N- (1-phenethylpiperidin-4-yl)cyclopropanecarboxamide)	9865	I
Zipeprol (1-methoxy-3[-4-(2-methoxy-2- phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol)	9873	I
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration	7365	II

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Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Norfentanyl (N-phenyl-N-(piperidin-4-yl) propionamide)	8366	II
Phenylacetone	8501	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Anileridine	9020	II
Coca Leaves	9040	II
Cocaine	9041	II
Etorphine HCl	9059	II
Dihydrocodeine	9120	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Levomethorphan	9210	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine intermediate-A	9232	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Metazocine	9240	II
Oliceridine (N-[(3-methoxythiophen-2yl)methyl] ({2-[9r)-9-(pyridin-2-yl)-6-oxaspiro[4.5] decan-9-yl] ethyl {time})amine fumarate).	9245	II
Metopon	9260	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Dihydroetorphine	9334	II
Opium tincture	9630	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Noroxymorphone	9668	II
Phenazocine	9715	II
Thiafentanil	9729	II
Piminodine	9730	II
Racemethorphan	9732	II
Racemorphan	9733	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Bezitramide	9800	II
Moramide-intermediate	9802	II

The company plans to import small quantities of the listed controlled substances to support research activities funded by the National Institute on Drug Abuse. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–07037 Filed 4–2–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1339]

Importer of Controlled Substances Application: Purisys, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Purisys, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 3, 2024. Such persons may also file a written request for a hearing on the application on or before May 3, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no

need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 8, 2024, Purisys, LLC, 1550 Olympic Drive, Athens, Georgia 30601–1602, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Nabilone	7379	II
Phenylacetone	8501	II
Ecgonine	9180	II
Levorphanol	9220	II
Thebaine	9333	II
Opium, raw	9600	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Noroxymorphone	9668	II
Poppy Straw Concentrate.	9670	II
Tapentadol	9780	II

The company plans to import Opium, Raw (9600), Opium, Powered (9639) and Opium, Granulated (9640) to manufacture an Active Pharmaceutical Ingredient (API) only for distribution to its customers. The company plans to import Phenylacetone (8501) and Poppy Straw Concentrate (9670), to bulk manufacture other Controlled substances for distribution to its customers. The company plans to import impurities of buprenorphine that have been determined by DEA to be captured under Thebaine (9333). In reference to Marihuana Extract (7350), Marihuana (7360) and Tetrahydrocannabinols (7370) the company plans to import as synthetic. No other activity for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–07035 Filed 4–2–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0073]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Crime Data Explorer (CDE) Feedback

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Federal Bureau of Investigation (FBI), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on February 20, 2024, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until May 3, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Edward L. Abraham, Crime and Law Enforcement Statistics Unit Chief, FBI, CJIS Division, Module D–1, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; *elabraham@fbi.gov,* 304–625–4830.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1110–0073. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* Crime Data Explorer Feedback Survey.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* There is no form number for this collection. The applicable component within DOJ is the Criminal Justice Information Services (CJIS) Division, FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Law enforcement, academia, and the general public.

Abstract: This survey is needed to collect feedback on the functionality of the CDE in order to make improvements to the application.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* 200 respondents.

7. *Estimated Time per Respondent:* 2 minutes.

8. *Frequency:* 1/annually.

9. *Total Estimated Annual Time Burden:* 7 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: March 28, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–06976 Filed 4–2–24; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

221st Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 221st open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on Tuesday, May 14, 2024.

The meeting will occur from 8:30 a.m. to approximately 4 p.m. (ET), with a one-hour break for lunch. The meeting will take place at the U.S. Department of Labor, 200 Constitution Avenue NW, Room C5521—Room 4, Washington, DC 20210. The meeting will also be accessible via teleconference and some participants, as well as members of the public, may elect to attend virtually. Instructions for public teleconference access will be available on the ERISA Advisory Council's web page at *https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council* approximately one week prior to the meeting.

The purpose of the open meeting is to set the topics to be addressed by the Council in 2024. Also, the ERISA Advisory Council members will receive an update from leadership of the Employee Benefits Security Administration (EBSA).

Organizations or members of the public wishing to submit a written statement may do so on or before Tuesday, May 7, 2024, to George Pantazopoulos, Designated Federal Officer, ERISA Advisory Council. Statements should be transmitted electronically as an email attachment in text or pdf format to *ERISAAdvisoryCouncil@dol.gov.* Statements transmitted electronically that are included in the body of the email will not be accepted. Relevant statements received on or before Tuesday, May 7, 2024, will be included in the record of the meeting and made available through the EBSA Public Disclosure Room. No deletions, modifications, or redactions will be made to the statements received as they are public records.

Individuals or representatives of organizations wishing to address the ERISA Advisory Council should forward their requests no later than Tuesday, May 7, 2024, via email to *ERISAAdvisoryCouncil@dol.gov* or by telephoning (202) 693–8654. Oral presentations will be limited to ten minutes, time permitting, but an extended statement may be submitted for the record.

Individuals who need special accommodations should contact the Designated Federal Officer no later than Tuesday, May 7, 2024, via email to *ERISAAdvisoryCouncil@dol.gov* or by telephoning (202) 693–8654.

For more information about the meeting, contact the Designated Federal Officer at the address or telephone number above.

Signed at Washington, DC, this 24th day of March, 2024.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2024–07019 Filed 4–2–24; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

[Docket No. OSHA–2024–0002]

Occupational Safety and Health Administration

Advisory Committee on Construction Safety and Health (ACCSH): Notice of Meetings

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of ACCSH Committee meeting.

SUMMARY: The Advisory Committee on Construction Safety and Health (ACCSH) will meet April 24, 2024, by teleconference and WebEx.

DATES: *ACCSH meeting:* ACCSH will meet from 1 p.m. to 5:30 p.m., EDT, Wednesday, April 24, 2024.

ADDRESSES:

Submission of comments and requests to speak: Submit comments and requests to speak at the ACCSH meeting by Thursday, April 18, 2024, identified by the docket number for this **Federal Register** notice (Docket No. OSHA–2024–0002), using the following method:

Electronically: Comments and requests to speak, including attachments, must be submitted electronically at: *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Requests for special accommodations: Submit requests for special accommodations for this ACCSH meeting by Thursday, April 18, 2024, to Ms. Gretta Jameson, OSHA, Directorate of Construction, U.S. Department of Labor; telephone: (202) 693–2020; email: *jameson.grettah@dol.gov*.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email: *meilinger.francis2@dol.gov*.

For general information about ACCSH: Ms. Terra Gaines, OSHA, Directorate of Construction, U.S. Department of Labor; telephone (202) 693–2483; email: *gaines.terra.b@dol.gov*.

Telecommunication requirements: For additional information about the telecommunication requirements for the meeting, please contact Ms. Gretta Jameson, OSHA, Directorate of Construction, U.S. Department of Labor; telephone (202) 693–2020; email: *jameson.grettah@dol.gov*.

For copies of this ***Federal Register*** *Notice:* Electronic copies of this **Federal Register** Notice are available at: *http://www.regulations.gov*. This notice, as well as news releases and other relevant information, are also available on OSHA's website at *www.osha.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

ACCSH advises the Secretary of Labor and the Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) in the formulation of standards affecting the construction industry, and on policy matters arising in the administration of the safety and health provisions under the Contract Work Hours and Safety Standards Act (Construction Safety Act (CSA)) (40 U.S.C. 3701 *et seq.*) and the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) (see also 29 CFR 1911.10 and 1912.3). In addition, the CSA and OSHA regulations require the Assistant Secretary to consult with ACCSH before the agency proposes occupational safety

and health standards affecting construction activities (40 U.S.C. 3704; 29 CFR 1911.10).

ACCSH operates in accordance with the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App. 2), and its implementing regulations (41 CFR 102–3 *et seq.*); and Department of Labor Manual Series Chapter 1–900 (3/25/2022). ACCSH generally meets two to four times a year.

II. Meeting

ACCSH Meeting

ACCSH will meet from 1 p.m. to 5:30 p.m., EDT, Wednesday, April 24, 2024. The meeting is open to the public.

Meeting agenda: The tentative agenda for this meeting includes:

- Heat Injury and Illness Prevention in Outdoor and Indoor Work Rulemaking;
- Infectious Diseases Rulemaking; and
- Public Comment period.

III. Meeting Information

Attending the meeting: Attendance at the ACCSH meeting will be by teleconference and WebEx only. Directions for attending the meeting by WebEx, or by phone, will be posted in the Docket and on the ACCSH web page, *https://www.osha.gov/advisory committee/accsh,* prior to the meeting.

Requests to speak and speaker presentations: Attendees who wish to address ACCSH must submit a request to speak, as well as any written or electronic presentation, by Thursday, April 18, 2024, using the method listed in the **ADDRESSES** section of this notice. The request must state:

- The amount of time requested to speak;
- The interest you represent (*e.g.,* business, organization, affiliation), if any; and
- A brief outline of your presentation.

PowerPoint presentations and other electronic materials must be compatible with PowerPoint 2010 and other Microsoft Office 2010 formats.

Alternately, you may request to address ACCSH briefly during the public-comment period. At her discretion, the ACCSH Chair may grant requests to address ACCSH as time and circumstances permit.

Docket: OSHA will place comments, requests to speak, and speaker presentations, including any personal information you provide, in the public docket without change, and those documents may be available online at: *http://www.regulations.gov*. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security Numbers and birthdates. OSHA also places in the public docket the meeting transcript, meeting minutes, documents presented at the meeting, and other documents pertaining to the ACCSH meeting. These documents are available online at: *http://www.regulations.gov*. To read or download documents in the public docket for this ACCSH meeting, go to Docket No. OSHA–2024–0002 at: *http://www.regulations.gov*. All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *http://www.regulations.gov*. All submissions are available for inspection and copying, when permitted, at the OSHA Docket Office. For information on using *http://www.regulations.gov* to make submissions or to access the docket, click on the ''Help'' tab at the top of the homepage. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available through that website and for assistance in using the internet to locate submissions and other documents in the docket.

Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice pursuant to 29 U.S.C. 655, 40 U.S.C. 3704, Secretary of Labor's Order No. 8–2020 (85 FR 58393), 5 U.S.C. App. 2, and 29 CFR part 1912.

Signed at Washington, DC, on March 28, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–07016 Filed 4–2–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2024–0005]

National Advisory Committee on Occupational Safety and Health (NACOSH): Notice of Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of NACOSH meeting.

SUMMARY: The National Advisory Committee on Occupational Safety and Health (NACOSH) will meet May 7, 2024. Committee members and the public will meet virtually via WebEx.

DATES: The NACOSH will meet from 9:00 a.m. to 4:30 p.m., ET, May 7, 2024.

ADDRESSES:

Submission of comments and requests to speak: Comments and requests to speak at the NACOSH meeting, including attachments, must be submitted electronically at *www.regulations.gov,* the Federal eRulemaking Portal by April 22, 2024. Comments must identify the docket number for this **Federal Register** notice (Docket No. OSHA–2024–0005). Follow the online instructions for submitting comments.

Registration: All persons wishing to attend this virtual meeting must register via the registration link on the NACOSH web page at *https://www.osha.gov/advisorycommittee/nacosh*. Upon registration, attendees will receive a WebEx link for remote access to the meeting.

Requests for special accommodations: Submit requests for special accommodations, including translation services, for this NACOSH meeting by April 22, 2024, to Ms. Carla Marcellus, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–1865; email: *marcellus.carla@dol.gov*.

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (Docket No. OSHA–2024–0005). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

Docket: To read or download documents in the public docket for this NACOSH meeting, go to *www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *www.regulations.gov.* All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov*.

For general information about NACOSH: Ms. Lisa Long, Deputy Director, Directorate of Standards and Guidance, OSHA, U.S. Department of

Labor; telephone: (202) 693–2409; email: *long.lisa@dol.gov*.

Telecommunication requirements: For additional information about the telecommunication requirements for the meeting, please contact Ms. Carla Marcellus, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–1865; email: *marcellus.carla@dol.gov*.

For copies of this ***Federal Register*** *Notice:* Electronic copies of this **Federal Register** notice are available at *www.regulations.gov*. This notice, as well as news releases and other relevant information, are also available at OSHA's web page at *https://www.osha.gov/advisorycommittee/nacosh*.

SUPPLEMENTARY INFORMATION:

I. Background

NACOSH was established by Section 7(a) of the Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651, 656) to advise, consult with, and make recommendations to the Secretary of Labor and the Secretary of Health and Human Services on matters relating to the administration of the OSH Act. NACOSH is a continuing advisory committee of indefinite duration.

NACOSH operates in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2), its implementing regulations (41 CFR part 102–3), and OSHA's regulations on NACOSH (29 CFR 1912.5 and 29 CFR part 1912a).

II. Meeting Information

Public attendance will be virtual via WebEx only. See registration information above under **ADDRESSES**. Meeting information will be posted in the docket (Docket No. OSHA–2024–0005) and on the NACOSH web page, *https://www.osha.gov/advisorycommittee/nacosh,* prior to the meeting.

NACOSH will meet from 9:00 a.m. to 4:30 p.m., ET on May 7, 2024.

Meeting agenda: The tentative agenda for this meeting includes:

- OSHA Updates;
- NIOSH Update; and
- Wage and Hour Division Update on Child Labor, Undocumented Minors, and Vulnerable Workers.

Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 29 U.S.C. 655(b)(1) and 656(b), 5 U.S.C. App. 2, 29 CFR parts 1912 and 1912a, and Secretary of Labor's Order No. 8–2020 (85 FR 58393, September 18, 2020).

Signed at Washington, DC, on March 28, 2024.

James S. Frederick,

Deputy Assistant Secretary for Occupational Safety and Health.

[FR Doc. 2024–07017 Filed 4–2–24; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 24–027]

Name of Information Collection: NASA New Technology Reporting System

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection; renewal of existing approved collection.

SUMMARY: NASA, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA).

DATES: Comments are due by May 3, 2024.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice. You may send comments, identified by NASA Notice Number 24–027, to the Federal e-Rulemaking Portal: *https://www.regulations.gov*. Follow the instructions for sending comments.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to NASA PRA Clearance Officer, Bill Edwards-Bodmer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, phone 757–864–7998, or email *hq-ocio-pra-program@mail.nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Personnel performing research and development are required by statutes, NASA implementing regulations, and OMB policy to submit reports of inventions, patents, data, and copyrights, including the utilization and disposition of same. The NASA New Technology Summary Report reporting form is being used for this purpose. This information is required to ensure the proper disposition of rights to inventions made in the course of NASA-funded research contracts. The requirement is codified in 48 CFR part 1827. The legislative authorities are 42 U.S.C. 2457 *et seq.,* and 35 U.S.C. 200 *et seq*.

II. Methods of Collection

NASA FAR Supplement clauses for patent rights and new technology encourage personnel to use an electronic form and provide a hyperlink to the electronic New Technology Reporting System (e-NTR) site: *http://invention.nasa.gov.* This website has been set up to help NASA employees and parties under NASA funding agreements (*i.e.,* contracts, grants, cooperative agreements, and subcontracts) to report new technology information directly to NASA via a secure internet connection.

III. Data

Title: NASA New Technology Reporting System.

OMB Number: 2700–0052.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses, colleges and university, and/or other for-profit institutions.

Estimated Annual Number of Activities: 3,372.

Estimated Number of Respondents per Activity: 1.

Annual Responses: 3,372.

Estimated Time per Response: 3 hours.

Estimated Total Annual Burden Hours: 10,116.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

William Edwards-Bodmer,

PRA Clearance Officer, National Aeronautics and Space Administration.

[FR Doc. 2024–07059 Filed 4–2–24; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 24–026]

Name of Information Collection: Survey of the Use of NASA Earth Observation Data by States, Tribes, and Territories

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: NASA, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA).

DATES: Comments are due by June 3, 2024.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 60 days of publication of this notice. You may send comments, identified by NASA Notice Number 24–026 to the Federal e-Rulemaking Portal: *https://www.regulations.gov.* Follow the instructions for sending comments.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to NASA PRA Clearance Officer, Bill Edwards-Bodmer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, phone 757–864–7998, or email *hq-ocio-pra-program@mail.nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

As part of a requirement from the CHIPS and Science Act of 2022 (sec. 10824, Pub. L. 117–167, 136 Stat. 1742) the NASA Administrator shall arrange for the conduct of a survey of the use of NASA Earth observation data by States, Tribal organizations, and territories. The collection of this information will enable the agency to understand how Earth observation data is used, how it might impact decision making, and where any gaps might exist.

II. Methods of Collection

Electronic, virtual focus groups, and in-person focus groups.

III. Data

Title: Survey of the Use of NASA Earth Observation Data by States, Tribes, and Territories.

OMB Number: 2700-new.

Type of review: New collection.

Affected Public: Officials representing states, tribes, and territories.

Estimated Annual Number of Activities: 2.

Estimated Number of Respondents per Activity: 1.

Annual Responses: 2,000.

Estimated Time per Response: 1.25 hours (focus group + quantitative survey).

Estimated Total Annual Burden Hours: 2,500.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

William Edwards-Bodmer,

PRA Clearance Officer, National Aeronautics and Space Administration.

[FR Doc. 2024–07058 Filed 4–2–24; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0077]

Interim Staff Guidance: Advanced Reactor Content of Application Project Chapter 10, Control of Occupational Dose

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issuing Interim Staff Guidance (ISG) DANU–ISG–2022–04, Chapter 10, ''Control of Occupational Dose.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0077 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0077. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–04, Chapter 10, ''Control of Occupational Dose,'' is available in ADAMS under Accession No. ML23277A142.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these

designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150–Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, Chapter 10, ''Control of Occupational Dose,'' that is the subject of this FRN, was developed because the current application and review guidance related to control of occupational doses is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap.'"	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information.'"	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste.'"	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose.'"	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations.'"	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program.'"	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs.'"	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications.'"	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations).'"	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS did not recommend any specific changes to DANU–ISG–2022–04.

Draft DANU–ISG–2022–04, Chapter 10, ''Control of Occupational Dose,'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33936) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41985). The NRC staff received two public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A151.

IV. Congressional Review Act

DANU–ISG–2022–04, Chapter 10, ''Control of Occupational Dose,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–04 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–04, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–04.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07026 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–263, 50–260, and 50–296; NRC–2024–0030]

Notice of Intent To Conduct Scoping Process and Prepare Environmental Impact Statement; Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; public scoping meeting and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will conduct a scoping process to gather information necessary to prepare an environmental impact statement (EIS) to evaluate the environmental impacts for an application for the subsequent license renewal (SLR) of the Renewed Facility Operating License Nos. DPR–33, DPR–52, and DPR–68 for Browns Ferry Nuclear Plant, Units 1, 2, and 3 (Browns Ferry). The NRC is seeking public comment on this action and has scheduled two virtual public scoping meetings.

DATES: The NRC will hold two virtual public scoping meetings on April 11, 2024, at 1 p.m. eastern time (ET) and on April 18, 2024, at 6 p.m. ET. Details on both meetings can be found on the NRC's Public Meeting Schedule at *https://www.nrc.gov/pmns/mtg.* Submit comments on the scope of the EIS by May 3, 2024. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. See Section IV, ''Public Scoping Meeting,'' of this notice for additional information.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://regulations.gov* and search for Docket ID NRC–2024–0030. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: BrownsFerryEnvironmental@nrc.gov.*
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jessica Umaña, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5207, email: *Jessica.Umana@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2024–0030 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://regulations.gov* and search for Docket ID NRC–2024–0030.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if it is available in ADAMS) is provided the first time that it is referenced.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.
- *Public Library:* A copy of the SLR application for Browns Ferry, including

the environmental report (ER), is available for public review at the following public library location: Athens-Limestone County Public Library, 603 S Jefferson Street, Athens, AL 35611.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2024–0030 in the subject line of your comment submission to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

By letter dated January 19, 2024 (ADAMS Package Accession No. ML24019A009), Tennessee Valley Authority, submitted to the NRC an application for subsequent license renewal of Renewed Facility Operating License No. DPR–33, DPR–52, and DPR–68, for Units 1, 2, and 3, for an additional 20 years of operation. This submission initiated the NRC's proposed action of determining whether to grant the SLR application. Browns Ferry Units 1, 2, and 3 are boiling water reactors designed by General Electric and are located on the north shore of Wheeler Reservoir in Limestone County Alabama at the Tennessee River Mile 294. The current renewed facility operating license for Units 1, 2, and 3, expire at midnight on December 20, 2033, June 28, 2034, and July 2, 2036, respectively. The SLR application was submitted pursuant to part 54 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for Renewal of Operating Licenses for Nuclear Power Plants,'' and seeks to extend the renewed facility operating licenses for Units 1, 2, and 3, to midnight on December 20, 2053, June 28, 2054, and July 2, 2056, respectively. A notice of receipt and availability of the application was published in the **Federal Register** on February 8, 2024 (89 FR 8725). A notice of acceptance for docketing of the application and of opportunity to request a hearing was published in the **Federal Register** on March 21, 2024 (89 FR 20254) and is available on the Federal rulemaking website (*https://www.regulations.gov*) by searching for Docket ID NRC–2024–0030.

III. Request for Comment

This notice informs the public of the NRC's intention to conduct environmental scoping and prepare an EIS related to the SLR application for Browns Ferry, and to provide the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR 51.29, ''Scoping-environmental impact statement and supplement to environmental impact statement,'' and 10 CFR 51.116, ''Notice of intent.''

The regulations in 36 CFR 800.8, ''Coordination with the National Environmental Policy Act,'' allow agencies to use their National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) (NEPA) process to fulfill the requirements of Section 106 of the National Historic Preservation Act of 1966 (54 U.S.C. 300101, *et seq.*) (NHPA).

Therefore, pursuant to 36 CFR 800.8(c), the NRC intends to use its process and documentation required for the preparation of the EIS on the proposed action to comply with Section 106 of the NHPA in lieu of the procedures set forth at 36 CFR 800.3 through 800.6.

In accordance with 10 CFR 51.53(c) and 10 CFR 54.23, Tennessee Valley Authority submitted an ER as part of the SLR application. The ER was prepared pursuant to 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' and is available in ADAMS under Accession No. ML24023A476. The ER will also be available for viewing at *https://www.nrc.gov/reactors/operating/licensing/renewal/applications/browns-ferry-subsequent.html.*

In addition, the SLR application, including the ER, is available for public review at the Athens-Limestone County Public Library, 603 S Jefferson Street, Athens, AL 35611.

The NRC intends to gather the information necessary to prepare a site-specific EIS related to the SLR application for Browns Ferry. The site-specific EIS will evaluate the environmental impacts of subsequent license renewal for Browns Ferry and reasonable alternatives thereto. Possible alternatives to the proposed action include the no action alternative and reasonable alternative energy sources. This notice is being published in accordance with NEPA and the NRC's regulations at 10 CFR part 51.

As part of its environmental review, the NRC will first conduct a scoping process for the site-specific EIS and, as soon as practicable thereafter, will prepare a draft site-specific EIS for public comment. Participation in this scoping process by members of the public and local, State, Tribal, and Federal government agencies is encouraged. The scoping process for the site-specific EIS will be used to accomplish the following:

a. Define the proposed action that is to be the subject of the site-specific EIS;

b. Determine the scope of the site-specific EIS and identify the significant issues to be analyzed in depth;

c. Identify and eliminate from detailed study those issues that are peripheral or are not significant or that have been covered by prior environmental review;

d. Identify any environmental assessments and other ElSs that are being or will be prepared that are related to, but are not part of, the scope of the site-specific EIS under consideration;

e. Identify other environmental review and consultation requirements related to the proposed action;

f. Indicate the relationship between the timing of the preparation of the environmental analyses and the NRC's tentative planning and decision-making schedule;

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the site-specific EIS to the NRC and any cooperating agencies; and

h. Describe how the site-specific EIS will be prepared, including any contractor assistance to be used.

The NRC invites the following entities to participate in scoping:

a. The applicant, Tennessee Valley Authority;

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards;

c. Affected State and local government agencies, including those

authorized to develop and enforce relevant environmental standards;

d. Any affected Indian Tribe;

e. Any person who requests or has requested an opportunity to participate in the scoping process; and

f. Any person who has petitioned or intends to petition for leave to intervene under 10 CFR 2.309.

IV. Public Scoping Meeting

In accordance with 10 CFR 51.26(b), the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to the proposed action and to determine the scope of issues to be addressed in the EIS.

The NRC is announcing that it will hold two virtual public scoping meetings for the Browns Ferry SLR site-specific EIS. A court reporter will transcribe all comments received during the public scoping meeting. To be considered, comments must be provided either at a transcribed public meeting or in writing, as discussed in the **ADDRESSES** section of this notice. The NRC will hold two virtual public scoping meetings on April 11, 2024, at 1 p.m. ET and on April 18, 2024, at 6 p.m. ET.

Persons interested in attending this meeting should monitor the NRC's Public Meeting Schedule website at *https://www.nrc.gov/pmns/mtg* for additional information and the agenda for the meeting. Please contact Ms. Jessica Umana no later than April 6, 2024, for the meeting on April 11, 2024, and April 13, 2024, for the meeting on April 18, 2024, if accommodations or special equipment is needed to attend or to provide comments, so that the NRC staff can determine whether the request can be accommodated.

The public scoping meeting will include: (1) an overview by the NRC staff of the environmental and safety review processes, the proposed scope of the site-specific EIS, and the proposed review schedule; and (2) the opportunity for interested government agencies, organizations, and individuals to submit comments or suggestions on environmental issues or the proposed scope of the Browns Ferry SLR site-specific EIS.

Participation in the scoping process for the Browns Ferry SLR site-specific EIS does not entitle participants to become parties to the proceeding to which the site-specific EIS relates. Matters related to participation in any hearing are outside the scope of matters to be discussed at this public meeting.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Ashley N. Waldron,

Acting Chief, Environmental Project Management Branch 1, Division of Rulemaking, Environment, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024–06990 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–269–SLR–2; 50–270–SLR–2; 50–287–SLR–2]

In the Matter of Duke Energy Carolinas, LLC, (Oconee Nuclear Station Units 1, 2, and 3); Order

On February 13, 2024, the Nuclear Regulatory Commission issued a notice in the **Federal Register** providing an opportunity to request a hearing and petition for leave to intervene with respect to the Draft Supplemental Environmental Impact Statement for Duke Energy Carolinas, LLC's subsequent license renewal application for Oconee Nuclear Station, Units 1, 2, and 3.[1] The **Federal Register** notice set a deadline of April 15, 2024, for filing a hearing request.

Subsequently, on March 18, 2024, Beyond Nuclear and Sierra Club (together, Petitioners) filed a motion to extend by two weeks, until April 29, 2024, the deadline for Petitioners to request a hearing in this proceeding.[2] The Petitioners represent that the applicant has agreed not to oppose this extension request provided that its deadline to respond to such a hearing request is also extended by seven days, to May 31, 2024.[3] In addition, the Petitioners state in the motion that the NRC Staff has not taken a position on the extension request.[4]

As good cause for the requested extension, the Petitioners cite conflicting litigation obligations, a personal commitment, and that they ''reasonably anticipated'' that the Commission would withdraw the hearing request in light of the circumstances in two other subsequent license renewal proceedings.[5] Under Commission precedent litigation burden is not good cause for an extension.[6]

Nevertheless, in this instance, the participants have consulted, the Petitioners and the applicant have reached agreement, and the motion is unopposed. Therefore, pursuant to my authority under 10CFR 2.346(b), I extend the deadline for all persons to file a hearing request in this proceeding until April 29, 2024. The deadline for answers to timely hearing requests shall be May 31, 2024, and the deadline for any replies shall be June 7, 2024. Petitions to intervene and requests for hearing shall be filed consistent with the instructions set out in the Electronic Submissions (E-Filing) section of the Hearing Notice.

It is so ordered.

For the Commission.

Dated at Rockville, Maryland, This 28th of March 2024.

Carrie Safford,

Secretary of the Commission.

[FR Doc. 2024–06983 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0076]

Interim Staff Guidance: Advanced Reactor Content of Application Project Chapter 9, Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–03, Chapter 9, ''Control of Routine Plant

[1] Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3; Draft Supplemental Environmental Impact Statement, 89 FR10,107 (Feb. 13, 2024) (Hearing Notice).

[2] *Motion by Beyond Nuclear and Sierra Club for Extension of Time to Submit Hearing Request* (Mar. 18, 2024) (ADAMS Accession no. ML24078A146).

[3] *Id.* at 1.

[4] *Id.* at 2.

[5] *Id.* at 1–2. The Petitioners cite subsequent license renewal proceedings for North Anna Power Station, Units 1 and 2, and Turkey Point Nuclear Generating, Units 3 and 4, the draft supplemental environmental impact statements of which were similarly noticed for hearing opportunities in accordance with Commission direction. CLI–22–3, 95 NRC 40, 42 (2022). In the *Turkey Point* proceeding, the Atomic Safety and Licensing Board certified a question to the Commission concerning language in CLI–22–3, specifically, whether the Staff should have waited to issue the notice of opportunity for hearing until the completion of the final supplemental environmental impact statement. *Florida Power & Light Co.* (Turkey Point Nuclear Generating Units 3 and 4), LBP–24–1, 99 NRC __, __(Jan. 31, 2024) (slip op. at 4). The Commission recently issued an order in which it accepted the Board's certification and found the Staff's interpretation of CLI–22–3 with respect to the timing of the hearing notice acceptable. *Florida Power & Light Co.* (Turkey Point Nuclear Generating Units 3 and 4), CLI–24–1, 99 NRC __, __(Mar. 7, 2024) (slip op. at 6).

[6] *See Consolidated Edison Co. of New York* (Indian Point, Units 1 and 2), CLI–01–8, 53 NRC 225, 229–30 (2001) (quoting *Niagara Mohawk Power Corp.* (Nine Mile Point, Units 1 & 2), 50 NRC 333, 343 (1999)).

Radioactive Effluents, Plant Contamination and Solid Waste.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0076 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0076. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–03, Chapter 9, ''Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste,'' is available in ADAMS under Accession No. ML23277A141.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, Chapter 9, ''Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste,'' that is the subject of this FRN, was developed because the current application and review guidance related to control of routine plant radioactive effluents, plant contamination, and solid waste is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program' ''	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs' ''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications' ''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations)' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content-of-Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS did not recommend any specific changes to DANU–ISG–2022–03.

Draft DANU–ISG–2022–03, Chapter 9, ''Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste,'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33930) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41986). The NRC staff received thirteen public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A150.

IV. Congressional Review Act

DANU–ISG–2022–03, Chapter 9, ''Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–03 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–03, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–03.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07025 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0079]

Interim Staff Guidance: Advanced Reactor Content of Application Project Chapter 12, Post-Manufacturing and Construction Inspection, Testing, and Analysis Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–06, Chapter 12, ''Post-manufacturing and construction Inspection, Testing, and Analysis Program.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0079 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available

information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2022–0079. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–06, Chapter 12, ''Post-manufacturing and construction Inspection, Testing, and Analysis Program,'' is available in ADAMS under Accession No. ML23277A144.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150–Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53, ''Licensing and Regulation of Advanced Nuclear Reactors,'' (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, Chapter 12, ''Post-manufacturing and construction Inspection, Testing, and Analysis Program [PITAP],'' that is the subject of this FRN, was developed because the current application and review guidance related to PITAP is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01. ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program' ''	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs' ''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications'	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations)' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS recommended changes to DANU–ISG–2022–06. As set forth in its letter dated March 18, 2024 (ADAMS Accession No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff considered the ACRS recommendations and, for the reasons stated in the staff letter, determined that changes to DANU–ISG–2022–06 were unnecessary.

Draft DANU–ISG–2022–06, Chapter 12, ''Post-manufacturing and construction Inspection, Testing, and Analysis Program,'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33920) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41987). The NRC staff received nine public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A153.

IV. Congressional Review Act

DANU–ISG–2022–06, Chapter 12, ''Post-manufacturing and construction Inspection, Testing, and Analysis Program,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–06 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–06, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–06.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07028 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0078]

Interim Staff Guidance: Advanced Reactor Content of Application Project Chapter 11, Organization and Human-System Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–05, Chapter 11, ''Organization and Human-System Considerations.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0078 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0078. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email:

Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the ''For **FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–05, Chapter 11, ''Organization and Human-System Considerations,'' is available in ADAMS under Accession No. ML23277A143.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, Chapter 11, ''Organization and Human-System Considerations,'' that is the subject of this FRN, was developed because the current application and review guidance related to organization and human-systems interface considerations is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01. ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program' ''	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs' ''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications' ''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations)' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS recommended changes to DANU–ISG–2022–05. As set forth in its letter dated March 18, 2024 (ADAMS Accession No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff considered the ACRS recommendations and, for the reasons stated in the staff letter, determined that changes to DANU–ISG–2022–05 were unnecessary.

Draft DANU–ISG–2022–05, Chapter 11, ''Organization and Human-System Considerations,'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33928) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41992). The NRC staff received twelve public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A152.

IV. Congressional Review Act

DANU–ISG–2022–05, Chapter 11, ''Organization and Human-System Considerations,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–05 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–05, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–05.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07027 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0108]

Information Collection: NRC Form 149, OCFO Invitational Traveler Request Form

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, NRC Form 149, ''OCFO Invitational Traveler Request Form.''

DATES: Submit comments by May 3, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0108 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0108.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML24046A101. The supporting statement is available in ADAMS under Accession No. ML24046A099.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, NRC Form 149, ''OCFO Invitational Traveler Request Form.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on December 15, 2023, 88 FR 86948.

1. *The title of the information collection:* NRC Form 149, OCFO Invitational Traveler Request Form.

2. *OMB approval number:* 3150–0247.

3. *Type of submission:* Revision.

4. *The form number, if applicable:* NRC Form 149.

5. *How often the collection is required or requested:* The collection is required when there is an invitational traveler that will be reimbursed by the NRC. This occurs on an as needed basis and does not have a regular schedule for submission.

6. *Who will be required or asked to respond:* The invitational traveler will be asked to respond and NRC staff that are associated with the purpose of the invitational traveler may also be asked to respond on an as needed basis.

7. *The estimated number of annual responses:* 435.

8. *The estimated number of annual respondents:* 435.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 109.

10. *Abstract:* The NRC provides reimbursement for people on invitational travel for the NRC. As such, the NRC would reimburse them through our Financial Accounting and Integrated Management Information System (FAIMIS). Additionally, the travel itself would be processed in our electronic travel systems (ETS2). Both the financial and travel systems must be set up appropriately for the invitational traveler to travel and receive reimbursement from the NRC. The information collected on Form 149 meets the requirements for the invitational traveler to have a profile created in FAIMIS and in ETS2. The information collected is necessary to meet the criteria for both systems.

Dated: March 29, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–07081 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0082]

Interim Staff Guidance: Advanced Reactor Content of Application Project, ''Risk-Informed, Performance-Based Fire Protection Program (for Operations)''

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–09, ''Risk-Informed, Performance-Based Fire Protection Program (for Operations).'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0082 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0082. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly

available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–09, ''Risk-Informed, Performance-Based Fire Protection Program (for Operations),'' is available in ADAMS under Accession No. ML23277A147.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150–Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled ''Risk-Informed, Performance-Based Fire Protection Program (for Operations),'' that is the subject of this FRN, was developed because the current application and review guidance related to fire protection programs for operations is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program' ''	ML23277A144	NRC–2022–0079

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations)''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS also recommended specific changes to DANU–ISG–2022–09. As set forth in its letter dated March 18, 2024 (ADAMS No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff revised DANU–ISG–2022–09 to address specific ACRS recommendations.

Draft DANU–ISG–2022–09, ''Risk-Informed, Performance-Based Fire Protection Program (for Operations),'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33922) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41990). The NRC staff received twenty-three public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A156.

IV. Congressional Review Act

DANU–ISG–2022–09, ''Risk-Informed, Performance-Based Fire Protection Program (for Operations),'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–09 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–09, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–09.

Dated: Month 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07031 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0080]

Interim Staff Guidance: Advanced Reactor Content of Application Project, Risk-Informed Inservice Inspection/ Inservice Testing Programs for Non-LWRs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–07, ''Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs.'' The purpose of this ISG is to provide guidance to prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0080 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0080. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG,

DANU–ISG–2022–07, ''Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs,'' is available in ADAMS under Accession No. ML23277A145.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR reactor applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, ''Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs,'' that is the subject of this FRN, was developed because the current application and review guidance related to ISI and IST programs are based on requirements found in 10 CFR 50.55a, ''Codes and standards,'' that are only applicable to, and focus on, large light water reactor (LWR) technologies. In addition, the current application and review guidance for large LWR ISI and IST programs may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap.'"	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information.'"	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste.'"	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose.'"	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations.'"	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program.'"	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs.'"	ML23277A145	NRC–2022–0080

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications.' ''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations).' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content-of-Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS recommended specific changes to DANU–ISG–2022–07. As set forth in its letter dated March 18, 2024 (ADAMS Accession No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff revised DANU–ISG–2022–07 to address specific ACRS recommendations.

Draft DANU–ISG–2022–07, ''Risk-Informed Inservice Inspection/Inservice Testing,' '' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33938) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41989). The NRC staff received forty-three public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A154.

IV. Congressional Review Act

DANU–ISG–2022–07, ''Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs,' '' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–07 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–07, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–07.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07064 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0075]

Interim Staff Guidance: Advanced Reactor Content of Application Project Chapter 2, Site Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Final staff guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–02, Chapter 2, ''Site Information.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0075 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0075. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–02, Chapter 2, ''Site Information,'' is available in ADAMS under Accession No. ML23277A140.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–

4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325, email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled, ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, Chapter 2, ''Site Information,'' that is the subject of this FRN, was developed because the current application and review guidance related to control of site information is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program' ''	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs' ''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications' ''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-informed Performance-Based Fire Protection Program (for Operations)' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS did not recommend any specific changes to DANU–ISG–2022–02.

Draft DANU–ISG–2022–02, Chapter 2, ''Site Information'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33940) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41991). The NRC staff received twelve public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A148.

IV. Congressional Review Act

DANU–ISG–2022–02, Chapter 2, ''Site Information,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–02 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–02, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–02.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07024 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0074]

Interim Staff Guidance: Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–01, ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0074 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0074. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ISG, DANU–ISG–2022–01, ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap,'' is available in ADAMS under Accession No. ML23277A139.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

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SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR),

''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

II. Discussion

The ARCAP ISG titled, ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG), that is the subject of this **Federal Register** notice (FRN), was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate FRNs notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of this section.

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Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program.' ''	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs' ''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications' ''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations)' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS also recommended specific changes to DANU–ISG–2022–01. As set forth in its letter dated March 18, 2024 (ADAMS Accession No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff revised DANU–

ISG–2022–01 to address specific ACRS recommendations.

Draft DANU–ISG–2022–01, ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap,'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33924) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41988). The NRC staff received sixty-eight public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A148.

IV. Congressional Review Act

DANU–ISG–2022–01, ''Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–01 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–01, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–01.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07023 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0081]

Interim Staff Guidance: Advanced Reactor Content of Application Project, ''Risk-Informed Technical Specifications''

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU–ISG–2022–08, ''Risk-Informed Technical Specifications.'' The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on April 3, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0081 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2022–0081. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
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- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O'Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1325; email: *James.O'Driscoll@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150–Al66). This ISG may need to be updated to conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150–AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff focused on two activities: the Advanced Reactor Content of Application Project (ARCAP) and the Technology-Inclusive Content of Application Project (TICAP). The ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR part 50 or 10 CFR

part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the ARCAP is broad and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled ''Review of Risk-Informed, Technology Inclusive Advanced Reactor Applications—Roadmap'' (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate **Federal Register** notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the ''Discussion'' section.

II. Discussion

The ARCAP ISG titled, ''Risk-Informed Technical Specifications,'' that is the subject of this FRN, was developed because the current application and review guidance related to technical specifications is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

Document description	ADAMS accession No.	*Regulations.gov* docket ID No.
Interim Staff Guidance DANU–ISG–2022–01, ''Advanced Reactor Content of Application Project, 'Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap' ''	ML23277A139	NRC–2022–0074
Interim Staff Guidance DANU–ISG–2022–02, ''Advanced Reactor Content of Application Project Chapter 2, 'Site Information' ''	ML23277A140	NRC–2022–0075
Interim Staff Guidance DANU–ISG–2022–03, ''Advanced Reactor Content of Application Project Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste' ''	ML23277A141	NRC–2022–0076
Interim Staff Guidance DANU–ISG–2022–04, ''Advanced Reactor Content of Application Project Chapter 10, 'Control of Occupational Dose' ''	ML23277A142	NRC–2022–0077
Interim Staff Guidance DANU–ISG–2022–05, ''Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations' ''	ML23277A143	NRC–2022–0078
Interim Staff Guidance DANU–ISG–2022–06, ''Advanced Reactor Content of Application Project Chapter 12, 'Post-manufacturing and construction Inspection, Testing, and Analysis Program' ''	ML23277A144	NRC–2022–0079
Interim Staff Guidance DANU–ISG–2022–07, ''Advanced Reactor Content of Application Project, 'Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs' ''	ML23277A145	NRC–2022–0080
Interim Staff Guidance DANU–ISG–2022–08, ''Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications' ''	ML23277A146	NRC–2022–0081
Interim Staff Guidance DANU–ISG–2022–09, ''Advanced Reactor Content of Application Project, 'Risk-Informed Performance-Based Fire Protection Program (for Operations)' ''	ML23277A147	NRC–2022–0082
RG 1.253, Revision 0, ''Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors''	ML23269A222	NRC–2022–0073
Regulatory Analysis for ARCAP ISGs	ML23093A099	NRC–2022–0074
Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance	ML23348A182	NRC–2022–0074
Response to the Advisory Committee on Reactor Safeguards Letter, ''Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance''	ML24024A025	NRC–2022–0074

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6–7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS did not recommend any specific changes to DANU–ISG–2022–08.

Draft DANU–ISG–2022–08, ''Risk-Informed Technical Specifications,'' was published in the **Federal Register** for public comment on May 25, 2023, (88 FR 33926) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the **Federal Register** dated June 28, 2023 (88 FR 41990). The NRC staff received eight public comments from stakeholders. The NRC staff's evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A155.

IV. Congressional Review Act

DANU–ISG–2022–08, ''Risk-Informed Technical Specifications,'' is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

V. Backfitting, Forward Fitting, and Issue Finality

DANU–ISG–2022–08 does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU–ISG–2022–08, applicants and licensees would not be required to comply with the positions set forth in DANU–ISG–2022–08.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief, Advanced Reactor Policy Branch, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–07030 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–238; NRC–2024–0060]

United States Maritime Administration; Nuclear Ship Savannah; License Termination Plan

AGENCY: Nuclear Regulatory Commission.

ACTION: Public meeting and request for comment.

SUMMARY: On October 23, 2023, the U.S. Nuclear Regulatory Commission (NRC) received from the United States Maritime Administration (MARAD, the licensee) a license amendment request to include a License Termination Plan (LTP) for the Nuclear Ship Savannah (NS Savannah). The LTP provides details about the known radiological information for the ship, the planned demolition and decommissioning tasks to be completed, and the final radiological surveys and data that must be obtained for termination of the NRC's license for NS Savannah. The NRC is requesting public comments on NS Savannah's LTP and will hold a public meeting to discuss the LTP.

DATES: The public meeting will be held on Wednesday, May 8, 2024, from 6 p.m. to 7:30 p.m., eastern time (ET), onboard the NS Savannah, online, or by phone. The NS Savannah is located at Pier 13 Canton Marine Terminal, 4601 Newgate Avenue, Baltimore, MD 21124. The public meeting is also available through an online webinar. See Section III ''Request for Comment and Public Meeting'' of this document for additional information. Submit comments by June 3, 2024. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0060. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Tanya E. Hood, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1387; email: *Tanya.Hood@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2024–0060 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0060.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2024–0060 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The United States Maritime Administration (MARAD, the licensee) is the holder of Facility Operating License, NS–1. The license provides, among other things, that the Nuclear Ship Savannah (NS Savannah) is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The NS Savannah is a pressurized water reactor ship located in Baltimore, MD.

The NS Savannah has been shutdown since November 8, 1970, and was

defueled on December 3, 1971. The licensee started the decommissioning process in 1971 in accordance with section 50.82 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Termination of license.'' In 1973, the U.S Atomic Energy Commission (NRC's predecessor agency) issued an amendment placing the reactor in a SAFSTOR condition. SAFSTOR is a method of decommissioning in which a nuclear facility is placed and maintained in a condition that allows the facility to be safely stored and subsequently decontaminated (deferred decontamination) to levels that permit release for unrestricted use. In 1976, the Possession-only license was issued as required by the 10 CFR 50.82 rule that was completely revised in 1996 (61 FR 39278, July 29, 1996).

The licensee submitted its Post-Shutdown Decommissioning Activities Report (PSDAR), Revision 0, on December 11, 2006 (ADAMS Accession No. ML063470625) and withdrew Revision 0 by letter dated January 26, 2007 (ADAMS Accession No. ML18120A039), prior to the NRC scheduling a PSDAR public meeting. By letter dated December 11, 2008 (ADAMS Accession No. ML083590349), the licensee submitted an updated PSDAR, Revision 1, to reflect that the there is no intent to immediately dismantle the ship itself following license termination. The scope of dismantlement described in the PSDAR is based on several fundamental assumptions, (1) the ship itself is not dismantled as part of DECON; (2) existing accesses are utilized to support dismantlement of systems and components; and (3) major structures will not be dismantled. These assumptions are based, in part, on National Historic Preservation Act requirements and satisfactory final status surveys (FSS). The licensee anticipates requesting license termination to be effective in December 2025, provided all prerequisite actions are complete at that time.

Based on this, and the fact that the ship is a registered National Historic Landmark, the licensee intends to pursue the DECON industrial work in a fashion that minimizes any physical affect to adjacent ship structure. DECON is a method of decommissioning in which structures, systems, and components that contain radioactive contamination are actively removed from the site and safely disposed of at a commercially operated low-level waste disposal facility or decontaminated to a level that permits the site to be released for unrestricted use. DECON may occur shortly after cessation of operations, or after a period of SAFSTOR. Unlike a land-based nuclear plant, the NS Savannah is waterborne, mobile and of unique historic significance, thus its decommissioning presents a number of unusual factors for consideration.

By application dated October 23, 2023 (ADAMS Accession No. ML23298A041), the licensee submitted their LTP to the NRC. Paragraph 50.82(a)(9) specifies that an application for license termination must be accompanied or preceded by an LTP, which is subject to NRC review and approval. The LTP addresses site characterization to ensure that the scope of FSS of the site cover all areas where contamination existed, remains, or has the potential to exist or remain, identification of remaining dismantlement activities, plans for site remediation, a description of the FSS plans to confirm that NS Savannah will meet the release criteria in 10 CFR part 20, subpart E, ''Radiological Criteria for License Termination,'' dose-modeling scenarios that ensure compliance with the radiological criteria for license termination, an estimate of the remaining site-specific decommissioning costs and an updated assessment of the environmental effects of decommissioning NS Savannah. Once approved, the LTP would become a supplement to the NS Savannah Defueled Safety Analysis Report.

According to 10 CFR 50.82(a)(9)(iii), after the licensee submits an LTP the NRC must hold a public meeting near the site. The purpose of the meeting is for the NRC staff to discuss the NRC's review of the LTP and to request public comments on the LTP. In addition, in accordance with 10 CFR 50.82(a)(9)(iii) and 20.1405, upon the receipt of an LTP from a licensee, NRC must publish a notice in the **Federal Register** and solicit comments from affected parties. Please see the related notice regarding the LTP proposed no significant hazards consideration determination and opportunity to request a hearing and petition to intervene (89 FR 22199, March 29, 2024).

III. Request for Comment and Public Meeting

The NRC is requesting public comments on the NS Savannah LTP. The NRC will conduct a public meeting to discuss the LTP and receive comments on Wednesday, May 8, 2024, from 6 p.m. to 7:30 p.m., ET onboard the NS Savannah, online, or by phone. The NS Savannah is located at Pier 13 Canton Marine Terminal, 4601 Newgate Avenue, Baltimore, MD 21124. Please contact Tanya E. Hood no later than May 6, 2024, if accommodations or special equipment are needed for you to attend or to provide comments, so that the NRC staff can determine whether the request can be accommodated.

Special services. The NS Savannah is not compliant with the Americans with Disabilities Act. The ship has some capability to accommodate persons with impaired mobility. For additional information regarding the meeting, see the NRC's Public Meeting Schedule website at *https://meetings.nrc.gov/pmns/mtg.* The agenda will be posted no later than 10 days prior to the meeting.

Dated: March 29, 2024.

For the Nuclear Regulatory Commission.

Shaun M. Anderson,

Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024–07010 Filed 4–2–24; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: New Information Collection, Research Agreement Application for the Use of OPM Record-Level Data, OMB Control No. 3206–NEW

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a new information collection—(ICR) 3206–NEW, titled ''Research Agreements for the Use of OPM Record-Level Data.''

DATES: Comments are encouraged and will be accepted until May 3, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Office of Personnel Management'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For more information, contact the Office of the Chief Financial Officer's Planning, Performance, and Evaluation unit, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, Attention: Megan Kays at (202) 860–8580 or via electronic mail to *evidence@opm.gov.*

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35), as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. OPM collects and maintains record-level data on job applicants, Federal employees, annuitants, and other beneficiaries of OPM's programs and services. Research Agreements for the Use of OPM Record-Level Data is OPM's proposed mechanism to share data to further policy-relevant Federal workforce research. OPM will collect information through a Research Agreement Application to enable OPM to determine whether providing record level data to a research entity is in the public interest. This is a new collection to establish OPM's Research Agreement program.

The information collection was previously published in the **Federal Register** on November 25, 2022, at 87 FR 72518, allowing for a 60-day public comment period. OPM received one public comment that was not relevant to the proposed collection. The purpose of this notice is to allow an additional 30 days for public comments. Therefore, we invite comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Office of Personnel Management.

Authority: 5 U.S.C. 4702.

Title: Research Agreements for the Use of OPM Record-Level Data.

OMB Number: 3206–NEW.

Frequency: Annually.

Affected Public: Individuals.

Number of Respondents: 20.

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 20 hours.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2024–06986 Filed 4–2–24; 8:45 am]

BILLING CODE 6325–67–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35165]

Deregistration Under Section 8(f) of the Investment Company Act of 1940

March 29, 2024.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice of applications for deregistration under Section 8(f) of the Investment Company Act of 1940.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of March 2024. A copy of each application may be obtained via the Commission's website by searching for the applicable file number listed below, or for an applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on April 23, 2024, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.*

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8010.

CGM Trust [File No. 811–00082]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On November 30, 2022, applicant made a liquidating distribution to its shareholders based on net asset value. Expenses of $986,416 incurred in connection with the liquidation were paid by the applicant and the applicant's investment adviser.

Filing Dates: The application was filed on March 24, 2023 and amended on March 18, 2024.

Applicant's Address: c/o Capital Growth Management, One International Place, 31st Floor, Boston, Massachusetts 02110.

Peak Income Plus Fund [File No. 811–23808]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On July 3, 2023, applicant made liquidating distributions to its shareholders based on net asset value. No expenses were incurred in connection with the liquidation.

Filing Date: The application was filed on July 18, 2023.

Applicant's Address: 225 Pictoria Drive, Suite 450, Cincinnati, Ohio 45246.

Pioneer ILS Bridge Fund [File No. 811–23172]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On October 27, 2023, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $1,216.87 incurred in connection with the liquidation were paid by the applicant's investment adviser.

Filing Date: The application was filed on March 1, 2024.

Applicant's Address: 60 State Street, Boston, Massachusetts 02109.

UCT Immensity Fund [File No. 811–23462]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on September 5, 2023, and amended on November 2, 2023, and February 28, 2024.

Applicant's Address: 2093 Philadelphia Pike #1426, Claymont, Delaware 19703.

UIC Trust [File No. 811–23455]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on September 1, 2023, and amended on November 2, 2023, and February 27, 2024.

Applicant's Address: 2093 Philadelphia Pike #1426, Claymont, Delaware 19703.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–07083 Filed 4–2–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the Optional Peg Rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 4.25 percent for the April–June quarter of FY 2024.

Pursuant to 13 CFR 120.921(b), the maximum legal interest rate for any Third Party Lender's commercial loan which funds any portion of the cost of a 504 project (see 13 CFR 120.801) shall be 6% over the New York Prime rate or, if that exceeds the maximum interest rate permitted by the constitution or laws of a given State, the maximum interest rate will be the rate permitted by the constitution or laws of the given State.

David Parrish,

Chief, Secondary Market Division.

[FR Doc. 2024–06981 Filed 4–2–24; 8:45 am]

BILLING CODE P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1233 (Sub-No. 2X)]

Allegheny Valley Railroad Company—Abandonment Exemption—in Allegheny County, Pa.

Allegheny Valley Railroad Company (AVR), has filed a verified notice of exemption under 49 CFR part 1152 subpart F—Exempt Abandonments to abandon an approximately 3.6-mile segment of rail line known generally as the ''Brilliant Branch'' located in Pittsburgh and Aspinwall, Allegheny County, Pa. (the Line). The Line consists of the following segments: (1) the Brilliant Branch, extending from milepost 0.7 in East Liberty (in the City of Pittsburgh), crossing AVR's Allegheny Branch and the Allegheny River, passing through the Borough of Aspinwall and ending at approximately milepost 3.0, in Pittsburgh; (2) the Brilliant Branch-West Leg Wye, beginning at approximately milepost 0.0 on AVR's Allegheny River Bridge in Aspinwall and ending at approximately milepost 0.5, in the Township of O'Hara, Pa.; and (3) a portion of the Allegheny Branch Connection in Pittsburgh beginning at approximately milepost 1.8, at the connection to the Brilliant Branch, and ending at approximately milepost 2.6, approximately 528 feet westerly of its connection to the Allegheny Branch. The Line traverses U.S. Postal Service Zip Codes 15206, 15208, and 15215.

AVR has certified that: (1) no local traffic has moved over the Line for at least two years; (2) any overhead traffic on the Line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a State or local government on behalf of such user) regarding cessation of service over the Line is pending with either the Surface Transportation Board (Board) or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports),[1] 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[2] this exemption will be effective on May 3, 2024, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues must be filed by April 12, 2024.[3] Formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by April 15, 2024.[4] Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed by April 23, 2024.

All pleadings, referring to Docket No. AB 1233 (Sub-No. 2X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on AVR's representative, Thomas J. Healey, Fletcher & Sippel LLC, 29 N Wacker Drive, Suite 800, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void ab initio.

AVR has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by April 8, 2024. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. If you require an accommodation under the

[1] In its verified notice, which AVR submitted on February 23, 2024, AVR requested that the Board waive the provision at 49 CFR 1105.11 calling for the carrier to use a form transmittal letter when sending its environmental and/or historic report to appropriate agencies. In a decision served on April 2, 2024, the Board denied the waiver request and deemed the filing date for AVR's verified notice to be March 14, 2024 (20 days after AVR re-served its environmental and historic report with the form cover letter).

[2] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[3] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[4] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

Americans with Disabilities Act, please call (202) 245–0245. Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), AVR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by AVR's filing of a notice of consummation by April 3, 2025, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Dated: March 29, 2024.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2024–07020 Filed 4–2–24; 8:45 am]

BILLING CODE 4915–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2024–0002]

Additional Hearings and Extension of Post-Hearing Comment Period: Request for Comments on Promoting Supply Chain Resilience

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of additional public hearings and extension of post-hearing comment period.

SUMMARY: The Office of the United States Trade Representative (USTR) will hold additional public hearings to inform objectives and strategies that advance U.S. supply chain resilience in trade negotiations, enforcement, and other initiatives, and is extending the period for submission of post-hearing comments.

DATES: You must submit comments and responses in accordance with the following schedule:

April 24, 2024: Due date for filing requests to appear and a summary of expected testimony at the additional public hearings.

May 14, 2024: USTR will convene a public hearing at the Minnesota Department of Employment and Economic Development, Great Northern Building, Jerome Hill Auditorium, 180 East Fifth Street, St. Paul, MN 55101, beginning at 10:00 a.m.

May 23, 2024: USTR will convene a virtual public hearing beginning at 10:00 a.m.

May 28, 2024: USTR will convene a public hearing in the Ted Weiss Federal Office Building, 30th Floor Conference Center, Conference Room 2, 290 Broadway, New York, NY 10007, beginning at 10:00 a.m.

June 4, 2024: Extended due date for submission of post-hearing written comments in response to testimony provided at any of the four public hearings in this proceeding.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal eRulemaking Portal: *https://www.regulations.gov* (*Regulations.gov*). The instructions for submitting comments are in sections IV and V below. The docket number is USTR–2024–0002. For alternatives to on-line submissions, please contact Sandy McKinzy at (202) 395–9483 in advance of the deadline.

FOR FURTHER INFORMATION CONTACT: Special Counsel Victor Ban at (202) 395–5962 or *supplychain@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 7, 2024, USTR requested comments to inform objectives and strategies that advance U.S. supply chain resilience in trade negotiations, enforcement, and other initiatives. In outlining a new trade policy vision promoting resilience, the notice explained that resilient supply chains provide a range of sourcing options; adapt, rebound, and recover with agility following shocks; uphold labor rights and environmental protections; and strengthen the U.S. manufacturing base and workforce. To help achieve these objectives, the notice sought information on developing sector-specific policy tools, strengthening domestic manufacturing and services, collaborating with like-minded trading partners and allies, and measuring resilience, among other topics. The notice also stated that ''USTR may arrange regional hearings or meetings subsequent to the public hearing'' scheduled to begin on May 2, 2024, at the U.S. International Trade Commission. *See* 89 FR 16608.

II. Additional Hearing Participation

USTR invites participation at these additional public hearings:

- *May 14, 2024:* USTR will convene a public hearing at the Minnesota Department of Employment and Economic Development, Great Northern Building, Jerome Hill Auditorium, 180 East Fifth Street, St. Paul, MN 55101, beginning at 10:00 a.m.
- *May 23, 2024:* USTR will convene a virtual public hearing beginning at 10:00 a.m.
- *May 28, 2024:* USTR will convene a public hearing in the Ted Weiss Federal Office Building, 30th Floor Conference Center, Conference Room 2, 290 Broadway, New York, NY 10007, beginning at 10:00 a.m.

Any person wishing to testify at one of the additional hearings must submit requests to appear by April 24, 2024. The request to appear at the additional hearings must specify the starting date of the relevant hearing and include a summary of testimony, and may be accompanied by a pre-hearing submission. To allow for possible questions from USTR staff, remarks at the additional hearings may be subject to time limits, to be communicated by USTR to witnesses in advance of the hearings. No witness may offer testimony at more than one public hearing.

Additionally, USTR will permit members of the public to observe remotely both the hearing to be convened by USTR at the U.S. International Trade Commission beginning on May 2, 2024, and the virtual hearing to be convened by USTR beginning on May 23, 2024. Audio and video access to both hearings will be provided at *www.ustr.gov/live.* Testimony at the hearing to be held at the U.S. International Trade Commission must be delivered in-person, in accordance with the procedures outlined in the initial notice. *See* 89 FR 16608.

III. Post-Hearing Comments

In light of the additional public hearings, USTR will extend the due date for submission of post-hearing written comments from May 16, 2024, to June 4, 2024.[1] Additionally, although the March 7, 2024 notice (89 FR 16608), specified that only ''persons who testified at the public hearing'' beginning on May 2, 2024, could submit post-hearing written comments, USTR will permit any person to submit post-hearing comments, so long as the comments respond to testimony provided at any of the four public hearings in this proceeding.

IV. Requirements for Submissions

To be assured of consideration, submit any request to appear at the

[1] Except for this extension, this notice does not modify any of the deadlines established in the initial notice of March 7, 2024. *See* 89 FR 16608.

additional hearings by the April 24, 2024 deadline, and any post-hearing written comments by the June 4, 2024 deadline. All submissions must be in English. USTR strongly encourages submissions via *Regulations.gov*. The docket number is USTR–2024–0002.

To submit via *Regulations.gov,* use Docket Number USTR–2024–0002 in the 'search for' field on the home page and click 'search.' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting 'notice' under 'document type' in the 'refine documents results' section on the left side of the screen and click on the link entitled 'comment.' *Regulations.gov* allows users to make submissions by filling in a 'type comment' field, or by attaching a document using the 'upload file' field. USTR prefers that you provide submissions in an attached document named according to the following protocol, as appropriate: Commenter Name or Organization_ Supply Chain Resilience. If you provide submissions in an attached document, please type 'see attached comments' in the 'comment' field on the online submission form.

Requests to appear at an additional hearing must include the name, address, email address, and telephone number of the person presenting the testimony in the 'type comment' field. Attach a summary of the testimony specifying the relevant additional hearing, and a pre-hearing submission if provided, by attaching a document using the 'upload file' field. The file name should include the name of the person who will be presenting the testimony. In addition, please submit a request to appear by email to *supplychain@ustr.eop.gov.* The subject line of the email must begin with the starting date of the relevant additional hearing in the format 'May 14' followed by the name of the person who will be presenting the testimony, and then 'Request to Appear'. In the body of the email, include the name, address, email address, and telephone number of the person presenting testimony.

USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If you use an application other than those two, please indicate the name of the application in the 'type comment' field.

Please include any information that might appear in a cover letter, exhibits, annexes, or other attachments in the same file as the comment itself, rather than submitting them as separate files.

Please include the name, email address, and telephone number of an individual USTR can contact if there are issues or questions with the submission.

You will receive a tracking number upon completion of the submission procedure at *Regulations.gov*. The tracking number is confirmation that *Regulations.gov* received your submission. Keep the confirmation for your records. USTR is not able to provide technical assistance for *Regulations.gov*.

For further information on using *Regulations.gov,* please consult the resources provided on the website by clicking on 'How to Use *Regulations.gov*' on the bottom of the home page. You can contact the *Regulations.gov* help desk at *regulationshelpdesk@gsa.gov* or 1–866–498–2945 for help with technical questions on submitting comments on *Regulations.gov*.

If you are unable to submit through *Regulations.gov* after seeking assistance from the help desk, please contact Sandy McKinzy at (202) 395–9483 before transmitting your document and in advance of the deadline to arrange for an alternative method of transmission. USTR will not accept hand-delivered submissions. USTR may not consider submissions that you do not make in accordance with these instructions.

General information concerning USTR is available at *https://www.ustr.gov.*

V. Business Confidential Information (BCI) Submissions

If you ask USTR to treat information you submit as BCI, you must certify that the information is business confidential and that you would not customarily release it to the public. For any comments submitted electronically containing BCI, the file name of the business confidential version should begin with the characters 'BCI.' You must clearly mark any page containing BCI with 'BUSINESS CONFIDENTIAL' on the top of that page. Filers of submissions containing BCI also must submit a public version that will be placed in the docket for public inspection. The file name of the public version should begin with the character 'P.' Follow the 'BCI' and 'P' with the name of the individual or organization submitting the comments.

VI. Public Viewing of Review Submissions

USTR will post written submissions in the docket for public inspection, except properly designated BCI. You can view comments on *Regulations.gov* by entering Docket Number USTR–2024–0002 in the search field on the home page.

Juan Millan,

Acting General Counsel, Office of the United States Trade Representative.

[FR Doc. 2024–06975 Filed 4–2–24; 8:45 am]

BILLING CODE 3390–F4–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of Draft Air Tour Management Plan and Draft Environmental Assessment and Public Meeting

AGENCY: Federal Aviation Administration (FAA), Transportation.

ACTION: Notice of Availability of Draft Air Tour Management Plan (ATMP) and Draft Environmental Assessment (EA) and public meeting.

SUMMARY: The FAA, in cooperation with the National Park Service (NPS), has initiated development of an ATMP for Canyon de Chelly National Monument (the Park) pursuant to the National Parks Air Tour Management Act of 2000 and its implementing regulations. This notice announces the public availability of the Draft ATMP and Draft EA for comment and the date of the public meeting for the Park in accordance with National Parks Air Tour Management Act of 2000 and National Environmental Policy Act (NEPA) of 1969. The purpose of the public meeting is to review the Draft ATMP with the public. The objective of the ATMP is to develop acceptable and effective measures to mitigate or prevent the significant adverse impacts, if any, of commercial air tour operations on the Park's resources and values.

DATES:

Comment Period

Comments must be received by 11:59 MDT on or before May 3, 2024. Comments will be received on the NPS Planning, Environment and Public Comment System (PEPC) website. The Park's website link is *https://parkplanning.nps.gov/projectHome.cfm?projectID=103419*.

Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold from public review your personal identifying information, we

cannot guarantee that we will be able to do so.

Public Meeting

The public meeting will be offered in-person and virtually at the dates and times listed below. Both meetings will convey the same information. Questions will be accepted during the virtual public meeting through a separate form. The link for the question form is provided in the **ADDRESSES** section. Questions asked during the in-person or submitted for the virtual public meeting are not considered an official comment as part of the public comment period. Attendees are encouraged to submit their comments for the official record via the link provided in this notice.

- *In-person public meeting:* Tuesday, April 16, 2024, from 10 a.m.–2 p.m. MDT
- *Virtual public meeting:* Wednesday, April 17, 2024, from 6 p.m.–7:30 p.m. MDT

ADDRESSES: The meeting will be offered in-person and virtually at the following locations:

Tuesday, April 16, 2024, from 10 a.m.–2 p.m. MDT
- Navajo Route 7, Ste. 4600, Chinle, AZ 86503
- *Phone:* (928) 674–2052

Wednesday, April 17, 2024, from 6 p.m.–7:30 p.m. MDT
- *Meeting Livestream: https://www.youtube.com/watch?v=LJdKCdtPw4g*
- *Submit questions for the meeting: https://forms.gle/6PCcyzMQrziCyLA46*

The meeting information will also be available at *Air Tour Management Plan | Federal Aviation Administration (faa.gov)* and on the NPS PEPC website for the Park listed above.

Contact: Any request for reasonable accommodation related to providing public comments on the Draft ATMP or Draft EA should be sent to the person listed on the Park's PEPC sites.

The U.S. Department of Transportation and U.S. Department of the Interior are committed to providing equal access to the meetings for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Sandra Fox, (202) 267–0928, *sandra.y.fox@faa.gov*.

SUPPLEMENTARY INFORMATION: The FAA is issuing this notice pursuant to the National Parks Air Tour Management Act of 2000 (Pub. L. 106–181) and its implementing regulations contained in title 14, Code of Federal Regulations (CFR) part 136, subpart B, National Parks Air Tour Management and the National Environmental Policy Act (NEPA) of 1969 and the Council of Environmental Quality NEPA Implementing Regulations (40 CFR parts 100–1508). The objective of this ATMP is to develop acceptable and effective measures to mitigate or prevent the significant adverse impacts, if any, of commercial air tour operations on the Park's resources and values. The FAA and the NPS are inviting comment from the public, Federal and state agencies, tribes, and other interested parties on the Draft ATMP and Draft EA for Canyon de Chelly National Monument.

The FAA and the NPS request that comments be as specific as possible in response to the Draft ATMP and Draft EA. All written comments become part of the official record. Written comments on the Draft ATMP and Draft EA can be submitted via PEPC or sent to the mailing address provided on the Park's PEPC site. Comments will not be accepted by fax or email.

The FAA and the NPS have determined that the ATMP constitutes a Federal undertaking subject to compliance with Section 106 of the National Historic Preservation Act and its implementing regulations (36 CFR part 800). The FAA and the NPS have consulted with tribes, State and Tribal Historic Preservation Officers, and other interested parties to identify historic properties and assess the potential effects of the ATMP on them.

The meetings will be open to the public. Members of the public who wish to participate can access the meetings in-person or virtually with the information provided in this notice.

Issued in Washington, DC, on March 29, 2024.

Sandra Fox,

Environmental Protection Specialist, FAA Office of Environment & Energy.

[FR Doc. 2024–07036 Filed 4–2–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No: FAA–2024–1077]

Deadline for Notification of Intent To Use the Airport Improvement Program (AIP) Primary, Cargo, and Nonprimary Entitlement Funds Available to Date for Fiscal Year 2024

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Federal Register Notice.

SUMMARY: This action announces May 20, 2024, as the deadline for each airport sponsor to notify the FAA if it will use its Fiscal Year (FY) 2024 entitlement funds to accomplish Airport Improvement Program (AIP) eligible projects. Each sponsor has previously identified to the FAA such projects through the Airports Capital Improvement Plan process. This action further announces May 20, 2024, as the deadline for an airport sponsor to submit a final grant application, based on bids, for grants that will be funded with FY 2024 entitlement funds only.

FOR FURTHER INFORMATION CONTACT: David F. Cushing, Manager, Airports Financial Assistance Division, APP–500, at (202) 267–8827.

SUPPLEMENTARY INFORMATION: Title 49 U.S.C. 47105(f) provides that the sponsor of an airport for which entitlement funds (referred to as apportionments in 49 U.S.C. 47114) are apportioned shall notify the Secretary, by such time and in a form as prescribed by the Secretary, of the airport sponsor's intent to submit a grant application for its available entitlement funds. Therefore, the FAA is hereby notifying such airport sponsors of the steps required to ensure that the FAA has sufficient time to carry over and convert remaining entitlement funds.

The AIP grant program is authorized by Public Law 118–41, the ''Airport and Airway Extension Act of 2024,'' enacted on March 8, 2024, which permits the FAA to make grants for planning and airport development and airport noise compatibility under the AIP through May 10, 2024. The funds allocated to the FAA to fund the AIP grant program are appropriated through September 30, 2024, by Public Law 118–42, the ''Consolidated Appropriations Act, 2024,'' enacted on March 9, 2024. Apportioned funds will be subject to allocation formulas prescribed by 49 U.S.C. 47114 and any other applicable legislative text.

This notice applies only to sponsors of airports that have entitlement funds

appropriated for FY 2024 to use on eligible and justified projects. State aviation agencies participating in the FAA's State Block Grant Program, as prescribed by 49 U.S.C. 47128, are responsible for notifying the FAA which covered nonprimary airports in their programs will be using their entitlement funds for eligible and justified projects.

An airport sponsor intending to apply for any of its available entitlement funds, including those unused, but still available in accordance with 49 U.S.C. 47117 from prior years, must notify the FAA of its intent to submit a grant application by 12:00 p.m. prevailing local time on Monday, May 20, 2024.

This notice must be in writing and stipulate the total amount the sponsor intends to use for eligible and justified projects during FY 2024, including those entitlement funds not obligated from prior years that remain available in accordance with 49 U.S.C. 47117 (also known as protected carryover). These notifications are critical to ensure efficient planning and administration of the AIP. Absent the notification of intent to submit a grant application by the above-mentioned deadline, the FAA will carry over the available entitlement funds on June 3, 2024. These funds will not be available again to the airport sponsor until the beginning of FY 2025.

The final grant application deadline for entitlement funds only is Monday, May 20, 2024. The final grant application funding requests should be based on bids, not estimates. As prescribed under 49 U.S.C. 47117, the FAA will carryover the remainder of available entitlement funds after August 5, 2024. These funds will not be available again to the airport sponsor until the beginning of FY 2025. Dates are subject to possible adjustment based on future legislation. As of the publication of this notice, the appropriations and the authorization legislation for the FAA expire on September 30, 2024, and May 10, 2024, respectively.

The FAA has determined these deadlines will expedite and facilitate the FY 2024 grant-making process.

Issued in Washington, DC, on March 28, 2024.

David F. Cushing,

Manager, Airports Financial Assistance Division.

[FR Doc. 2024–07001 Filed 4–2–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2024–0052]

Request for Comments on the Renewal of a Previously Approved Collection: Determining Vessel Services Categories for Purposes of the Cargo Preference Act

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0540 (Determining Vessel Services Categories For Purposes of the Cargo Preference Act) will be used to create a list of Vessel Self-Designations. We are required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before June 3, 2024.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2024–0052 through one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to *www.regulations.gov* including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: James Mead, Office of Cargo and Commercial Sealift, Maritime Administration, 1200 New Jersey Avenue SE, Washington DC 20590, Telephone: 202–366–5723 or Email: *james.mead@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Determining Vessel Services Categories For Purposes of the Cargo Preference Act.

OMB Control Number: 2133–0540.

Type of Request: Extension without change of a Previously Approved Information Collection.

Abstract: OMB 2133–0540 (Determining Vessel Services Categories For Purposes of the Cargo Preference Act) is used in the designation of service categories of individual vessels, which is required for compliance with the Cargo Preference Act under a Memorandum of Understanding entered into by the U.S. Department of Agriculture, U.S. Agency for International Development, and the Maritime Administration (MARAD). MARAD will use the data submitted by vessel operators to create a list of Vessel Self-Designations.

Respondents: Vessel owners/operators or their appointed agents.

Affected Public: Business or other for-profit entities owning and/or operating ocean vessels.

Estimated Number of Respondents: 200.

Estimated Number of Responses: 200.

Estimated Hours per Response: 0.25.

Annual Estimated Total Annual Burden Hours: 50.

Frequency of Response: Once annually (if needed).

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–07087 Filed 4–2–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated

Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley T. Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On March 22, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. LARRANAGA HERRERA, Jesus Norberto (a.k.a. ''Chuy''; a.k.a. ''El 30''; a.k.a. ''Treinta''), Culiacan, Sinaloa, Mexico; DOB 14 Apr 1993; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. LAHJ930414HSLRRS06 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of Executive Order 14059 of December 15, 2021, ''Imposing Sanctions on Foreign Persons Involved in the Global Illicit Drug Trade,'' 86 FR 71549 (December 17, 2021) (E.O. 14059) for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

2. LEON VALDEZ, Jesus Manuel (a.k.a. ''El Guero de Las Trancas''; a.k.a. ''El Guero Trancas''; a.k.a. ''Guero de Las Trancas''; a.k.a. ''Guero Trancas''), Las Trancas, Tamazula, Durango, Mexico; DOB 08 May 1977; POB Durango, Mexico; nationality Mexico; Gender Male; C.U.R.P. LEVJ770508HDGNLS02 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

3. LIZARRAGA MARTINEZ, Victor (a.k.a. ''El 20''; a.k.a. ''El Veinte''), Tacuichamona, Culiacan, Sinaloa, Mexico; Pueblos Unidos, Culiacan, Sinaloa, Mexico; DOB 23 Mar 1972; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. LIMV720323HSLZRC07 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

4. LIZARRAGA SANCHEZ, Karla Gabriela (a.k.a. ''LIZARRAGA, Gaby''), Mexico; DOB 14 Jun 1993; POB Sinaloa, Mexico; nationality Mexico; Gender Female; C.U.R.P. LISK930614MSLZNR04 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

5. NUNEZ HERRERA, Alan Gabriel, Mexico; DOB 29 Sep 1993; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. NUHA930929HSLXRL02 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

6. ROBLEDO ARREDONDO, Ivan Yareth, Calle San Felipe 3208, Fracc. Los Angeles, Culiacan, Sinaloa 80014, Mexico; DOB 01 May 1993; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. ROAI930501HSLBRV04 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

7. ROBLEDO ARREDONDO, Adilene Mayre (a.k.a. ROBLEDO, Adilene), Calle San Felipe 3208, Fracc. Los Angeles, Culiacan, Sinaloa 80014, Mexico; DOB 01 Sep 1997; POB Sinaloa, Mexico; nationality Mexico; Gender Female; C.U.R.P. ROAA970901MSLBRD05 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

8. TIRADO ANDRADE, Jesus, Mexico; DOB 01 Dec 1996; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. TIAJ961201HSLRNS08 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

9. VERDUZCO CASTRO, Rolando, Mexico; DOB 17 Mar 1987; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. VECR870317HSLRSL01 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

10. VERGARA MEZA, Alexis, Mexico; DOB 18 Jan 1996; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. VEMA960118HSLRZL05 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

11. VERGARA MEZA, Edy, Mexico; DOB 04 May 1992; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. VEME920504HSLRZD03 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

12. MARIN GONZALEZ, Porthos, Calle San Jorge 4217, Fracc. Santa Fe, Culiacan, Sinaloa, Mexico; DOB 11 Jan 1996; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. MAGP960111HSLRNR03 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(i)(B) for having provided, or attempted to provide, financial, material, or technological support for, or goods or services in support of, the SINALOA CARTEL, a person sanctioned pursuant to E.O. 14059.

13. MARIN GONZALEZ, Arturo D'Artagnan, Mexico; DOB 09 Dec 1997; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. MAGA971209HSLRNR05 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(i)(B) for having provided, or attempted to provide, financial, material, or technological support for, or goods or services in support of, the SINALOA CARTEL, a person sanctioned pursuant to E.O. 14059.

14. GARCIA VELAZCO, Jorge Alejandro, San Luis Rio Colorado, Sonora, Mexico; DOB 12 Jan 1987; POB Sinaloa, Mexico; nationality Mexico; Gender Male; R.F.C. GAVJ870112DP3 (Mexico); C.U.R.P. GAVJ870112HSLRLR00 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(i)(B) of E.O. 14059 for having provided, or attempted to provide, financial, material, or technological support for, or goods or services in support of, the SINALOA CARTEL, a person sanctioned pursuant to E.O. 14059.

15. GONZALEZ CORDERO, Mayra Gisel, San Luis Rio Colorado, Sonora, Mexico; DOB 25 Sep 1985; POB Baja California, Mexico; nationality Mexico; Gender Female; C.U.R.P. GOCM850925MBCNRY07 (Mexico) (individual) [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, CELULANDIA TALLER & STORE SLRC, a person sanctioned pursuant to E.O. 14059.

Entities

16. SMART DEPOT (a.k.a. ''SMART DEPOT MAZATLAN''; a.k.a. ''SMART DEPOT PUERTO CANCUN''; a.k.a. ''SMART DEPOTMX TU CELLULAR AL INSTANTE''; a.k.a. ''SMARTDEPOT''; a.k.a. ''SMARTDEPOTMX''), Boulevard Sinaloa 1061, Las Quintas, Culiacan, Sinaloa 80020, Mexico; Avenida Reforma S/N, Gran Plaza Mazatlan, Local I29, Alameda, Mazatlan, Sinaloa 82123, Mexico; Boulevard Kukulcan KM 1.5, Local B32, Puerto Juarez, Marina Puerto, Cancun, Quintana Roo 77500, Mexico; Organization Type: Retail sale of information and communications equipment in specialized stores [ILLICIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(i)(B) for having provided, or attempted to provide, financial, material, or technological support for, or goods or services in support of, the SINALOA CARTEL, a person sanctioned pursuant to E.O. 14059.

17. BUFALUSS (a.k.a. BUFALUS; a.k.a. ''BUFALUBUFF''), Calle Cancun 1555, Culiacan, Sinaloa, Mexico; Calle San Felipe 3208, Fracc. Los Angeles, Culiacan, Sinaloa 80014, Mexico; Culiacan, Sinaloa, Mexico; Organization Type: Restaurants and mobile food service activities [ILLICIT–DRUGS–EO14059] (Linked To: ROBLEDO ARREDONDO, Adilene Mayre; Linked To: ROBLEDO ARREDONDO, Ivan Yareth).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Adilene Mayre ROBLEDO ARREDONDO and Ivan Yareth ROBLEDO ARREDONDO, persons sanctioned pursuant to E.O. 14059.

18. DULCE VOLCAN (a.k.a. ''DULCEVOLCANCLN''), Culiacan, Sinaloa, Mexico; Calle Cancun 156, Col. Isla Musala, Tachintle, Culiacan, Sinaloa 80065, Mexico; Organization Type: Restaurants and mobile food service activities [ILLICIT–DRUGS–EO14059] (Linked To: ROBLEDO ARREDONDO, Adilene Mayre; Linked To: ROBLEDO ARREDONDO, Ivan Yareth).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Adilene Mayre ROBLEDO ARREDONDO and Ivan Yareth ROBLEDO ARREDONDO, persons sanctioned pursuant to E.O. 14059.

19. ROYAL ROOM DRESS (a.k.a. ''ROYALROOMDRESS''), Culiacan, Sinaloa, Mexico; Calle Justo Sierra 2976 (esquina con Boulevard Sabinos), Col. La Campina, Culiacan, Sinaloa, Mexico; Organization Type: Retail sale of clothing, footwear and leather articles in specialized stores [ILLICIT–DRUGS–EO14059] (Linked To: ROBLEDO ARREDONDO, Adilene Mayre).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Adilene Mayre ROBLEDO ARREDONDO, a person sanctioned pursuant to E.O. 14059.

20. TOTAL LOOK (a.k.a. ''OUTLET_TLOOK''; f.k.a. ''TOTAL_LOOKCLN''), Culiacan, Sinaloa, Mexico; website *www.totallook.mx;* Organization Type: Retail sale of clothing, footwear and leather articles in specialized stores [ILLICIT–DRUGS–EO14059] (Linked To: ROBLEDO ARREDONDO, Adilene Mayre).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Adilene Mayre ROBLEDO ARREDONDO, a person sanctioned pursuant to E.O. 14059.

21. CELULANDIA TALLER & STORE SLRC (a.k.a. CELULANDIA TALLER & STORE SAN LUIS SON; a.k.a. CELULANDIA TALLER AND STORE SAN LUIS SON; a.k.a. CELULANDIA TALLER AND STORE SLRC; a.k.a. ''CELULANDIA_SLRC''; a.k.a. ''CELULANDIASLRC''; a.k.a. ''CTS SLRC''), San Luis Rio Colorado, Sonora, Mexico; Avenida Libertad y 14, Residencias, San Luis Rio Colorado, Sonora, Mexico; Avenida Obregon y 18, San Luis Rio Colorado, Sonora, Mexico; website *https://celulandiatallerstore.negocio.site/;* Organization Established Date 19 Aug 2017; Organization Type: Retail sale of information and communications equipment in specialized stores; R.F.C. GAVJ870112DP3 (Mexico) [ILLICIT–DRUGS–EO14059] (Linked To: GARCIA VELAZCO, Jorge Alejandro; Linked To: GONZALEZ CORDERO, Mayra Gisel).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Jorge Alejandro GARCIA VELAZCO, a person sanctioned pursuant to E.O. 14059.

Dated: March 22, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–07007 Filed 4–2–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Collection Activities; Requesting Comments on Form 1099–Q

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 1099–Q, Payments from Qualified Education Programs (under Sections 529 and 530).

DATES: Written comments should be received on or before June 3, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include OMB Control No. 1545–1760 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620–2128, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *jason.m.schoonmaker@irs.gov.*

SUPPLEMENTARY INFORMATION: The IRS is currently seeking comments concerning the following information collection tools, reporting, and recordkeeping requirements:

Title: Payments from Qualified Education Programs (Under Sections 529 and 530).

OMB Number: 1545–1760.

Form Number: Form 1099–Q.

Abstract: Form 1099–Q is used to report distributions from private and state qualified tuition programs as required under Internal Revenue Code sections 529 and 530.

Current Actions: There are no changes to the burden previously approved by OMB. This submission is for renewal purposes.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 3,649,000.

Estimated Time per Respondent: 0 hours, 13 minutes.

Estimated Total Annual Burden Hours: 802,780.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 29, 2024.

Jason M. Schoonmaker,

Tax Analyst.

[FR Doc. 2024–07072 Filed 4–2–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Tax Counseling for the Elderly (TCE) Program—Availability of Application for Federal Financial Assistance

AGENCY: Internal Revenue Service (IRS), Treasury,

ACTION: Notice.

SUMMARY: This document provides notice of the availability of the application packages for the 2025 Tax Counseling for the Elderly (TCE) Program.

DATES: Application instructions are available electronically from the IRS on May 1, 2024, by visiting: *IRS.gov* (key word search—''TCE'') or through *Grants.gov* by searching the Catalog of Federal Domestic Assistance (CFDA) Number 21.006. The deadline for applying to the IRS for the Tax Counseling for the Elderly (TCE) Program is May 31, 2024. All applications must be submitted through *Grants.gov*.

ADDRESSES: Internal Revenue Service, Grant Program Office—TCE, 401 West Peachtree Street NW, Stop 420–D, Atlanta, Georgia 30308 at *tce.grant.office@irs.gov.*

SUPPLEMENTARY INFORMATION: Authority for the Tax Counseling for the Elderly (TCE) Program is contained in Section 163 of the Revenue Act of 1978, Public Law 95–600.

Daniel F. Maier,

Chief, Grant Program Office, IRS, Stakeholder Partnerships, Education & Communication.

[FR Doc. 2024–06857 Filed 4–2–24; 8:45 am]

BILLING CODE 4830–01–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: April 4, 2024, 11 a.m. to 2 p.m., eastern time.

PLACE: The meeting will take place at the Hotel Indigo Savannah Historic District, 201 West Bay Street, Savannah, GA 31401. This meeting will also be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 972 4708 8227, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJMvc-6opjMoGNO5RDEfdkyiWxp4Xm0F7YbF.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the ''Board'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Welcome and Call to Order—UCR Board Chair

The UCR Board Chair will welcome attendees, call the meeting to order, call roll for the Board, confirm the presence of a quorum, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify publication of the meeting notice on the UCR website and distribution to the UCR contact list via email, followed by subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Board Agenda—UCR Board Chair

For Discussion and Possible Board Action

The proposed Agenda will be reviewed. The Board will consider action to adopt.

Ground Rules

➢ Board actions taken only in designated areas on the agenda

IV. Approval of Minutes of the February 29, 2024, UCR Board Meeting—UCR Board Chair

For Discussion and Possible Board Action

Draft Minutes from the February 29, 2024, UCR Board meeting will be reviewed. The Board will consider action to approve.

V. Report of FMCSA—FMCSA Representative

The Federal Motor Carrier Safety Administration (FMCSA) will provide a report on any relevant agency activity, including the status of the FMCSA's Notice of Proposed Rulemaking concerning the 2025 UCR Fee Rulemaking.

VI. Revolving Door Policy—UCR Board Member

For Discussion and Possible Board Action

UCR Board Member, Ryan Nance will lead a discussion regarding a proposal for a revolving door policy. The proposed policy will be reviewed. The Board may consider action to approve.

VII. UCR Legal Counsel Report—UCR Legal Counsel

For Discussion and Possible Board Action

UCR Legal Counsel will lead a discussion regarding a proposed procedure to amend the UCR Agreement. The proposed procedure will be reviewed. The Board may consider action to approve.

VIII. Amendments to the Existing UCR Plan Whistleblower Policy—UCR Legal Counsel and UCR Executive Director

For Discussion and Possible Board Action

UCR Legal Counsel and the UCR Executive Director will discuss amendments to the existing UCR Whistleblower Policy. The Board may take action to amend the existing UCR Whistleblower Policy.

IX. Subcommittee Reports

Audit Subcommittee—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair

A. The Audit Subcommittee Recommends to the UCR Board the Adoption of an Auto-Renew Policy Developed for the Voluntary, Annual, Renewal of UCR Registrations—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, UCR Executive Director and SeikoSoft Representatives

For Discussion and Possible Subcommittee Action

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, UCR Executive Director, and Seikosoft Representatives will summarize an Auto-renew Policy adopted by the Audit Subcommittee and recommended to the UCR Board. The summary will include a discussion of the language recommended by the Audit Subcommittee providing for an auto-renew policy for the voluntary, annual, automatic renewal of UCR Plan registrations and for SeikoSoft to incorporate the language and business rules of this auto-renew policy into the National Registration System. The Audit Subcommittee recommends that the UCR Board adopt an Auto-Renew policy containing specific language implementing a voluntary, annual, automatic renewal of UCR Plan registrations. The UCR Board may take action to adopt an Auto-Renew Policy.

B. Review States' Audit Compliance Snapshot for Registration Rates Audit Percentages for Years 2023 and 2024—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will review audit compliance rates for the states for UCR Plan registration years 2023 and 2024, including related compliance percentages for FARs, registration motor carrier compliance percentages, unregistered motor carriers in tiers 5 and 6, retreat audits, and broker registration percentages. The Audit Subcommittee Chair will also describe recent efforts by the Audit Subcommittee to reinstitute a retreat audit program based on vehicle inspections.

Finance Subcommittee—UCR Finance Subcommittee Chair and UCR Depository Manager

A. Distribution From the UCR Depository for Under-Cap States—UCR Administrator

The UCR Finance Subcommittee Chair and the UCR Administrator will provide an update on the timing for a distribution of fees from the UCR Depository to states that have not yet reached their revenue entitlements for the 2024 registration year.

B. UCR Administrative Fund Update—UCR Administrator

The UCR Administrator will provide an update on the financial status of the administrative fund for the 2 months ended February 29, 2024.

Education and Training Subcommittee—UCR Education and Training Subcommittee Chair

A. Updates on Key Projects—UCR Education and Training Subcommittee Chair

The UCR Education and Training Subcommittee Chair will provide updates on key projects. The projects that will be discussed include the optimization and redesign of the website, the educational audit taskforce related to the learning management system, and the creation of a videos explaining the purpose of the UCR Plan and the National Registration System it operates.

Industry Advisory Subcommittee—UCR Industry Advisory Subcommittee Chair

No significant action to report.

Enforcement Subcommittee—UCR Enforcement Subcommittee Chair

No significant action to report.

Dispute Resolution Subcommittee—UCR Dispute Resolution Subcommittee Chair

No significant action to report.

X. Contractor Reports—UCR Board Chair

UCR Executive Director Report

The UCR Executive Director will provide a report covering his recent activity for the UCR Plan including any changes in the dates of UCR meetings in 2024.

UCR Administrator Report (Kellen)

The UCR Chief of Staff will provide a management update covering recent activity for the Depository, Operations, and Communications.

DSL Transportation Services, Inc.

DSL Transportation Services, Inc. will report on the latest data from the FARs program, Tier 5 and 6 unregistered motor carriers, and other matters.

Seikosoft

Seikosoft will provide an update on its recent/new activity related to the UCR's National Registration System.

XI. Other Business—UCR Board Chair

The UCR Board Chair will call for any other business, old or new, from the floor.

XII. Adjournment—UCR Board Chair

The UCR Board Chair will adjourn the meeting.

The agenda will be available no later than 6:00 p.m. Eastern time, March 27, 2024, at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2024–07178 Filed 4–1–24; 4:15 pm]

BILLING CODE 4910–YL–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: April 5, 2024, 10 a.m. to 1 p.m., eastern time.

PLACE: This meeting will take place at the Hotel Indigo Savannah Historic District, 201 West Bay Street, Savannah, GA 31401. The meeting will also be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 913 0691 7041, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJUud—hrzwqHtVjNAMPKfakqjzkaqE-JS-H.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Enforcement Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Enforcement Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Enforcement Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda

IV. Review and Approval of Subcommittee Minutes From the December 8, 2023 Meeting—UCR Enforcement Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the December 8, 2023 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

V. Review of Enforcement Rates—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee will review a variety of tools and activities undertaken in 2023 to conduct enforcement activities in the states.

VI. Discussion of Roadside Enforcement for Carriers Who Are Under-Registered—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair, and Representatives From Seikosoft

The Subcommittee Chair will lead a discussion on the possibility of roadside enforcement for carriers who have been identified as under-registered.

VII. Discussion on how Enforcement Can Support and Contribute to Inspection Audits—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee Chair will lead a discussion on how enforcement can support and contribute to inspection audits.

VIII. Establish Awards Criteria for Annual UCR Enforcement and Biannual UCR Enforcement Awareness Initiatives—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Chair will lead a discussion on the awarding of annual UCR Enforcement Awards. This includes criteria for best enforcement efficiency rate, most violations issued overall, and an annual award to the inspector who issues the most UCR violations. The Subcommittee may take action to recommend such options to the Board of Directors.

IX. Enforcement Training PPT Development—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee Chair will provide an update on the progress of the creation of the enforcement training PowerPoint; a working session to finalize the project will follow.

X. Other Business—UCR Enforcement Subcommittee Chair

The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

XI. Adjournment—UCR Enforcement Subcommittee Chair

The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, March 29, 2024 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2024–07175 Filed 4–1–24; 4:15 pm]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0149]

Agency Information Collection Activity: Application for Conversion Government Life Insurance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2024.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0149'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0149'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility;

(2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Application for Conversion Government Life Insurance, VA Form 29–0152.

OMB Control Number: 2900–0149.

Type of Review: Extension of a currently approved collection.

Abstract: This form is used by Veterans to convert to a permanent plan of insurance. The information on the form is required by law, U.S.C. 1904 and 1942.

Affected Public: Individuals and households.

Estimated Annual Burden: 1,125 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 4,500.

By direction of the Secretary:

Dorothy Glasgow,

VA PRA Clearance Officer, (Alt) Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–07014 Filed 4–2–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Wednesday,
No. 65 April 3, 2024

Part II

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2550

Amendment to Prohibited Transaction Class Exemption 84–14 for Transactions Determined by Independent Qualified Professional Asset Managers (the QPAM Exemption); Final Rule

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

[Application No. D–12022]

Z–RIN 1210 ZA07

Amendment to Prohibited Transaction Class Exemption 84–14 for Transactions Determined by Independent Qualified Professional Asset Managers (the QPAM Exemption)

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Final amendment to class exemption.

SUMMARY: This document gives notice of a granted amendment to prohibited transaction class exemption 84–14 (the QPAM Exemption). The QPAM Exemption provides relief from certain prohibited transaction restrictions of Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA) and Title II of ERISA, as codified in the Internal Revenue Code of 1986, as amended (the Code).

DATES: The amendment is effective June 17, 2024.

FOR FURTHER INFORMATION CONTACT: Brian Mica, telephone (202) 693–8540, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Title I of ERISA broadly prohibits transactions between plans and any ''party in interest''—who, in general, are people or entities closely connected to ERISA-covered employee benefit plans as defined in ERISA section 3(3). Title II of ERISA, codified in the Code, includes parallel prohibitions applicable to ''disqualified persons'' [1] who, in general, are persons or entities closely connected to plans [2] as defined in Code section 4975(e)(1).

Absent an exemption, ERISA section 406(a)(1)(A) through (D) and Code section 4975(c)(1)(A) through (D) prohibit, among other things, sales, leases, loans, and the provision of services between these parties. Congress enacted these prohibitions to protect plans, their participants and beneficiaries, and IRA owners [3] from the potential for abuse that arises when plans and IRAs engage in transactions with closely connected parties.

The Department grants this exemption, which was proposed on its own motion, pursuant to its authority under ERISA section 408(a) and Code section 4975(c)(2).[4] As required by ERISA section 408(a) and Code section 4975(c)(2), the Department finds that the exemption is administratively feasible, in the interests of Plans and their participants and beneficiaries and protective of the rights of participants and beneficiaries of Plans and IRA owners.

The QPAM Exemption permits an investment fund [5] holding assets of Plans and IRAs that is managed by a ''qualified professional asset manager'' (QPAM) to engage in transactions with a ''party in interest'' or ''disqualified person'' to Plans or an IRAs, subject to protective conditions.[6] This amendment modifies Section I(g) of the exemption, a provision under which a QPAM may become ineligible to rely on the QPAM Exemption for a period of 10 years if the QPAM, various affiliates, or certain owners of the QPAM are convicted of certain crimes. As discussed in detail below, this amendment: (1) requires a QPAM to provide a one-time notice to the Department that the QPAM is relying upon the exemption; (2) updates the list of crimes enumerated in the prior version of Section I(g) to explicitly include foreign crimes that are substantially equivalent to the listed crimes; (3) expands the circumstances that may lead to ineligibility; and (4) provides a one-year winding down (transition) period to help Plans and IRAs avoid or minimize possible negative impacts of terminating or switching QPAMs or adjusting asset management arrangements when a QPAM becomes ineligible pursuant to Section I(g), and gives QPAMs a reasonable period to seek an individual exemption, if appropriate.[7]

This amendment also: (1) provides clarifying updates to Section I(c) regarding a QPAM's authority over investment decisions; (2) adjusts the asset management and equity thresholds in the QPAM definition in Section VI(a); and (3) adds a new recordkeeping provision in Section VI(u). The amendment will affect participants and beneficiaries of Plans, IRA owners, the sponsoring employers of such Plans or IRAs (if applicable) and other plan sponsors, QPAMs, and counterparties engaging in transactions covered under the QPAM Exemption.

Background of the QPAM Exemption

In 1984, the Department published the QPAM Exemption, which permits an investment fund managed by a QPAM to engage in a broad range of transactions with parties in interest with respect to a Plan, subject to protective conditions. The Department developed and granted the QPAM Exemption based on the premise that it could provide broad exemptive relief from the prohibitions of ERISA section 406(a)(1)(A) through (D) and Code section 4975(c)(1)(A) through (D) for transactions in which a Plan engages with a Party in Interest only if the commitments and investments of Plan assets and the negotiations leading thereto are the sole responsibility of an independent investment manager.

Section I of the QPAM Exemption (the General Exemption) [8] provides broad

[1] The term ''disqualified person'' is defined in Code Section 4975(e)(2) and is similar to definition of the term ''party in interest'' codified in ERISA section 3(14). All references to ''party in interest'' in this Preamble and the QPAM exemption include ''disqualified person.''

[2] For purposes of the exemption that term ''Plans'' includes plans and Individual Retirement Accounts (IRAs) described in Code section 4975(e)(1) and ERISA-covered employee benefit plans described in ERISA section 3(3) (referred to as ''Plans,'' and ''IRAs'' herein). Although the Department is using the same definition of ''plan'' in the final amendment that previously existed in the QPAM Exemption, the Department is finalizing a ministerial change which will capitalize this term when referring to plans impacted by the amendment.

[3] For purposes of this Final Amendment, the term ''IRA owner'' refers to the individual for whom an IRA (as defined in the Final Amendment) is established.

[4] The exemption also is granted in accordance with procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637 (October 27, 2011)). Please note that effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. (2018), transferred the authority of the Secretary of the Treasury to issue exemptions to the Secretary of Labor. Therefore, this notice of amendment to the QPAM Exemption is issued solely by the Department.

[5] For purposes of the QPAM Exemption, an investment fund includes single customer and pooled separate accounts maintained by an insurance company, individual trusts, and common, collective, or group trusts maintained by a bank, and any other account or fund subject to the discretionary authority of the QPAM. *See* Section VI(b) of the QPAM Exemption.

[6] Class Exemption for Plan Asset Transactions Determined by Independent Qualified Professional Asset Managers, 49 FR 9494 (Mar. 13, 1984) as corrected at 50 FR 41430 (Oct. 10, 1985), as amended at 66 FR 54541 (Oct. 29, 2001), 70 FR 49305 (Aug. 23, 2005), and 75 FR 38837 (July 6, 2010).

[7] As further discussed below, the Department has substituted the term ''transition period'' for the term ''winding-down period'' that it used in the proposed amendment. The terms have the same meaning.

[8] The Department proposed a ministerial change to replace ''Part'' with ''Section'' in the QPAM Exemption. For consistency, the Department is using only the term ''Section'' throughout this preamble. The Department also proposed a ministerial change to capitalize defined terms in the QPAM Exemption and is using those capitalized

prohibited transaction relief for a QPAM-managed Investment Fund to engage in transactions with a Party in Interest, but it does not include relief for the QPAM to engage in any transactions involving its own self-dealing or conflicts of interest or kickbacks, which are prohibited under ERISA section 406(b)(1) through (3) and 4975(c)(1)(E) and (F). This important limitation on the relief in the QPAM Exemption serves as a key protection for Plans that are affected by the exemption. The QPAM Exemption also includes conditions designed to ensure that the QPAM does not engage in transactions with a Party in Interest that has the power to influence the QPAM's decision-making processes. Additionally, QPAMs remain subject to the fiduciary duties of prudence and undivided loyalty set forth in ERISA section 404 with respect to their client Plans.

The General Exemption covers many different types of transactions. For example, the exemption provides relief for a QPAM to use fund assets to purchase an asset from certain Parties in Interest [9] to a Plan that is invested in the fund. The General Exemption also facilitates much more complex transactions, such as when a QPAM designs a fund to replicate the return of certain commodities indices by investing in futures, structured notes, total return swaps, and other derivatives where a Party in Interest to a Plan that invested in the fund is involved in the transaction.[10] In addition to the General Exemption, the QPAM Exemption also contains ''Specific Exemptions'' in Sections II, III, and IV, which the Department is not modifying in this amendment.

When it proposed the QPAM Exemption in 1982, the Department expressly indicated that any entity acting as a QPAM, and those who are in a position to influence the QPAM's policies, are expected to maintain a high standard of integrity.[11] Accordingly, the exemption includes Section I(g), which provides that a QPAM is ineligible to rely on the exemption for a period of 10 years if the QPAM, various affiliates, or owners of a five (5) percent or more interest in the QPAM are convicted of certain crimes. Ineligibility begins as of the date of the judgment of the trial court, regardless of whether the judgment remains under appeal.

The Qualified Professional Asset Manager

A QPAM is defined as a bank, savings and loan association, insurance company, or registered investment adviser that meets specified asset and equity thresholds set forth in the exemption and acknowledges in a Written Management Agreement that it is a fiduciary with respect to each of its client Plans. The Department noted in the 1982 proposed exemption that these categories of asset managers are subject to regulation by federal or state agencies and expressed the view that large financial services institutions would be able to withstand improper influence from Parties in Interest (*i.e.,* maintain independence).[12] As a general matter, the Department's position continues to be that transactions entered into on behalf of Plans with a Party in Interest are most likely to conform to ERISA's general fiduciary standards when the decision to enter into the transaction is made by an independent fiduciary.

The QPAM's independence and discretionary control over asset management decisions protect Plans from the danger that a Party in Interest will exercise improper influence over decision-making regarding Plan assets. The QPAM acts as a fundamental protection against the possibility that Parties in Interest could otherwise favor their own competing financial interests at the expense of Plans, their participants and beneficiaries, and IRA owners. Because the Department relies upon the QPAM as a key protection against such improper conduct and the threat posed by conflicts of interest, it is critically important that the QPAM, and those who are in a position to influence its policies, maintain a high standard of integrity. QPAMs must have the authority to make decisions on a discretionary basis without direct oversight for each transaction by other Plan fiduciaries. Given the scope of their discretion, it is imperative that the QPAM, its Affiliates, and certain owners avoid engaging in criminal conduct and other serious misconduct that would jeopardize Plan assets or call into question the Department's reliance on the QPAM's oversight as a key safeguard for Plan participants and beneficiaries and IRA owners.

Purpose and Approach for the Final Amendment

Substantial changes have occurred in the financial services industry since the Department granted the QPAM Exemption in 1984. These changes include industry consolidation and an increasingly global reach for financial services institutions, both in their affiliations and their investment strategies, including those for Plan assets. In the years since 1984, the Department has repeatedly considered applications for individual exemptions in connection with convictions for crimes causing ineligibility under Section I(g). Through processing these applications, the Department has gained extensive experience analyzing QPAMs' failures to comply with Section I(g) of the QPAM Exemption as a result of corporate convictions in domestic and foreign jurisdictions. This experience has affirmed the Department's position that an ineligibility condition tied to criminal convictions provides necessary protection to Plans, their participants and beneficiaries, and IRA owners.

In practice, Section I(g) has effectively required QPAMs that become ineligible to seek an individual exemption to continue their reliance on the QPAM Exemption. Since 2013, the Department has received an increasing number of individual exemption requests involving Section I(g) ineligibility due to criminal convictions occurring within the corporate family of large financial institutions. To ensure that these exemptions are protective of Plans and participants and beneficiaries and in their interests as required by ERISA section 408(a) and Code section 4975(c)(2), the Department has required applicants to fully and accurately disclose: (1) the criminal conduct that led to their ineligibility, including whether the QPAM was involved; (2) the specific reasons they should be permitted to continue acting as a QPAM notwithstanding the criminal conduct; (3) the efforts they have undertaken to promote a culture of compliance in their corporate family; and (4) the steps they will take in the future to ensure Plans, their participants and beneficiaries, and IRA owners are protected. In these individual QPAM exemptions, the Department included additional protections, such as a comprehensive independent compliance audit and allowing client Plans to withdraw from their asset management arrangements with the ineligible QPAM without penalty. These exemptions have also required the QPAM to indemnify or hold their client Plans harmless in the event that the QPAM, or an Affiliate, or

terms throughout this preamble as they are being finalized in this amendment.

[9] The plural form has the same meaning as the singular defined term ''Party in Interest.''

[10] *See e.g.,* Notice of Proposed Exemption involving Credit Suisse AG, 79 FR 52365, 52367 (Sept. 3, 2014).

[11] Proposed Class Exemption for Plan Asset Transactions Determined by Independent Qualified Professional Asset Managers, 47 FR 56945, 56947 (Dec. 21, 1982).

[12] *Id.* at 56947.

owner of a five (5) percent or more interest engages in future misconduct.

Exemption applicants have consistently represented to the Department that Plan investors would be harmed if a QPAM abruptly loses exemptive relief as of the conviction date, as dictated by Section I(g). Although Section I(g) ineligibility does not bar a QPAM from acting as a discretionary asset manager for Plan assets after a conviction, applicants have informed the Department that the loss of exemptive relief under the QPAM Exemption has the potential to disrupt Plan investments and investment strategies, especially for transactions involving Plan counterparties that also are relying upon the relief provided in the QPAM Exemption.[13] According to these applicants, Plans may also experience transition costs if a Plan fiduciary needs to find an alternative asset manager on short notice after a QPAM becomes ineligible.

To protect Plans against the immediate disruption and costs caused by their QPAMs losing eligibility immediately upon conviction, the Department has granted several one-year temporary individual exemptions to QPAMs facing ineligibility. These individual exemptions provided the Department with sufficient time to engage in a more intensive review of information submitted by the applicants to determine whether a longer-term individual exemption was warranted to provide extended relief at the end of the one-year period.[14] Moreover, since 2013, both the one-year and longer-term exemptions have provided Plans with the important opportunity to exit from their asset management arrangements with a QPAM without the imposition of certain fees, penalties, or charges.

Regulatory Administrative Record for the Proposed Amendment

The developments discussed above prompted the Department to propose the amendment to the QPAM Exemption on July 27, 2022, with an initial 60-day comment period that was set to expire on September 26, 2022 (the Proposed Amendment).[15] After the Department published the Proposed Amendment, it received two letters requesting an extension of the comment period.[16] The Department responded to the requests by extending the initial comment period for an additional 15 days until October 11, 2022, in a **Federal Register** Notice published on September 7, 2022,[17] and received 31 comment letters during this initial extended comment period.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Acting Assistant Secretary of the Employee Benefits Security Administration (EBSA) certified that the Proposed Amendment would not have a significant economic impact on a substantial number of small entities. After consulting with the Small Business Administration's Office of Advocacy (SBA), however, the Department decided to publish a Supplementary Initial Regulatory Flexibility Analysis (IRFA) that explained the Proposed Amendment's potential impact on small entities.[18] The Department requested comments on the IRFA by October 11, 2022, the same deadline as the extended comment period for the Proposed Amendment.

In the September 7, 2022, **Federal Register** notice, the Department announced that it would hold a virtual public hearing on its own motion on November 17, 2022 (and if necessary, on November 18, 2022), to provide an opportunity for all interested parties to testify on material information and issues regarding the Proposed Amendment.[19] The Department received 13 requests to testify at the hearing. The notice also indicated the Department would: (1) reopen the public comment period from the hearing date until approximately 14 days after the Department publishes the hearing transcript on EBSA's website; and (2) publish a **Federal Register** notice announcing that the Department posted the hearing transcript to EBSA's website and providing the closing date for the reopened comment period.

The Department held the virtual public hearing on November 17, 2022, and reopened the comment period on the hearing date.[20] The reopened comment period closed on January 6, 2023, and the Department received 150 additional comments.[21]

On March 23, 2023, the Department reopened the Proposed Amendment's comment period again because it understood that at least one interested party may have had additional information to provide the Department that was not submitted by the January 6, 2023 comment period deadline.[22] The reopened comment period provided an opportunity for all interested parties to submit additional information until April 6, 2023, and the Department received seven comments during this reopened comment period.[23]

The rulemaking process has provided the Department with a robust administrative record. After careful consideration of the approximately 200 comments received during the public comment periods and testimony presented at the public hearing, the Department is finalizing the Proposed Amendment (the Final Amendment), with the revisions discussed below.

Section I(g)—Reporting to the Department, Written Management Agreement, and Ineligibility

Reporting to the Department—Note: This Requirement has been moved from Subsection I(g)(1) of the Proposed Amendment to Section I(k) of this Final Amendment.

The Proposed Amendment would have required each QPAM that relies upon the exemption to report its legal name (and any name the QPAM may be operating under) by email to the Department at *QPAM@dol.gov*.[24] The Department proposed that the QPAM would need to provide this notification to the Department only once unless the legal or operating name(s) of the QPAM relying upon the exemption was changed. The Department also indicated its intent to maintain a current list of entities relying upon the QPAM Exemption on its publicly available website.

[13] *See e.g.,* Notice of Proposed Exemption involving JP Morgan Chase & Co., 81 FR 83372, 83363 (Nov. 21, 2016).

[14] In such cases, the Department requires prominent notice be provided to client Plans along with additional protective conditions to ensure Plan assets are protected while longer-term prohibited transaction relief is considered.

[15] 87 FR 45204.

[16] *See* Public Comment #1 from American Bankers Association et al. and Public Comment #2 from American Retirement Association. The extension requests can be accessed here: *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07/.*

[17] 87 FR 54715.

[18] 87 FR 56912 (Sep. 16, 2022).

[19] 87 FR 54715.

[20] The hearing did not continue on November 18, 2022, because the Department was able to schedule all witnesses that requested to testify on one day.

[21] *See https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07.*

[22] 88 FR 17466.

[23] *See https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07.*

[24] For instance, assume a corporate family is comprised of legal entities named: Corporate Parent A, Investment Manager B, Broker-Dealer C, Retail Bank D, and Institutional Bank E (doing business as InstiBank). Investment Manager B and Institutional Bank E are the only entities acting as QPAMs. Investment Manager B would notify the Department that it is acting as a QPAM and its legal name is Investment Manager B. Institutional Bank E would notify the Department that it is acting as a QPAM and its legal name is Institutional Bank E, but it is doing business as InstiBank.

The Department received a variety of comments on this proposed reporting requirement. Some commenters opposed the requirement in part because no other prohibited transaction exemption requires ''registration'' or a listing on a publicly available website. Commenters also indicated that the publication of a list of QPAMs on the Department's website has the potential to mislead Plan participants and beneficiaries and IRA owners into thinking that a manager's inclusion or exclusion signifies whether the Department has endorsed its eligibility to rely on the exemption.

After considering these comments, the Department is finalizing the notice provision with the modifications discussed below. The notice requirement provides the Department with knowledge of the investment managers that are relying on the exemption and will serve as an important reminder to investment managers relying on the QPAM Exemption that the ''QPAM'' title and status are tied to an administrative prohibited transaction exemption that requires compliance with the exemption's conditions.

With respect to publishing the list on its website, the Department has significant experience publicly posting information in a manner that is not misleading. Additionally, the Department notes that a wide variety of information regarding investment advisers, including disciplinary violations, currently is publicly available through BrokerCheck.[25] The importance of having this information publicly available to provide Plan fiduciaries and participants and beneficiaries, and IRA owners with the ability to know whether their investment managers (or potential managers) are relying on the QPAM Exemption outweighs any harm that could occur if the information were misleading.

Commenters also noted that it is important for the Department to ensure that it has appropriate resources to maintain the list of QPAMs and keep it current. The Department appreciates this concern. Although there will likely be an initial wave of QPAMs reporting to the Department, the Department anticipates that minimal resources will be necessary to keep an updated list over the long-term.

Commenters also expressed concern that a QPAM could easily overlook the requirement to update the Department when it changes its legal or trade name, which could lead it to commit a series of inadvertent prohibited transactions that would only end when the QPAM reports its updated name to the Department. Related to this concern, commenters also requested the Department clarify that an inadvertent failure to report would not be considered Prohibited Misconduct[26] or otherwise jeopardize a manager's ability to rely on the QPAM Exemption.

The Department did not intend for the reporting requirement to create compliance issues for QPAMs that could jeopardize the availability of the prohibited transaction relief in the QPAM Exemption. Therefore, to avoid inadvertent failures during the period immediately after an entity begins relying on the QPAM Exemption or changes its name, the Department has revised the proposed provision to provide QPAMs with an initial 90-day period to report to the Department and an additional 90-day period to cure inadvertent failures to report. If the QPAM fails to report within the initial 90-day period, it must submit an explanation during the 90-day cure period for why it failed to provide timely notice. If, at the end of the 180 days, a QPAM still has failed to report, or has not provided the required explanation, the exemption will not be available for transactions that occur until the failure is fully cured. Furthermore, the Department confirms that an isolated instance of failing to report generally would not be considered Prohibited Misconduct that would result in ineligibility under Section I(g)(1)(B).

Several commenters also indicated that the Proposed Amendment did not appear to provide any mechanism for an entity to ''de-register'' after it initially reports to the Department. In response to this comment, the Department added new language to the end of Section I(k) (Subsection I(g)(1) of the Proposed Amendment) to allow an entity that reported to the Department to notify the Department that it no longer is relying on the exemption. After the Department receives this notice, it will remove the entity from its list of QPAMs that are relying on the QPAM Exemption.

Another commenter recommended that if the Department is seeking a list of entities operating as QPAMs, the Department could assign a new separate identifying code to QPAMs that would be used to report the QPAMs' services to a Plan on Schedule C of the Form 5500. While the Department appreciates this comment and suggestion, modifying the Form 5500 is not part of this amendment, and the Department's objective would not be met using the current Form 5500 for this purpose.

Finally, a proponent of the requirement noted that the Department cannot effectively monitor QPAM compliance if it cannot even identify QPAMs or estimate the number and amount of assets managed by QPAMs. The Department notes that in addition to assisting the Department in monitoring compliance, the reporting requirement will ensure the Department has better information regarding the number of QPAMs that are relying on the exemption, which will provide important data the Department can use to estimate impacts if it considers future amendments to the exemption. Therefore, the Department has retained this requirement in the Final Amendment because it is important for firms that are relying on the exemption to provide identifying information to the Department and for such firms to establish a compliance framework that is sufficient to ensure that they can always satisfy the exemption's conditions.

Written Management Agreement (WMA)—Proposed Subsection I(g)(2)[27]

As previously stated in this preamble, the fundamental premise of Section I(g) has always been for a QPAM and those in a position to control or influence its policies to act with integrity. The Proposed Amendment included a new requirement for all QPAMs to update their WMAs to include a provision that in the event the QPAM, its Affiliate, or five percent or more owners engage in conduct resulting in a Criminal Conviction or Participation In Prohibited Misconduct, the QPAM would not restrict its client Plans' ability to terminate or withdraw from their arrangement with the QPAM.[28] The proposed requirement also would have prevented QPAMs from imposing certain fees, penalties, or charges on client Plans in connection with terminating or withdrawing from a QPAM-managed Investment Fund.[29]

[25] BrokerCheck is an online tool provided by FINRA that provides information regarding brokers and investment advisers such as employment history, certifications, licenses, and any violations. *https://brokercheck.finra.org/*.

[26] Prohibited Misconduct was defined in proposed Section VI(s). See below for additional discussion of comments regarding the Proposed and Final Amendment definition.

[27] Subsection I(g) of the Proposed Amendment has been renumbered and the requirements in Proposed Section I(g)(2) are now contained in Section I(i) in this Final Amendment.

[28] The terms ''Criminal Conviction'' and ''Prohibited Misconduct'' are discussed in more detail below.

[29] This would not apply to reasonable fees, appropriately disclosed in advance, that are

Continued

Finally, the Proposed Amendment would have required QPAMs to include a provision in their WMAs that they would indemnify, hold harmless, and promptly restore actual losses to each client Plan for any damages directly resulting from a violation of applicable laws, a breach of contract, or any claim arising out of the failure of such QPAM to remain eligible for relief under the QPAM Exemption as a result of conduct that leads to a Criminal Conviction or Participation in Prohibited Misconduct.

Many commenters expressed concerns with these proposed WMA provisions. They were particularly opposed to the WMA condition being imposed on all QPAMs immediately upon the effective date of the provision, and not only those QPAMs who become ineligible under Section I(g).[30] Other commenters indicated that these WMA provisions should simply be imposed as conditions that are not required to be included in contracts or as contractual guarantees.

Many commenters indicated that the process to update WMAs is difficult and complicated and would take much longer to comply with than the Department's proposed 60-day effective date. Some commenters indicated that at least 18 months would be required to come into compliance, and that the amendment process would be very costly. These commenters noted that even if a manager made only the required amendments to its WMA, such amendments typically would require investor consent, including consent by non-Plan investors who might be adversely affected by the changes. Additionally, if QPAMs were required to include a new indemnification clause in their WMA, commenters indicated that QPAMs would likely also need to update and revise their agreements with many other parties to address the same contingencies that necessitate the new indemnifications and other required changes for their client Plans. Finally, some commenters suggested that if the Department requires QPAMs to include these provisions in their WMAs, the requirement should apply only to contracts that are executed or materially modified after the effective date of the Final Amendment.

After carefully considering these comments, the Department has decided to remove the requirement for all QPAMs to revise their WMAs. Instead, the Department has moved the condition into the Transition Period provision of this Final Amendment. This modification means that after the effective date of the Final Amendment, only QPAMs that become ineligible to rely on the exemption will have to comply with the indemnification and penalty-free withdrawal provisions. As a result, the Final Amendment's Transition Period provision will operate in a similar manner to recent Section I(g) individual exemptions granted by the Department, which have imposed indemnification and penalty-free withdrawal requirements on QPAMs only after they become ineligible under Section I(g).

The Final Amendment indicates that any QPAM that experiences a Section I(g) triggering event must provide client Plans with a One-Year Transition Period and comply with the associated conditions that are discussed below. In this Final Amendment, the Department made some minor non-substantive adjustments to the language in the Proposed Amendment regarding the prohibited transaction relief available and obligations of the QPAM during the Transition Period. The Final Amendment indicates that relief under the exemption during the Transition Period is available for a maximum period of one year after the Ineligibility Date if the QPAM complies with each condition of the exemption throughout the one-year period. No relief will be available for any transactions (including past transactions) effected during the One-Year Transition Period unless the QPAM complies with each condition of the exemption during such one-year period.

A few commenters opined that the requirement that the QPAM agree not to restrict a Plan's ability to withdraw from an Investment Fund that invests in illiquid assets such as a private equity or real estate fund, may present additional challenges and harm Plans' investment returns. The Department understands the additional challenges associated with funds that are less liquid. However, as noted in the Proposed Amendment, a QPAM that faces ineligibility may seek supplemental individual exemption relief from the Department. As also noted in the Proposed Amendment, an applicant may request a more limited scope of relief for a supplemental individual exemption that captures only those transactions that present liquidity problems. The individual exemption process is best suited for addressing those concerns and the Department stresses the importance of submitting an individual exemption application as soon as possible after a QPAM learns that a Section I(g) triggering event is expected to occur. Applying promptly is not only consistent with the QPAM's fiduciary obligations, but also helps ensure that the Department has sufficient time to review the exemption application before the end of the One-Year Transition Period.

Some commenters maintained that QPAMs should not have to indemnify and restore losses beyond what is already required under ERISA because ERISA already provides sufficient protections for Plans to recover losses. The Department disagrees. Until now, the exemption lacked additional safeguards to ensure Plans and IRA owners are not exposed to substantial collateral costs that result from criminal or other misconduct that is beyond their control. When QPAMs breached their obligations and faced the loss of QPAM status, they commonly argued that the Department should grant relief, notwithstanding their misconduct, lest the Plans and IRA owners sustained the collateral costs and injury associated with the loss of QPAM status. The express obligation to indemnify and restore losses caused by the QPAM's own misconduct mitigates this danger and prevents Plans from being locked into disadvantageous relationships with firms that have proved unable or unwilling to meet the exemption's conditions.

Commenters also indicated that client Plans and QPAMs should be allowed to negotiate indemnification because liability and indemnification provisions are often already in place, which are intended to protect Plans if a non-exempt prohibited transaction or breach of fiduciary duty occurs. The Department is concerned that all client Plans do not have the same bargaining leverage to negotiate the type of indemnification provisions included in the Final Amendment. Moreover, such commenters did not provide any specific examples of the types of indemnification provisions that may

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specifically designed to prevent generally recognized abusive investment practices or specifically designed to ensure equitable treatment of all investors in a pooled fund in the event such withdrawal or termination may have adverse consequences for all other investors would be excepted. If such fees, penalties, or charges occur, they must be applied consistently and in a like manner to all such investors.

[30] Many commenters used terms such as ''disqualified'' or ''disqualification'' in their comment letters to describe ineligibility under Section I(g). The Department has used the terms ''ineligibility'' and ''ineligible'' throughout this preamble for consistency with the heading for Section I(g) in this Final Amendment and to avoid confusion that the term ''disqualified'' indicates that the definition of ''qualified professional asset manager'' is not satisfied.

already be included in their agreements with Plan customers. Nevertheless, the Department's modification in the Final Amendment to limit the WMA requirements to the Transition Period should mitigate this concern because the requirement will only be imposed upon entities experiencing an event that triggers Section I(g).

Some commenters focused on the term ''actual losses'' and argued that this standard should not include the costs for Plans to transition to an alternative asset manager because such costs are not normally paid for by a terminated manager. The Department believes that this argument is misplaced. Whether a cost is normally paid for by a terminated manager is not determinative of whether the Department should include a provision in the Final Amendment to protect Plans as mandated by ERISA section 408(a) and Code section 4975(c)(2). When an asset manager becomes ineligible to rely upon the relief provided in the QPAM Exemption due to a violation of Section I(g), which is outside the control of the client Plan, it is appropriate for the wrongdoer to bear the associated costs.

Commenters also noted the ambiguity regarding the full range of costs that are required to be indemnified. Relatedly, commenters indicated that asset managers will be unable to insure against such losses. They argued that it is very difficult, if not impossible, to quantify ''investment losses resulting from foregone investment opportunities'' for a variety of reasons, including the type of investment manager, the ebbs and flows of investment needs and opportunities, and the costs or needs of a replacement manager.

The Department acknowledges that there is uncertainty regarding the full range of such costs, but notes that it has consistently imposed these indemnification and loss restoration obligations in recent individual exemptions following violations of Section I(g), and that the affected firms have nevertheless chosen to continue acting as QPAMs after receiving relief from the Department. Commenters have provided no evidence that the condition has resulted in the imposition of unwarranted costs upon Plans or QPAMs, or that there had been any significant adverse impacts stemming from imposition of the condition in the context of individual exemptions. Nor have they provided any compelling evidence suggesting that the costs caused by further breaches after felony convictions, or the associated uncertainties, are better borne by the affected Plans than by the QPAMs. In the Department's view, it is wholly appropriate that the QPAM, rather than the Plan, sustain the costs stemming from the QPAM's failure to meet the exemption's conditions or violations of the law. Moreover, by limiting the WMA requirements to the Transition Period provisions in the Final Amendment, the Department sharply reduces the scope of the QPAM's potential liability and the need to determine possible costs up front. As noted above, this Final Amendment simply adopts the same overall approach to Section I(g) ineligibility that has been a core component of the Department's recently granted Section I(g) individual exemptions.[31]

One commenter also noted that the WMA requirement in subsection I(g)(2)(C) of the Proposed Amendment referenced Code section 4975 excise taxes. The commenter indicated that since the indemnification runs to the Plan and a Plan is not liable for excise taxes, this provision does not make sense. After considering this comment, the Department has retained the reference to the excise taxes. This provision is intended to ensure that a QPAM does not impose costs or fees on a Plan in connection with excise taxes incurred by the QPAM.

Finally, a commenter argued that the provision should not cover non-prosecution agreements (NPAs), deferred prosecution agreements (DPAs), or any other ineligibility trigger captured within the definition of Prohibited Misconduct. As discussed below, the Department has modified the scope of NPAs and DPAs captured within the definition of Prohibited Misconduct. The Department believes that conduct severe enough to warrant an NPA or DPA should trigger the same conditions as Criminal Convictions. Therefore, while the Final Amendment reflects the modified scope of the NPAs and DPAs that are affected, the Department declines to remove this protection as it applies to NPAs and DPAs covered under the Final Amendment.

[31] *See e.g.,* Exemption From Certain Prohibited Transaction Restrictions Involving Pacific Investment Management Company LLC, 88 FR 42953 (July, 5, 2023); Exemption for Certain Prohibited Transaction Restrictions Involving Citigroup, Inc., 88 FR 4023 (Jan. 23, 2023); Exemption for Certain Prohibited Transaction Restrictions Involving DWS Investment Management Americas, Inc. (DIMA or the Applicant) and Certain Current and Future Asset Management Affiliates of Deutsche Bank AG, 86 FR 20410 (April 18, 2021).

Types of Misconduct and Entities That Cause Ineligibility—Proposed Subsection I(g)(3)[32] and Sections VI(r) and VI(s)

Criminal Convictions

Since 1984 when the QPAM Exemption was initially granted, Section I(g) ineligibility has captured convictions of QPAMs, their Affiliates, and five percent or more owners of the QPAM. As noted above, because the Department relies upon the QPAM as a key protection in the exemption, it is critically important that the QPAM, and those who are positioned to influence its policies, maintain a high standard of integrity. QPAMs, affiliates, and related parties that engage in serious criminal misconduct do not display the requisite standard of integrity expected of such entities under the exemption.

While the Department did not propose any changes to the scope of entities captured by Section I(g),[33] some comments focused on the breadth of Section I(g), including the proposed expansion of Section I(g) to capture the Participation In Prohibited Misconduct by a QPAM, its Affiliates, or its owners of a five (5) percent or more interest. Some commenters noted that the financial services industry has experienced significant consolidation in the decades since the QPAM Exemption was granted, with the result that a QPAM may be a small part of a very large organization. One commenter also suggested that the Department's proposed expansion of the ineligibility provision to include Prohibited Misconduct would impose an unjustified penalty based on the size and complexity of firms relying on the exemption.

Some commenters contended that existing Section I(g) of the QPAM Exemption results in unjust application of automatic ineligibility. Commenters suggested that Section I(g) should focus on crimes committed by affiliates that are positioned to influence the QPAM's policies or have power or influence to compromise the QPAM's ERISA compliance, or crimes that involve the QPAM itself. According to one commenter, there should be a direct relationship between the crime and the services provided by the QPAM. A

[32] Subsection I(g)(3) of the Proposed Amendment has been renumbered as Subsection I(g)(1) of the Final Amendment.

[33] The Department recognizes that the proposed inclusion of Prohibited Misconduct may seem to broaden the scope of entities captured, but the Department characterizes that as broadening the scope of misconduct. The Proposed Amendment did not change the five percent ownership threshold or definition of Affiliate that is applicable to Section I(g).

variety of commenters expressed disagreement with what they perceived to be the Department's position, *i.e.,* that remote convictions call a QPAM's integrity into question. These commenters asserted that Section I(g) imposes ineligibility in circumstances where the entities or individuals engaging in criminal conduct are not, in fact, in a position to influence the QPAM's policies. One commenter also opined that remote convictions resulting in ineligibility run counter to the purposes of ERISA section 408(a). Another commenter suggested that the Department should reserve ineligibility only for the most egregious convictions of the QPAM involving ERISA assets. Others preferred the Department's narrow approach in PTE 2020–02 because it limits ineligibility to the entity providing investment advice or other affiliates engaged in the business of providing investment advice to Plans.

At the same time, some of these commenters indicated that inclusion of criminal convictions as an ineligibility trigger at the QPAM entity level could be appropriate. Similarly, some commenters agreed that crimes committed by a parent entity that can exercise management and control over the QPAM's day-to-day business and decision-making could be relevant for an ineligibility provision based on criminal convictions. A few commenters suggested that the Department rely on the ''controlled group of corporations'' or ''under common control'' standards as defined in Code section 414(b) and (c) if it decides to retain the current breadth of Section I(g).

The Department disagrees with the suggestion that disqualification is appropriate only when the QPAM itself was directly involved in the crime or only when the crime specifically involves plan assets or services to ERISA-covered plans. Serious crimes of the sort enumerated in Section I(g) are directly relevant to a corporate family's culture of compliance. When a company with multiple affiliated entities has engaged in such conduct or ignored criminal misconduct when it is occurring (or possibly even endorsed the misconduct), the likelihood that the same or similar conduct will be ignored when engaged in at the QPAM entity increases. This is particularly true where the bad actor is the corporate parent of the QPAM, but also rings true when it is an affiliated company that is controlled by the same corporate parent as the QPAM.

Affiliated and related companies commonly hold themselves out as an integrated entity, have common or overlapping supervisory and control structures, and share a common corporate culture. Accordingly, serious criminal misconduct is a red flag indicating potential compliance problems that extend beyond the specific actors that directly engaged in the misconduct. Similarly, the commission of any of the enumerated criminal offenses is relevant to the assessment of likely future misconduct beyond the narrow confines of the particular customers and service providers directly affected by the conduct that resulted in a conviction. If, for example, a company engaged in embezzlement or price-fixing with respect to non-plan customers, there is little basis for plan customers to be sanguine about the improbability of such conduct with respect to plan customers and plan assets.

Moreover, the practical impact of the exemption's disqualification provisions is not that QPAMs are precluded from making their case to the Department that the criminal conviction should not result in a lengthy bar from reliance on the exemption. Rather, the consequence is that the disqualified QPAM would have to apply for an individual exemption if it wishes to rely on the class exemption for a period that extends beyond the Transition Period. In the context of such an individual exemption application, the QPAM would be in a better position to present evidence on the scope of its involvement in the criminal conduct, its independence from any bad actors, current corporate culture and compliance structures, and other information relevant to assessing whether it should be permitted to continue relying on this exemption, notwithstanding the conviction. Similarly, the Department would have the time and ability to consider such issues on a case-specific and context-sensitive basis that takes into account the evidence submitted as part of a formal record. Also, based on the Department's experience processing individual exemption applications, many of the convictions and criminal misconduct the Department has dealt with over the past decade have not involved conduct that is isolated to remotely related affiliates within the QPAM's corporate ownership structure.[34]

Financial Industry Consolidation

The Department recognizes that the legal landscape for the financial services industry has changed since 1984. When the QPAM Exemption was originally granted, there were established legal and regulatory barriers in the U.S. that prevented banking, securities, and insurance companies from consolidating. However, the passage of the Graham-Leach-Bliley Act in 1999[35] removed these barriers, which led many commercial banks, investment banks, securities firms, and insurance companies to consolidate. The Department understands that significant consolidation has occurred since 1999 and that the scope of entities captured by Section I(g) has not been revisited since those and other changes occurred in the financial services industry. The Department continues to stand by the original premise for Section I(g), which largely is focused on entities who are in control-based relationships with a QPAM, can influence the activities of a QPAM or are likely to share a common corporate culture.

The Department reminds QPAMs, as it did in the Proposed Amendment, that control-based relationships remain directly relevant for triggering ineligibility under Section I(g) because of the Affiliate definition.[36] Meaningful control can exist even when entities that have small ownership interests in a QPAM are positioned to influence the QPAM's decision to engage or refrain from engaging in conduct that can form the basis for a Criminal Conviction or Participation In Prohibited Misconduct. The Department continues to believe that corporate malfeasance at entities that control, are under common control with, or are controlled by the QPAM indicates the possibility of increased risk of harm to client Plans and IRA owners . The Department notes that a controlling relationship exists when one entity directly or indirectly has or exercises a significant influence over the management or policies of another entity. Control in this context does not require that the first entity has the ability to exercise complete domination or absolute authority over all aspects of the management or policies of the second entity.

Foreign Criminal Convictions

The Department has a longstanding practice of considering individual exemption applications from QPAMs in connection with foreign convictions.[37]

[34] Even in situations where the convicted entity appeared remote, the Department has seen pervasive compliance failures at various other entities within the corporate family, including at parent entities.

[35] Public Law 106–102; 113 Stat. 1338.

[36] The Affiliate definition continues to include ''[a]ny person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with'' the QPAM. *See* Section VI(d) for a complete definition.

[37] *See, e.g.,* Prohibited Transaction Exemption (PTE) 2020–01, 85 FR 8020 (Feb. 12, 2020); PTE

The Proposed Amendment would have added a definition of Criminal Conviction that was intended to remove any doubt that Section I(g) applies to foreign convictions that are substantially equivalent to the listed U.S. federal or state crimes. In the Proposed Amendment, the Department specifically requested comments on this section, including whether there are certain types or aspects of criminal behavior that deserve additional focus. The Department also indicated that QPAMs should interpret the scope of this provision broadly with respect to foreign convictions and consistent with the Department's statutorily mandated focus on the protection of Plans in ERISA section 408(a) and Code section 4975(c)(2).

The Department stated that in situations where a crime raises particularly unique issues related to the substantial equivalence of the foreign Criminal Conviction, the QPAM may seek the Department's views regarding whether the foreign crime, conviction, or misconduct is substantially equivalent to a U.S. federal or state crime. However, the Department cautioned that any QPAM submitting a request for review should do so promptly, and whenever possible, before a judgment is entered in a foreign conviction so the QPAM has sufficient time to complete the notice obligations under the One-Year Transition Period.

The Department also requested comment on whether there should be an additional process for requesting the Department's determination regarding whether a foreign conviction is substantially equivalent to a domestic conviction. The Department asked whether particular factors, such as the elements of the crime and the nature of the tribunal or investigating entity, should be considered in making such a determination.

Many commenters provided input regarding the explicit inclusion of foreign crimes in the Proposed Amendment. At least one commenter indicated that it did not agree that the status of foreign convictions under Section I(g) (as it has existed since 1984) has been a settled matter. As amended, Section I(g) will remove all doubt regarding the coverage of foreign criminal convictions, which are now specifically referenced in the exemption's text.

Some commenters indicated that the Proposed Amendment did not provide the intended certainty regarding foreign convictions because there could be difficulty determining whether any given foreign crime is a felony, or whether it is substantially equivalent to a felony under U.S. law.[38] Some commenters also expressed skepticism that the Department has the competence and jurisdiction to interpret foreign law fairly and accurately for these purposes. A variety of commenters also raised questions regarding the proposed ''substantially equivalent'' standard, and expressed concern that foreign jurisdictions may not adhere to basic due process protections. Multiple commenters suggested that the Department should establish a formal process by which a QPAM may request a determination from the Department regarding whether a foreign conviction is substantially equivalent to a domestic conviction before it results in ineligibility. One commenter recommended that this should include an opportunity for the QPAM to present its position as to why a foreign conviction may not be substantially equivalent to a domestic conviction. Another commenter suggested the ''substantially equivalent'' standard for foreign criminal convictions should apply only where the factual record of such conviction, when applied to United States federal criminal law, would likely lead to a criminal conviction in the United States. Other commenters expressed further concerns that the Proposed Amendment would inappropriately equate criminal convictions levied in countries that have less robust or reliable legal systems with those convictions handed down by U.S. courts. One commenter suggested that the Proposed Amendment has the potential to play into the hands of foreign nations that intend to harm investment managers having substantial operations in the United States or its allies. The Department notes that although the crimes listed explicitly in Section I(g) use the term ''felony,'' the crimes adopted by reference from ERISA section 411 are not, nor have they ever been, limited to felonies.

To add clarity and ensure consistency between Section (r)(1) and (r)(2), the Department added the phrase ''or released from imprisonment, whichever is later'' to the sentence, ''(r) 'Criminal Conviction' means the person or entity that: (2) is convicted by a foreign court of competent jurisdiction or released from imprisonment, whichever is later, as a result of a crime, however denominated by the laws of the relevant foreign government, that is substantially equivalent to an offense described in (r)(1), above. . . .''

With respect to the ''substantially equivalent'' standard for foreign crimes, the Department did not add a formal process to the Final Amendment to make such determinations. The Department does not expect that questions of this nature will arise frequently, but when they do, impacted entities may contact the Office of Exemption Determinations for guidance, as they have done for many years. In general, the Department has not had difficulty determining whether the foreign crimes were substantially equivalent to domestic crimes and does not expect to have any difficulty with these determinations in the future. Additionally, the One-Year Transition Period, and the ability to apply for an individual exemption, provide parties with the time and the opportunity to address any issues about the import of any specific foreign conviction and its relevance to ongoing relief from full application of the prohibited transaction provisions. The Department is not aware that any convictions have occurred in foreign nations with the intent to harm U.S.-based investment managers and believes there is a low likelihood that this has occurred. Further, the types of foreign crimes that the Department has seen in recent QPAM individual exemption requests have consistently related to the subject financial institution's management of financial transactions and/or culture of compliance. These underlying foreign crimes have included the following:

- attempting to peg, fix, or stabilize the price of an equity in anticipation of a block offering in Japan (PTE 2023–13, 88 FR 26336 (April 28, 2023));
- illicit solicitation and money laundering for the purposes aiding tax evasion in France (PTE 2019–01, 84 FR 6163 (February 26, 2019)); and
- spot/futures-linked market price manipulation in South Korea (PTE 2015–15, 80 FR 53574 (September 4, 2015)).

Nevertheless, to address the concern expressed in the public comments that convictions have occurred in foreign nations with the intent to harm U.S.-based investment managers, the Department has revised the definition Criminal Conviction in Section VI(r)(2) of this Final Amendment to exclude

2019–01, 84 FR 6163 (Feb. 26, 2019); PTE 2016–11, 81 FR 75150 (Oct. 28, 2016); PTE 2016–10, 81 FR 75147 (Oct. 28, 2016); PTE 2012–08, 77 FR 19344 (March 30, 2012); PTE 2004–13, 69 FR 54812 (Sept. 10, 2004); and PTE 96–62 (''EXPRO'') Final Authorization Numbers 2003–10E, 2001–02E, and 2000–30E, available at *https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/exemptions/expro-exemptions-under-pte-96-62*.

[38] One commenter also noted that several jurisdictions such as the United Kingdom, Canada, Ireland, Australia, and New Zealand do not rely on a legal category of ''felony'' which could compound issues for making a substantially equivalent determination in such cases.

foreign convictions and imprisonments that occur within foreign jurisdictions that are included on the Department of Commerce's list of ''foreign adversaries.'' [39]

A few commenters also indicated that the proposed changes to Section I(g) are unnecessarily broad in application and will impose unnecessary costs and burdens on Plans. The Department's experience, however, is that the overall number of QPAMs and client Plans that have been impacted by Section I(g) violations has been small compared to the total number of QPAMs and client Plans,[40] and the Department believes that this will continue to be the case. Thus, there should not be a significant change to the costs or burdens imposed on Plans as a result of explicitly including foreign convictions in Section I(g). In any event, when misconduct rises to the level that it results in ineligibility under Section I(g), the resultant costs and burdens are appropriate to ensure that a QPAM's client Plans are adequately protected when a QPAM becomes ineligible.

Some commenters recognized that when the foreign affiliate itself is providing investment management services to a Plan, the integrity of the foreign affiliate may be relevant. Commenters indicated that if the Department includes foreign convictions, ineligibility should be limited at least to entities that fall into the tax code definition of ''Controlled Group'' with respect to a QPAM. The Department appreciates the recognition by these commenters that at least some misconduct in foreign jurisdictions is relevant to the QPAM's integrity. However, the Department disagrees that the correct standard for determining when misconduct could be relevant should be limited to the ''Controlled Group'' definition. The Department believes that the approach taken in the exemption with regards to the scope of entities captured by Section I(g) in the ownership test and definition of Affiliate provides significant protections for Plans and participants and the commenter has not provided a reasoned basis why altering this scope would provide additional protections. Therefore, the Department has not altered the scope of entities captured by Section I(g) with respect to Criminal Convictions.

Proponents of the Proposed Amendment's addition of foreign crimes to Section I(g) indicated that large financial institutions that engage in financial crimes usually do so across multiple jurisdictions, arbitraging regulatory loopholes and pressuring weaker jurisdictions to curtail regulation. They urged the Department not to ignore foreign activity due to the modern realities of multinational financial institutions.

The Department agrees that criminal convictions for the types of crimes identified in the QPAM Exemption are relevant to a QPAM's willingness and ability to manage Plan assets with integrity, care, and undivided loyalty, regardless of whether the crime occurs in a domestic or foreign jurisdiction. Foreign crimes of the sort described in the Final Amendment call into question a firm's culture of compliance just as much as domestic crimes. Fraud, embezzlement, tax evasion, and the other listed crimes are signs of potential serious compliance and integrity failures, whether prosecuted domestically or in foreign jurisdictions. In the modern era of increased globalization and multinational companies, corporate parents and affiliates may reside in jurisdictions other than the United States. Their criminal misconduct in other jurisdictions is no less concerning to the Department than when such misconduct occurs in the United States. In fact, if foreign convictions were not included in Section I(g), the exemption would potentially impose more lenient conditions on foreign-based conglomerates than it does on U.S.-based entities, which is not the Department's intention, because it is not sufficiently protective of Plans.

A few commenters suggested alternatives to the Department's approach to foreign convictions in the Proposed Amendment. One commenter suggested that the Department should adopt an approach modeled after the Security and Exchange Commission's (SEC's) consideration of foreign crimes when determining whether to disqualify persons from serving in various capacities at an Investment Company under the Investment Company Act of 1940. It is the Department's understanding that, under the Investment Company Act of 1940, disqualification is automatic for specified domestic crimes, but that the SEC provides notice and a hearing before disqualification for foreign crimes.[41]

After consideration of the comment and the differences in statutory text and purposes at issue under ERISA, the Code, and the Investment Company Act of 1940, the Department has decided not to adopt the commenter's suggestion. The QPAM Exemption permits entities to enter into transactions that ERISA and the Code otherwise prohibit because of the danger they pose to Plans, their plan participants and beneficiaries, and IRA Owners. Before the Department grants an exemption from the law's strict prohibitions, it has an obligation to find that the exemption is in the interest of participants and protective of their rights. Under the QPAM Exemption, these findings crucially turn on the financial institution's culture of compliance. Misconduct that results in a criminal conviction of an entity under Section I(g) of the QPAM Exemption, whether domestic or foreign, calls into serious question whether the QPAM has the integrity and culture of compliance on which the exemption is premised. Accordingly, after conviction of a serious crime, a financial institution, its affiliates, and related parties should not expect to have the automatic right to continue to engage in transactions that are otherwise illegal, but for the exemption. Nevertheless, the firm may always apply to the Department for an individual exemption based on a full and fair consideration of the firm's criminal conduct and the relevant facts, circumstances, and context, if the firm believes that it should still receive a dispensation from application of the otherwise generally applicable prohibited transaction provisions, as companies have done over the years.

Relatedly, a commenter suggested the QPAM could be required to certify that its failure to meet the requirements of the QPAM Exemption arose solely from the foreign affiliate's criminal conduct and that no entities holding Plan assets

[39] 15 CFR 7.4. The list of foreign adversaries currently includes the following foreign governments and non-government persons: The People's Republic of China, including the Hong Kong Special Administrative Region (China); the Republic of Cuba (Cuba); the Islamic Republic of Iran (Iran); the Democratic People's Republic of Korea (North Korea); the Russian Federation (Russia); and Venezuelan politician Nicolás Maduro (Maduro Regime). The Secretary of Commerce's determination is based on multiple sources, including the National Security Strategy of the United States, the Office of the Director of National Intelligence's 2016–2019 Worldwide Threat Assessments of the U.S. Intelligence Community, and the 2018 National Cyber Strategy of the United States of America, as well as other reports and assessments from the U.S. Intelligence Community, the U.S. Departments of Justice, State and Homeland Security, and other relevant sources. The Secretary of Commerce periodically reviews this list in consultation with appropriate agency heads and may add to, subtract from, supplement, or otherwise amend the list. Section VI(r)(2) of the Final Amendment will automatically adjust to reflect amendments the Secretary of Commerce makes to the list.

[40] This belief is based on the number of QPAMs suggested by commenters and represented in an updated estimate in this Final Amendment versus the number of QPAMs and client Plans identified in individual exemption applications.

[41] *See* Investment Company Act of 1940, 15 U.S.C. 80a–9.

actively Participated In the criminal conduct that is the subject of the conviction. Based on the certification, the Department could inquire further and make its decision based on the facts of the specific situation. Another alternative offered by a commenter was simply to require a QPAM to notify a Plan of the conviction, and then allow the Plan sponsor to decide whether to continue its arrangement with the QPAM.

The Department's focus is on the protection of Plans and their participants and beneficiaries, as it decides whether to give QPAMs relief from the requirements of otherwise applicable law (*i.e.,* the categorical prohibitions of ERISA Section 406(a) and Code section 4975(c)(1)). The Department declines to take the other recommended approaches because as explained in other parts of this preamble, the Department is not merely concerned about crimes that have already impacted Plan assets, but compliance frameworks that have an increased potential to place Plan assets at risk. Criminal Convictions, even in foreign jurisdictions, for the types of crimes and by the entities captured by Section I(g) raise significant concerns. The Department disagrees with the suggestion that it would be sufficiently protective of Plans, their participants, and beneficiaries simply to require notice of the QPAM's criminal conviction and leave it to the fiduciaries to decide whether to engage in otherwise prohibited transactions with the QPAM. When Congress enacted ERISA, it chose not to broadly empower plan fiduciaries to opt out of the prohibited transaction provisions on a voluntary basis, but rather charged the Department with the responsibility to craft protective conditions that meet the statutory standards set forth in ERISA section 408(a).

The crimes enumerated in Section I(g) are serious violations that call into question the willingness and ability of the QPAM to adhere consistently to the fiduciary norms and standards that are critical to entrusting them with license to engage in otherwise illegal transactions. To the extent a QPAM believes that it should be permitted to engage in such transactions after the expiration of the Transition Period, notwithstanding its conviction, the Department has concluded that the interests of Plan participants and beneficiaries and IRA Owners are best protected by the procedural protections, public record, and notice and comment process associated with individual exemption applications. In the context of an individual exemption application, the Department has unique authority to efficiently gather evidence, consider the issues, and craft protective conditions that meet the statutory standard. If the Department concludes, consistent with the statutory standards set forth in ERISA 408(a) and Code section 4975(c)(2), that an individual exemption is appropriate, Plan fiduciaries remain free to make their own independent determinations whether to engage in transactions with the QPAM. In the first instance, however, the Department must consider the unique facts and circumstances surrounding the conviction based on its statutory role and obligations, and craft appropriate conditions if it appears that an exemption is proper. The Department has a critical role in providing appropriate regulatory protections, even in situations where a Plan fiduciary has some authority, discretion, and obligations of its own.

Prohibited Misconduct

The Department proposed to add a new category of misconduct that could lead to ineligibility under Section I(g), described as ''participating in Prohibited Misconduct.'' [42] Proposed Section VI(s) defined Prohibited Misconduct as:

(1) any conduct that forms the basis for a non-prosecution or deferred prosecution agreement that, if successfully prosecuted, would have constituted a crime described in Section VI(r);

(2) any conduct that forms the basis for an agreement, however denominated by the laws of the relevant foreign government, that is substantially equivalent to a non-prosecution agreement or deferred prosecution agreement described in subsection VI(s)(1);

(3) engaging in a systematic pattern or practice of violating the conditions of this exemption in connection with otherwise non-exempt prohibited transactions;

(4) intentionally violating the conditions of this exemption in connection with otherwise non-exempt prohibited transactions; or

(5) providing materially misleading information to the Department in connection with the conditions of the exemption.

The Department explained in the preamble of the Proposed Amendment that the term ''participating in'' referred not only to actively participating in the Prohibited Misconduct but also to knowingly approving of the conduct or having knowledge of such conduct without taking appropriate and proactive steps to prevent such conduct from occurring, including reporting the conduct to appropriate compliance personnel. The Department proposed that, where a QPAM's ineligibility is linked to Prohibited Misconduct under any portion of Section VI(s), the Department would provide affected entities with a written warning and an opportunity to be heard.

The Department requested comments on the extent to which Proposed Section VI(s) was appropriately tailored to target non-criminal activity by the QPAM (or its owners of a five (5) percent or more interest, or Affiliates) that raised integrity issues that had the potential to harm Plans and whether additional or alternative elements were warranted. The Department also requested comments regarding whether to add any conduct as Prohibited Misconduct, and if so, to include an explanation for how such actions would implicate a QPAM's integrity. The Department also requested comments as to whether any of the proposed Prohibited Misconduct should be removed and an explanation of why such conduct does not affect the QPAM's integrity.

With respect to these provisions, the Department explained in the Proposed Amendment that it intended to rely on its enforcement authority and program to detect a QPAM's Participation In the types of Prohibited Misconduct included in proposed subsections VI(s)(3) through (5).[43] In the Proposed Amendment, the Department built in due process components so that ineligibility would occur only in limited circumstances, and even in those circumstances, the process to make the QPAM ineligible would have begun only after two initial steps: (1) an investigation by the appropriate field office, and (2) receipt by the QPAM thereafter of a written warning that the Department was contemplating issuing a Written Ineligibility Notice. The Proposed Amendment's Written Ineligibility Notice process would have allowed the QPAM the opportunity to be heard before the Department were to issue an actual notice, which would have made the QPAM ineligible to use the exemption from the date the Department issued the notice, except that the mandatory One-Year Transition Period would have been applicable in the same manner as with ineligibility caused by a Criminal Conviction.

General Comments on Proposed Prohibited Misconduct Provision

One supporter of the Proposed Amendment indicated that inclusion of additional categories of misconduct was appropriate because the commenter

[42] As proposed, this definition applied to Participation In Prohibited Misconduct by the QPAM or its five percent or more owners and Affiliates.

[43] Section VI(s) has been renumbered in the Final Amendment as section VI(s)(1), (2)(A), (B), and (C).

believed that Section I(g)'s limited focus on crimes that resulted in a conviction had contributed to serial misconduct by corporate wrongdoers. The commenter expressed concern that some corporate wrongdoers could take advantage of loopholes to avoid a conviction when the conduct was ultimately serious enough to warrant a conviction.

Many opponents of the amendment recommended that the ''Prohibited Misconduct'' standard and provisions be deleted entirely. They stated that the expansion of Section I(g) to include Prohibited Misconduct erodes certainty that the QPAM Exemption provides regarding eligibility.

Specific Comments Regarding Including Non-Prosecution Agreements (NPAs) and Deferred Prosecution Agreements (DPAs) as Prohibited Misconduct

Some commenters recommended that the Department consult with the Department of Justice (DOJ) and the SEC to get a better sense of how the proposed inclusion of NPAs and DPAs as Prohibited Misconduct would impact their enforcement abilities. Some commenters also noted that financial institutions may agree to a NPA or DPA for reasons that are unrelated to ERISA. These commenters opined that the Department seemed to be mischaracterizing the nature and use of NPAs and DPAs, as well as their objectives (such as avoiding the collateral consequences of penalizing innocent parties). According to some commenters, prosecutors do not enter into these agreements lightly or with the intention of allowing financial institutions to ''sidestep'' the consequences of their actions. Some commenters also asserted that even where an institution believes it has not engaged in wrongdoing and would prevail on the merits in a court of law, they may prefer to enter into a NPA or DPA for a variety of reasons. For example, one commenter indicated that even where an institution believes it has not engaged in wrongdoing and would prevail on the merits in a court of law, it may prefer to enter into a NPA or DPA if it is concerned with its reputation on unrelated matters (that do not rise to the level of covered convictions) that could be introduced during a protracted trial.

Some commenters also offered alternatives to ineligibility in connection with NPAs or DPAs. For instance, one commenter suggested that the Department could require a QPAM that enters into one of these agreements to notify each Plan it manages that: (1) the QPAM has entered such an agreement; and (2) the Plan can terminate its relationship with the QPAM if it chooses to do so, without penalty.

Some commenters expressed additional concern that financial institutions will be less willing to enter into NPAs or DPAs if doing so would result in ineligibility under the QPAM Exemption. These commenters indicated that they believed this outcome may not be in the public interest. For instance, one commenter suggested that if entering into a DPA or NPA would effectively end a firm's ERISA investment management business, the firm may not be able to enter into the agreement, even when doing so is the best resolution for the government prosecutor involved.

A proponent of the Department's Proposed Amendment to include NPAs and DPAs as ineligibility triggers noted that since the exemption was proposed in 1982, the use of NPAs and DPAs has skyrocketed, with many companies avoiding prosecution for serious misconduct due to factors unrelated to their culpability. The commenter opined that to fully protect Plans from unscrupulous behavior by asset managers, the Department must, as proposed, include NPAs and DPAs within the definition of Prohibited Misconduct that triggers QPAM ineligibility when the conduct at issue involves a listed crime.

Another commenter identified a lack of clarity as to whether an NPA or DPA would have to involve the manager's parent or whether it could involve the manager's most remote affiliate or an entity with only a five percent ownership interest in the manager.

Several commenters also expressed specific concerns over expanding QPAM ineligibility to agreements with foreign governments that are substantially equivalent to domestic NPAs and DPA. These commenters expressed concern that the proposal provided the Department with unfettered discretion to determine whether a foreign NPA or DPA entered into by the QPAM or an Affiliate was substantially equivalent to a domestic NPA or DPA, and they questioned whether the Department has the necessary proficiency in criminal justice and international law, or jurisdictional authority to make such determinations.

Other commenters also suggested that it would be difficult for the Department to apply the substantially equivalent standard in the context of foreign NPAs and DPAs due to the claimed vagaries of foreign laws and prosecutorial practices and the effect of expanding the reach of Section I(g) in this manner on law enforcement efforts by other U.S. agencies and the possible extraterritorial impact on non-U.S. law enforcement and U.S. relations with foreign governments.

One commenter stated that Department should not treat the conduct of an affiliate which has no or little nexus or relationship to the QPAM as disqualifying and pointed out the practical considerations that are necessary to identifying foreign equivalents of these agreements as well as the significant risk that these agreements may be imposed in foreign jurisdictions that do not provide due process protections. Another commenter asserted that the connection of foreign agreements to a QPAM's compliance culture is speculative and tenuous and does not provide any meaningful protection to participants and beneficiaries.

One commenter claimed that including foreign equivalents of NPAs and DPAs has the potential to play into the hands of foreign nations that wish to harm the operations of U.S.-based investment managers. For example, the commenter suggested that rogue foreign nations could bring dubious claims against a U.S.-based investment manager and force them to execute a DPA or NPA with that government in order to continue operations in that foreign country.

Another commenter questioned how the Department would know if something would be ''successfully'' prosecuted for purposes of the requirement in Section VI(s) that the NPA or DPA be based on allegations that, if successfully prosecuted, would have constituted a crime described in Section VI(r) of the exemption.

The Department's Response to Comments and Treatment of DPAs and NPAs Under the Final Amendment

In response to these comments, the Department consulted with the DOJ and the SEC to affirm its understanding of NPAs and DPAs, particularly the level of culpability on the part of the QPAM that would accompany such an agreement. Based on these consultations, the Department understands that, as a matter of course, these domestic NPAs and DPAs are accompanied by Statements of Fact that establish the basis for criminal liability. In most cases, the offending party avoids prosecution for the crime on the basis of the party's agreement to enter into, and comply with, the terms of the agreement.

After considering comments on the Proposed Amendment's inclusion of NPAs and DPAs as Prohibited Misconduct in the Proposed Amendment, the Department has

determined to include this provision in the Final Amendment with a modification discussed below.

In cases where the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM has executed an NPA or DPA, the Department has precisely the same concerns about the QPAM's compliance culture, and its ability and willingness to adhere to its fiduciary obligations and the exemption conditions, as it does when any of these parties have been formally convicted of the crime. The cause for concern about the QPAM is not the conviction *per se,* but rather the serious misconduct that underlies the conviction. In these cases, responsible federal or state officials have resolved serious claims of misconduct against parties through the execution of a formal agreement voluntarily entered into with the parties. In these circumstances, if the alleged misconduct is sufficient to form the basis for an NPA or DPA that is entered into by the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM, it is appropriate to treat the agreement as cause for ineligibility under Section I(g), subject to the parties' ability to apply for an individual exemption before, during, or after the One-Year Transition Period provided for in this exemption.

Moreover, any due process concerns with including NPAs and DPAs as Prohibited Misconduct are addressed by the change to the Prohibited Misconduct provision in the Final Amendment providing that ineligibility does not occur until after a QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM has executed an NPA or DPA. Those agreements result from criminal investigations and are voluntarily entered into by the parties. QPAMs and other affected entities that enter into an NPA or DPA generally will be afforded the numerous due process protections that are associated with criminal investigations and negotiating these agreements.

Under the revised provision in the Final Amendment, QPAMs, their Affiliates, or five (5) percent or more owners that enter into an NPA or DPA should have sufficient time to prepare for the implications of becoming ineligible under this Final Amendment as a result of the process surrounding the negotiation and execution of the agreement. In either case, the QPAM must commence the One-Year Transition Period and submit an individual exemption application for extended relief a soon as possible if it wants to continue using the QPAM exemption after the One-Year Transition Period expires.

After considering comments on the Proposed Amendment's inclusion of foreign-equivalent NPAs and DPAs in the Proposed Prohibited Misconduct definition, the Department has decided to remove foreign equivalent agreements from the definition of Prohibited Misconduct in Section VI(s) of the Final Amendment. While the Department is confident in its ability to apply the foreign equivalence standard to NPAs and DPAs entered into by the QPAM or its Affiliates, and although the Department has concerns about conduct that might give rise to a foreign equivalent NPA or DPA, it has concluded that it has insufficient information on those agreements to treat them as a cause for ineligibility under Section I(g). In this context, the Department notes that it has not received individual exemption requests from QPAMs or their Affiliates in which a foreign equivalent agreement was implicated.

The Department also is not aware of any instances where foreign governments have used agreements that are substantially equivalent to domestic NPAs and DPAs to harm U.S.-based investment managers and, as with foreign criminal convictions, we believe there is a low likelihood that this activity has occurred. However, in light of the comments, the Department has concluded that it does not have sufficient certainty about the use of these agreements outside the U.S., and about the procedural protections associated with the agreements in foreign jurisdictions, to justify finalizing this particular part of the proposed Prohibited Misconduct provision at this time. Therefore, the Department's position is that the uncertainties surrounding foreign agreements raised by some commenters outweigh the protective benefits that would accrue to Plans and their participants and beneficiaries by including foreign agreements in the Prohibited Misconduct provision.

Although the Department is removing the foreign equivalent of NPAs or DPAs as an ineligibility trigger, the Final Amendment to Section I(g)(2) requires the QPAM to notify the Department when the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM executes a domestic or foreign equivalent NPA or DPA. This notice will give the Department the ability to take appropriate additional action in specific cases and will provide the Department with broader information about these practices as the QPAM exemption continues to be relied upon by parties in the future. The Department notes that QPAMs should err on the side of caution when determining whether an agreement with a foreign government entity is the substantial equivalent of a domestic NPA or DPA that must be reported to the Department pursuant to amended Section I(g)(2).

After reviewing and considering the comments offering alternatives to ineligibility in connection with NPAs or DPAs, in particular only requiring QPAMs to provide a notice to Plans, the Department's position is that mere notice to the Plans is not sufficiently protective to address circumstances where a NPA or DPA with a U.S. federal or state prosecutor's office or regulatory agency reflects serious misconduct by the QPAM. Further, solely relying on a QPAM's notification to Plans that the QPAM committed serious misconduct would not be an appropriate justification for the Department to ignore such serious misconduct and to forego taking appropriate action.

In response to the comment asserting that a lack of clarity exists regarding whether an NPA or DPA would have to involve the QPAM's parent or whether it could involve the QPAM's most remote affiliate or an entity with only a five (5) percent ownership interest in the manager, the Department has clarified in the Final Amendment that the Prohibited Misconduct provision in Section VI(s)(1) includes NPAs and DPAs entered into by the QPAM, or any Affiliates, or owners of five (5) percent or more of the QPAM, with a U.S. federal or state prosecutor's office or regulatory agency.

In response to comments that questioned how the Department would know if something would be ''successfully'' prosecuted, the Department notes that the focus of the provision is not on whether a criminal prosecution would have been successful if the case had not been settled, but rather whether the allegations by state or federal officials that resulted in the NPA or DPA described one of the disqualifying crimes set forth in VI(r). The provision does not require the Department to know if something would be successfully prosecuted. Instead, it requires the Department to determine whether the conduct associated with the NPA or DPA would ''if successfully prosecuted'' constitute Prohibited Misconduct as defined in paragraph VI(s)(1). In such cases, the parties have

voluntarily entered into a settlement based on allegations of disqualifying misconduct. There is sufficient cause for concern in all such cases about the entities' culture of compliance to trigger ineligibility, start the One-Year Transition Period, and require the parties to seek an individual exemption if they would like to continue to receive an exemption permitting them to engage in conduct that is otherwise prohibited by ERISA and the Code. Moreover, as noted above, NPAs and DPAs are commonly supported by Statements of Fact that establish the basis for criminal liability by the parties entering into the agreements.

While the Department is removing foreign equivalents of NPAs and DPAs as Section I(g) ineligibility events in the Final Amendment, as discussed above it is adding a notice requirement that applies when the QPAM, its owners of a five (5) percent or more *interest,* or Affiliates enter into a foreign equivalent of an NPA or DPA or Participate In Prohibited Misconduct as defined in Section VI(s). Specifically, Section I(g)(2) requires the QPAM to submit a notice to *QPAM@dol.gov* within 30 calendar days after the Ineligibility Date for the Prohibited Misconduct as determined under Section (I)(h)(2) or the execution date of the substantially-equivalent foreign NPA or DPA, if the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM, Participates In any Prohibited Misconduct as defined in Section VI(s) or enters into an agreement with a foreign government that is substantially equivalent to a NPA or DPA described in section VI(s)(1). The QPAM must include a description of the Prohibited Misconduct in the notice and provide the name of and contact information for the person or entity that is responsible for handling this matter to the Department.

The Department clarifies that the Prohibited Misconduct conditions in Section VI(s)(1), regarding entering into an NPA or DPA with a U.S. federal or state prosecutor's office or regulatory agency, and the corresponding notification requirement in Section I(g)(2), are prospective only, and therefore only apply to QPAMs, their Affiliates, and owners of a five (5) percent or more interest who have executed NPAs or DPAs on or after June 17, 2024 based on facts that, if successfully prosecuted, would have constituted a crime specified in VI(r) of the Final Amendment.

Specific Comments Regarding Prohibited Misconduct Under the Written Warning Letter and Ineligibility Notice Process

In the Proposed Amendment, the Department specifically requested comments on the sufficiency of the due process protections provided in connection with the Prohibited Misconduct provision. Several commenters expressed concern that the due process protections of the written warning letter and Written Ineligibility Notice provisions were insufficient. For example, some commenters stated that:

- the proposed standards were inadequate to protect the due process rights of QPAMs, because the process provided the Department with potentially unlimited discretion to decide what types of misconduct would trigger ineligibility to be made by an independent, disinterested decision-maker;
- the Department's ineligibility process lacks sufficient due process and a final determination by a neutral third-party judge, and therefore, provides the Department with unilateral discretion;
- due process requires an adversarial process that is adjudicated by an independent third party;
- if the ineligibility process for Prohibited Misconduct is retained, the Department should develop a process that includes: (1) rules for establishing a factual record, including adequate time and opportunity for the accused institution to review, challenge, and supplement the record; (2) formal rules for soliciting input from federal, state, and/or foreign prosecutors involved in the negotiated agreement at issue, if any; (3) procedures for selecting an independent decision-maker responsible for making factual and legal determinations; (4) procedural guardrails to ensure that Department officials involved in alleging Prohibited Misconduct are not able to engage in conduct that would bias the decision-maker (*e.g.,* prohibiting ex parte communications); and (5) an automatic stay of any agency determinations during the pendency of federal litigation challenging the determination;
- If the Department does not remove the written warning letter and Written Ineligibility Notice process from the final exemption, the final exemption must provide an opportunity for review by an administrative law judge, court, or similar truly independent decision maker with the authority to decide whether a QPAM will be disqualified, as opposed to providing that authority to itself.

Additionally, some commenters expressed concern that proposed definition of the phrase ''participating in'' was vague and overbroad.

The Department's Response to Specific Comments Regarding the Written Warning Letter and Written Ineligibility Notice

After considering the due process concerns expressed in comments regarding the Proposed Amendment, the Department is removing from the Final Amendment the written warning letter and Written Ineligibility Notice process that was associated with Prohibited Misconduct. The Department now is requiring the requisite factual determinations for Prohibited Misconduct defined in Section V(s)(2) to have been made in specified judicial proceedings.

Specifically, under the Final Amendment, a QPAM will become ineligible under Section I(g) as a result of Prohibited Misconduct as defined in Section VI(s)(2) if the QPAM, any Affiliates thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM is found or determined in a final judgment, or court-approved settlement by a federal or state criminal or civil court in a proceeding brought by the Department, the Department of Treasury, the Internal Revenue Service, the Securities and Exchange Commission, the Department of Justice, the Federal Reserve Bank, the Office of the Comptroller of the Currency, the Federal Depository Insurance Corporation, the Commodities Futures Trading Commission, a state regulator, or state attorney general to have Participated In one or more of the following categories of conduct irrespective of whether the court specifically considers this exemption or its terms:

(A) engaging in a systematic pattern or practice of conduct that violates the conditions of this exemption in connection with otherwise non-exempt prohibited transactions;

(B) intentionally engaging in conduct violates the conditions of this exemption in connection with otherwise non-exempt prohibited transactions; or

(C) providing materially misleading information to the Department or the Department of Treasury, the Internal Revenue Service, the Securities and Exchange Commission, the Department of Justice, the Federal Reserve Bank, the Office of the Comptroller of the Currency, the Federal Depository Insurance Corporation, the Commodities Futures Trading Commission, a state regulator or a state attorney general in

connection with this exemption's conditions.

By removing the warning letter and Written Ineligibility Notice process and instead providing for ineligibility only after a Conviction, a court's final judgment, or a court-approved settlement, QPAMs, their Affiliates, and/or owners of a five (5) percent or more interest thereby are disqualified only after the culpable entity was afforded full due process in a legal proceeding overseen by a court. Section V(s)(2) is much narrower than the proposal inasmuch as it covers the types of misconduct specified in the proposal only when the misconduct is established in court proceedings brought by state or federal regulators. It ensures that the finding of misconduct was subject to the robust procedural protections provided by such proceedings.

Furthermore, by removing the warning letter and Written Ineligibility Notice process, and redefining Prohibited Misconduct in Section VI(s)(2) to be based on legal process that results in a court's final judgment or court-approved settlement, the QPAM will have been provided with sufficient notice that the conduct at issue is Prohibited Misconduct that causes ineligibility. This will give QPAMs sufficient time to apply for an individual exemption during the One-Year Transition Period.

More generally, the Department notes that the modification in the Final Amendment removes the Department from the process of making a factual determination that Prohibited Misconduct has occurred. Instead, for purposes of ineligibility due to Prohibited Misconduct in Section VI(s)(2), the court's final judgment (or approved settlement) must resolve the factual issue of whether any of these parties Participated In the conduct that constitutes Prohibited Misconduct as defined in Section VI(s)(2). Under the provision, the court does not have to make a specific legal finding regarding whether such conduct constitutes Prohibited Misconduct as defined in Section VI(s)(2) of the exemption, but rather whether, as a factual matter, the parties engaged in the specific conduct defined as Prohibited Misconduct in Section VI(s)(2). The Department has made changes to Section VI(s)(2) to make this distinction clear. The Department cautions QPAMs, their Affiliates, and owners of a five (5) percent or more interest that final judgments and court-approved settlements that include a finding that such conduct has occurred will cause immediate ineligibility under Section I(g). In these situations, a QPAM that intends to continue to rely on the QPAM exemption following the One-Year Transition Period that begins on the Ineligibility Date should submit an exemption application to the Department as soon as possible.

As mentioned above, some commenters expressed concern that the proposed definition of the phrase ''participating in'' was vague and overbroad. The Department disagrees with this concern. The parameters of the definition are similar to other definitions and conditions the Department has included in administrative exemptions it has issued since ERISA's enactment almost fifty years ago. Additionally, the commonly accepted definition of what it means to ''participate in'' conduct is well understood. The Proposed Amendment specifically provided additional guidance in the text of Proposed Section I(g)(3)(B) regarding what the Department meant by using the term ''participating in.'' [44] Therefore, the Department has not changed the definition of ''Participating In'' in the Final Amendment but has included in the definition the defined terms ''Participate In,'' ''Participates In,'' ''Participated In,'' and ''Participation In'' for clarity and accuracy and has moved the definition to the Definitions and General Rules in Section VI(t).[45]

Costs Associated With Ineligibility Based on Participating In Prohibited Misconduct

Several commenters also noted that regardless of the reason for ineligibility, Plans would be exposed to substantial costs if a QPAM becomes ineligible. These commenters recommended that the Department exercise extreme caution before causing more QPAMs to face ineligibility. Some commenters also expressed concerns that the imposition of ineligibility is harmful to the Plans and their participants and beneficiaries and prevents appointing fiduciaries from exercising discretion to determine the best course of action for the Plan by placing constraints on the Plan's choice of QPAMs.

The Department notes that the Proposed Amendment and this Final Amendment appropriately place the burden associated with the costs of ineligibility on the QPAM. In response to the comment, the Department included the One-Year Transition Period in the Final Amendment to reduce the costs and burdens associated with the possibility of ineligibility, and to provide affected QPAMs with an opportunity to apply for individual exemptions with appropriate conditions. Therefore, the Department disagrees that the ineligibility provision unduly prevents fiduciaries from exercising their discretion.

In crafting the amendments, the Department was also mindful that the conduct that constitutes Prohibited Misconduct under the terms of the exemption is quite serious and that engaging in such conduct calls into question the QPAM's culture of compliance. The grant of an exemption involves a discretionary determination by the Department to permit parties to engage in conduct that is otherwise categorically prohibited by ERISA and the Code and it requires specific findings aimed at ensuring that the exemption is appropriately protective of the Plan and participant interests at stake in the regulation of tax-preferred retirement plans. While the prohibited transaction provisions constrain fiduciary choice, those constraints are expressly imposed by the statute for the protection of plan participants and beneficiaries. An exemption is not justified merely by pointing to a constraint expressly imposed by law and noting that it interferes with fiduciary discretion; all prohibited transaction provisions constrain fiduciary choice. The conditions of the QPAM Exemption are publicly and widely available, and the possibility that a QPAM could become ineligible if it participates in serious misconduct is clear. Moreover, if a fiduciary does not want to provide the additional protections included in this Final Amendment, it may pursue other options to receive prohibited transaction relief, such as using another relevant class prohibited transaction exemption or seeking an individual prohibited transaction exemption. Additionally, the sophistication of fiduciaries varies dramatically based on a variety of factors. The Department has an obligation to protect Plans and their participants and beneficiaries, even if an individual Plan fiduciary views such protections as unnecessary.

However, as noted above, the Department modified the scope of the Prohibited Misconduct provision in the Final Amendment; first, by removing foreign agreements that are equivalent to

[44] The preamble also specifically stated, ''For purposes of proposed Section VI(s), the term 'participating in' refers not only to actively participating in the Prohibited Misconduct but also to knowingly approving of the conduct or having knowledge of such conduct without taking appropriate and proactive steps to prevent such conduct from occurring, including reporting the conduct to appropriate compliance personnel.'' 87 FR at 45209.

[45] Due to this change, the Recordkeeping provision is redesignated as Section VI(u).

NPAs and DPAs from the definition of Prohibited Misconduct in Section VI(s)(1) and second, by basing ineligibility as a result of Prohibited Misconduct defined in Section VI(s)(2) on a factual finding or determination by a court that the conduct described in Section VI(s)(2)(A) through (C) occurred, which should reduce the number of QPAMs that become ineligible. Moreover, the indemnification provision will ensure that Plans are not bearing the costs of ineligibility for QPAMs that become ineligible.

Both Categories of Prohibited Misconduct Only Will Apply Prospectively

Finally, several commenters requested clarification that the Prohibited Misconduct provisions of Section VI(s)(1) and (2) will result in ineligibility of a QPAM only on a prospective basis. In response, the Department confirms that ineligibility tied to Prohibited Misconduct related to executing NPAs and DPAs in Section VI(s)(1) of the Final Amendment will be applied only on a prospective basis that commences on the execution date of NPAs or DPAs with a U.S. federal or state prosecutor's office or regulatory agency that falls on or after June 17, 2024.

Similarly, under the Final Amendment, Section VI(s)(2) determinations of Prohibited Misconduct will apply prospectively as of the date of a court's final judgment or court-approved settlements that fall on or after June 17, 2024.

Violations of the Exemption and Misleading Statements

One commenter requested that the Department provide examples of Prohibited Misconduct for violations of the exemption or misleading statements so that firms are not caught off guard for Participating In Prohibited Misconduct. Another commenter requested clarification that inadvertent technical errors, such as failure to timely notify the Department of a legal name change, should not be deemed to be providing materially misleading information to the Department. As a general matter, the Department's position is that such inadvertent technical errors do not result in Prohibited Misconduct, particularly when such errors are corrected consistent with ERISA and Code standards, as applicable. Similar to Convictions, the exemption's Prohibited Misconduct provisions are aimed at protecting Plans and IRA owners from conduct that calls into question a QPAMs integrity and compliance culture and inadvertent technical errors, especially such errors that are promptly corrected, should not amount to such conduct.

With respect to mistakes in timely reporting a legal name change, the Department modified the reporting requirement in this Final Amendment to address such issues, as discussed above in connection with the reporting requirement. As discussed in detail above, the modifications in the Final Amendment to the definition of Prohibited Misconduct in Section V(s)(2) whereby requisite factual determinations are made through a judicial proceeding will put a QPAM and its Affiliates on notice regarding conduct that is defined as Prohibited Misconduct in Section V(s)(2)(A) through (C).

Section I(h)—Timing of Ineligibility

The Proposed Amendment did not include any direct changes to the ten-year ineligibility period under current Section I(g).[46] The Department added a new provision, Section I(h), that specified the timing of ineligibility. In the Proposed Amendment, for Prohibited Misconduct, the ineligibility period would have begun as of the date of a Written Ineligibility Notice, whereas, for a Criminal Conviction, it would have begun on the date the trial court enters its judgment.[47] The Proposed Amendment clearly stated that for a foreign conviction, ineligibility would begin on ''the date of the judgment of any court in a foreign jurisdiction that is the equivalent of a U.S. federal or state trial court. . . .'' This refers to a trial court of original or primary jurisdiction, such as a court of first instance.[48] The period of ineligibility would have begun on the conviction date, regardless of whether the judgment is appealed or the appeal has suspensive effect. Only upon a subsequent final judgment reversing the conviction would a person no longer be considered ''convicted'' for purposes of this exemption.

This Final Amendment retains the ineligibility start date for a Criminal Conviction as the date the trial court enters its judgment. However, because the Final Amendment does not include the proposed warning and Written Ineligibility Notice process, the timing for Prohibited Misconduct in Section I(h)(2) of the Final Amendment has been modified. In the Final Amendment, the ineligibility period for Participating In Prohibited Misconduct begins on the date, on or after June 17, 2024 that the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM:

(A) executes an NPA or DPA described in Section VI(s)(1)); or

(B) is found or determined in a final judgment in certain federal or state court proceedings (regardless of whether the judgment is appealed) or a court-approved settlement to have Participated In the conduct that meets the definition of Prohibited Misconduct in Section VI(s)(2).

In the Proposed Amendment the Department specifically sought comments on the timing of ineligibility. One commenter suggested that the Winding-Down (Transition) Period should be restructured into two distinct periods: the first to allow a QPAM to apply for an individual exemption, and the second period to prevent disruption and assist Plans in the event a transition is needed to a new QPAM. The Department believes it has functionally provided this structure in the Final Amendment. The One-Year Transition Period provides time for transition that was not previously included in the exemption. As noted earlier in this preamble, an ineligible QPAM should initiate an individual exemption request as soon as it reasonably believes its Plan clients likely will be harmed without additional prohibited transaction relief after the Transition Period ends. The Department notes that it will continue to consider individual exemption requests for ineligible QPAMs to be able to continue providing services, as well as requests for additional transitional relief to allow their client Plans to search for and hire a new asset manager.

Proposed Section I(i)[49]—Warning and Opportunity to be Heard in Connection With Prohibited Misconduct—Written Ineligibility Notice

The Department proposed an additional process that would be tied to a determination that a QPAM had participated in Prohibited Misconduct. In the proposal, before issuing a Written Ineligibility Notice in connection with Prohibited Misconduct to the QPAM, the Department indicated it would have issued a written warning, identified the Prohibited Misconduct, and provided 20

[46] The One-Year Transition Period, however, has an impact on how a QPAM approaches the first year after experiencing an ineligibility trigger.

[47] For convictions that also result in imprisonment of a person, the end of the ten-year period is counted from the date of release from imprisonment.

[48] This is generally considered to be the lowest level court in a particular jurisdiction that has the power to render a judgment of conviction.

[49] Certain sections of the Final Amendment have been renumbered and Section I(i) in the Final Amendment has been redesignated as the *One-Year Transition Period Due to Ineligibility.*

days for the QPAM to respond. The Proposed Amendment also indicated that if the QPAM failed to respond to the written warning within 20 days, the Department would have issued the Written Ineligibility Notice. However, if the QPAM responded within the 20-day timeframe, the Department would have provided the QPAM with the opportunity to be heard either in person (including by phone or a videoconference) or in writing, or a combination of both, before the Department decided whether it would have issued the Written Ineligibility Notice.

As discussed under the *Specific Comments Regarding Prohibited Misconduct under the Written Ineligibility Notice Process* heading above, some commenters questioned the sufficiency of the process leading to a warning letter and Written Ineligibility Notice, citing due process concerns and specifically, the lack of an adversarial process adjudicated by an independent third party (such as review by an administrative law judge or federal court). Relatedly, another commenter indicated that these provisions within the Proposed Amendment would have provided the Department with too much discretion to cause a QPAM's ineligibility. One commenter specifically noted the additional due process protections provided through the court system for Criminal Convictions are not present for a QPAM that Participates In Prohibited Misconduct. Another commenter noted that the lack of an appeals process as part of the proposed Written Ineligibility Notice process could provide the Department with unchecked power.

As more fully discussed above under the *Specific Comments Regarding Prohibited Misconduct under the Written Ineligibility Notice Process* heading, in response to the process concerns expressed by commenters, the Department has removed the proposed warning letter and Written Ineligibility Notice process and modified the definition of Prohibited Misconduct under Section VI(s). Removing the proposed warning letter and Written Ineligibility Notice process from this Final Amendment, and instead providing that a QPAM's ineligibility under Section VI(s)(2) only occurs after a Conviction, a court's final judgment, or a court-approved settlement, will afford QPAMs, their Affiliates, and owners of a five (5) percent or more interest with substantial due process in a legal proceeding that is overseen by a court, not the Department. Also, this Final Amendment provides that ineligibility occurs under Section VI(s)(1) when a QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM executes an NPA or DPA with a U.S. federal or state prosecutor's office or regulatory agency, which generally will afford QPAMs and their Affiliate(s) and owner(s) with the due process protections that are associated with related criminal investigations.

Section I(i)—Mandatory One-Year Transition Period

Certain sections of the Final Amendment have been renumbered and Proposed Section I(j) is now Section I(i) in the Final Amendment. As part of the Proposed Amendment, the Department included a mandatory one-year Winding-Down Period that would have begun on the Ineligibility Date. The Winding-Down Period was designed to provide Plans with the ability to wind down their relationships with a QPAM immediately after the QPAM becomes ineligible to rely on the exemption. Satisfaction of the conditions of the Winding-Down Period would affect the availability of relief for all transactions covered by this exemption. As proposed, the Department intended to include relief for past transactions and any transaction continued during a one-year Winding-Down Period.

One commenter indicated that the term ''winding-down'' was pejorative and should be replaced with more neutral nomenclature such as a term indicating it is a transition period. The Department did not intend for the term to be pejorative. Therefore, the Department has substituted the word ''Transition'' for ''Winding-Down'' to avoid the possible unintended implication that the Department intended the term ''Winding-Down'' to mean that the QPAM was necessarily going out of business as a QPAM on the Ineligibility Date. The Department stresses, however, that future relief based on an individual exemption application is not guaranteed, and the new term should not be read to suggest otherwise.

As noted above, the QPAM is free to apply for an individual exemption that would enable it to continue its eligibility to act as a QPAM and engage in transactions that would otherwise be prohibited after the expiration of the Transition Period, although there is no guarantee that the Department will grant such an exemption. Prohibited transaction relief during the Transition period would be subject to compliance with all conditions of the exemption except Section I(g)(3), which is renumbered Section I(g)(1) in this Final Amendment.

The Proposed Amendment provided that once the Transition Period begins, relief under the QPAM Exemption would only be available for transactions undertaken for the QPAM's existing clients—*i.e.,* the QPAM's client Plans that had a pre-existing Written Management Agreement (as required under Section VI(a)) on the Ineligibility Date for transactions entered into before the Ineligibility Date. Thus, after the Ineligibility Date, the QPAM would be prohibited from engaging in new transactions in reliance on the QPAM Exemption for existing client Plans. Additionally, if the QPAM obtained new client Plans during the Transition Period, the Proposed Amendment would not provide relief under the QPAM Exemption for any transactions the QPAM entered into on their behalf, unless such relief was granted in a separate individual exemption.

The Department designed the proposed Transition Period to mitigate the cost and disruption to Plans, their participants and beneficiaries, and IRA owners that can occur when a QPAM becomes ineligible for relief. The proposed One-Year Transition Period was intended to give a QPAM's client Plans time to decide whether to hire an alternative discretionary asset manager that is eligible to operate as a QPAM or continue their relationship with the ineligible QPAM. The Department believed that a One-Year Transition Period would be necessary to ensure that Plans have sufficient time to engage in a search for an alternative QPAM or discretionary asset manager if they decide it is in the Plan's best interest to do so.

The proposed Transition Period conditions required the QPAM to provide notice of its ineligibility to its existing client Plans and the Department (via *QPAM@dol.gov*) within 30 days after the Ineligibility Date. The proposed notice was required to: (1) include an objective description of the facts and circumstances upon which the Criminal Conviction or Written Ineligibility Notice [50] is based; (2) be written with sufficient detail, consistent with the QPAM's duties of prudence and undivided loyalty under ERISA, to fully inform a Plan fiduciary of the nature and severity of the criminal conduct or Prohibited Misconduct; and (3) be sufficient enough to enable such Plan fiduciary to satisfy its fiduciary duties of

[50] The Written Ineligibility Notice has been removed from this Final Amendment therefore, the term ''Written Ineligibility Notice'' in Section I(i) has been replaced with the term ''Prohibited Misconduct'' in the Final Exemption.

prudence and loyalty under Title I of ERISA when hiring, monitoring, evaluating, and retaining the QPAM.

The Proposed Amendment required that within 30 days after the Ineligibility Date, the QPAM would have to notify its client Plans that, as required by the proposed WMA provisions, the QPAM will not restrict the client's ability to terminate or withdraw from its arrangement with the QPAM. Thus, the QPAM would not be permitted to impose any fees, penalties, or charges on client Plans in connection with the process of terminating or withdrawing from a QPAM-managed Investment Fund except for reasonable fees, appropriately disclosed in advance, that are specifically designed to prevent generally recognized abusive investment practices or specifically designed to ensure equitable treatment of all investors in a pooled fund in the event such withdrawal or termination may have adverse consequences for all other investors. If such fees, penalties, or charges occur, they must be applied consistently and in a like manner to all such investors.

The Proposed Amendment also required the QPAM to indemnify, hold harmless, and promptly restore losses to each client Plan for any damages resulting from a violation of applicable laws, a breach of contract, or any claim arising out the QPAM's ineligibility. For purposes of this provision, the Proposed Amendment indicated that actual losses specifically include losses and costs arising from unwinding transactions with third parties and from transitioning Plan assets to an alternative discretionary asset manager.

Additionally, to ensure Plans were protected from bad actors, the Proposed Amendment required the QPAM not to employ or knowingly engage any individual that Participated In conduct that is the subject of a Criminal Conviction or Prohibited Misconduct. For Criminal Convictions, this would apply regardless of whether the individual is separately convicted in connection with the criminal conduct. The Proposed Amendment indicated that the QPAM must adhere to this requirement no later than the Ineligibility Date.

Finally, the Proposed Amendment prohibited the QPAM from relying on the relief provided in the QPAM Exemption after the One-Year Transition Period unless the Department granted the QPAM an individual exemption allowing it to continue relying upon the exemption. The Proposed Amendment provided that the Transition Period would not be suspended while an individual exemption application is pending with the Department.

The Department requested comments on the Transition Period, including whether one year is the appropriate length of time and whether there are additional protections for Plan participants and beneficiaries and IRA owners that the Department should consider.

Many commenters argued that the proposed prohibition on the QPAM engaging in any new transactions during the Transition Period, even for existing clients, should be removed. These commenters indicated that QPAMs who become ineligible should be permitted to make new investments during the Transition Period on behalf of their client Plans that conform to investment guidelines approved by a Plan fiduciary during the Transition Period. In support of this position, commenters indicated that when QPAMs have been engaged to carry out an investment strategy that requires them to continually make new investments, the proposed prohibition on engaging in new transactions for existing clients could be particularly detrimental. For instance, there could be a series of transactions that require ongoing adjustments (such as in the case of swaps and other derivatives), and an inability to adjust these transactions could detrimentally impact the QPAM's client Plans and counterparties alike.

After considering these comments, the Department agrees that to avoid the potential harm that QPAMs' client Plans could suffer if their investments are effectively frozen, it is appropriate to remove the prohibition on QPAMs entering into new transactions for existing client Plans during the Transition Period. The Department reminds QPAMs that they must meet their fiduciary obligations of prudence and loyalty set forth in ERISA section 404 when making investment decisions on behalf of their ERISA-covered Plan clients and IRA clients (to the extent that ERISA section 404 is applicable) during the Transition Period.

One commenter suggested that the Department included the Transition Period provisions in the Proposed Amendment because it clearly assumed that QPAMs' client Plans would want to fire their asset manager. The Department did not intend to convey this view in the Proposed Amendment. The Department included this provision in the Proposed Amendment to provide an ineligible QPAM's client Plans with an off-ramp if they choose to terminate their relationship with the asset manager. The Department's sole reason for including the Transition Period provisions is to protect the affected Plans. Thus, for example, if a Plan chooses to retain its relationship with a QPAM that becomes ineligible, it may do so, but the Department's intention is to prevent Plans from being locked into a contractual arrangement with an ineligible QPAM.

Multiple commenters indicated that the process for replacing a larger Plan's investment manager typically takes more than one year and suggested alternative timeframes for the Transition Period. For example, commenters suggested the Department extend the Transition Period to at least 18 months or two years, and another commenter offered the alternative of having the Transition Period last at least until after the Department makes a final determination regarding whether to grant or deny the QPAM's individual exemption application.

After considering these comments, the Department decided not to change the timeframe for the Transition Period in the Final Amendment. The Department recognizes that in some cases a longer Transition Period could be necessary but determined the best way to address this circumstance is through the individual exemption process on a case-by-case basis. Performing the necessary analysis during the individual exemption process will ensure the Department has sufficient information to appropriately consider whether additional protections are necessary for impacted Plans based on the QPAM's particular facts and circumstances. The Department does not believe it is appropriate to extend the Transition Period until a formal decision on an individual exemption has been made as the Department processes individual exemption applications on a case-by-case basis and the timeframes for each case vary. Therefore, the duration of the Transition Period would be uncertain.

One commenter noted that the Department's participant disclosure regulation requires any change to a defined contributions plan's designated investment alternatives to be disclosed to participants at least 30 days (but not more than 90 days) in advance. The commenter indicated that it appeared that the Department has not considered the practical limitations of such notices on the duration of the Transition Period. The one-year duration of the Transition Period, however, provides more than sufficient time to accommodate the requirements of the participant disclosure regulation. If additional relief is needed beyond the one-year period, the QPAM may request a supplemental individual exemption to ensure that such a change is made accordingly.

One commenter asserted that the Proposed Amendment did not clearly indicate the QPAM's obligations to non-ERISA investors in a pooled fund or how these investors would be treated. Another commenter suggested that the Department should focus on the issue of pooled funds, where QPAMs will need to balance the interests of Plans leaving the fund with those Plans remaining in the fund. The Proposed Amendment and this Final Amendment treat non-ERISA and Plan investors in a similar manner to the way the Department has addressed this issue in individual exemptions related to Section I(g) ineligibility. Specifically, the provision prohibiting a QPAM from imposing fees, penalties, or charges in the Proposed Amendment includes an explicit exception for ''reasonable fees, appropriately disclosed in advance, that are specifically designed to: (a) prevent generally recognized abusive investment practices or (b) ensure equitable treatment of all investors in a pooled fund in the event such withdrawal or termination may have adverse consequences for all other investors, provided that such fees are applied consistently and in a like manner to all such investors.'' The Department has retained this exception in this Final Amendment, which addresses the commenter's concern.

Some commenters indicated that Plans should be given more control over the decision to continue relying on the QPAMs. The commenters suggested that the Department give Plans the ability to decide whether to terminate or withdraw from their relationship with a QPAM and the flexibility to determine a timeline for withdrawal. One commenter asserted that Plans choose asset managers based on their reputation and expertise in specific areas of asset management. The commenter added that the Plan is in the best position to determine whether it is in the Plan's best interests to terminate or withdraw from their relationship with the QPAM. As discussed above, however, ultimately the decision on whether to grant relief from ERISA and the Code's prohibited transaction provisions rests with the Department. In the Department's view, the individual exemption process provides a full, fair, and open process for the Department to determine whether a QPAM should be permitted to engage in otherwise prohibited transactions post-conviction, and if so, the conditions which should be placed on such relief. To the extent QPAMs obtain such individual exemptions, Plans remain free to rely upon them to engage in transactions that would otherwise be prohibited if the QPAMs meet the conditions that are specified in the exemptions.

Finally, one commenter noted that to fully effectuate the intent of the Transition Period provisions for stable value investment contracts, the length of the period should be based on the duration of the underlying investment portfolio or as otherwise provided under the terms of the contract for an extended or amortized termination. The Department declines to give preferential treatment to QPAMs responsible for such investment contracts in this manner. Here too, the individual exemption process is best suited to address any specific issues or concerns based on the nature of the QPAM's investments or investment practices.

Finally, the Department made a few additional ministerial changes to the Transition Period provisions in the Final Amendment. First, the Department capitalized the term ''Transition Period.'' [51] Second, the Department modified the first sentence of the Transition Period provision to clarify its focus on client Plans, by replacing the phrase ''engage in'' with ''provide,'' and by dividing the first sentence into two sentences to improve readability. Third, the Department replaced the Proposed Amendment's reference to subsection I(g)(2) (regarding the WMA) with a reference to subsection I(i) because the Department moved the WMA requirements to this subsection. Finally, as noted above, since the Written Ineligibility Notice provisions have been removed from the Final Amendment, the term ''Written Ineligibility Notice'' as used in this Section in the Proposed Amendment, now has been replaced with the term ''Prohibited Misconduct.''

Section I(j)—Requesting an Individual Exemption

The Proposed Amendment included a new Section I(k),[52] which provided that a QPAM that is ineligible or anticipates becoming ineligible may apply for supplemental individual exemption relief. The Proposed Amendment's Section I(k) instructed an applicant, as part of such a request, to review the Department's most recently granted individual exemptions involving Section I(g) ineligibility with the expectation that similar conditions will be required if an exemption is proposed and granted. Proposed Section I(k) also indicated that if an applicant wished to exclude any term or condition from its exemption, the applicant would need to accompany such request with a detailed explanation of the reason such change is necessary and in the interest of and protective of the Plan, its participants and beneficiaries, and IRA owners. Proposed Section I(k) indicated that the Department would review such requests consistent with the requirements of ERISA section 408(a) and Code section 4975(c)(2).

To facilitate the processing of an individual exemption application, proposed Section I(k) also instructed applicants to provide detailed information in their applications quantifying the specific cost or harms in dollar amounts, if any, that Plans would suffer if a QPAM could not rely on the exemption after the Transition Period, including the specific dollar amounts of investment losses resulting from foregone investment opportunities and any evidence supporting the proposition that investment opportunities would only be available to Plans on less advantageous terms.

Proposed Section I(k) also indicated that an applicant should not construe the Department's acceptance of an individual exemption application as a guarantee that the Department will grant an individual exemption. Therefore, a QPAM that submits an individual exemption application must ensure that it manages Plan assets prudently and loyally during the Transition Period with the understanding that final approval of an individual exemption is not guaranteed.

The Proposed Amendment reinforced that for the Department to make the necessary statutory findings under ERISA section 408(a) and Code section 4975(c)(2), applicants also should anticipate that the Department may condition individual exemptive relief on a certification by a senior executive officer of the QPAM (or comparable person) that: (1) all of the conditions of the Transition Period were met, and (2) an independent audit reviewing the QPAM's compliance with the conditions of the Transition Period has been completed.[53] QPAMs affected by a conviction also should not wait until late in the Transition Period to apply for an individual exemption.

The Department received a few comments on this new provision. One commenter noted that the conditions that have been incorporated into the most recent individual exemption that

[51] The Department capitalized the term in other Sections of the Final Amendment as well.

[52] Section I(k) of the Proposed Amendment has been renumbered in the Final Amendment as Section I(j).

[53] The Department additionally clarifies that the certification of the independent audit would come at some point after an individual exemption is granted and the One-Year Transition Period has ended.

apply to a particular QPAM may not be appropriately tailored to a subsequent application and fact pattern. Another commenter indicated that the Department is increasingly adopting onerous conditions for granting individual exemptions and seems even less likely to grant them. Yet another commenter opined that an ineligible QPAM may be unlikely to receive an individual exemption that is usable.

Considering the serious corporate criminal misconduct the Department has seen in Section I(g) individual exemption applications and audits submitted to the Department as required by granted individual exemptions, the Department remains convinced that the proper starting point for individual exemption conditions should be the Department's most recently-issued individual exemptions. This procedural standpoint is neither new nor undisclosed. For decades, the Department has generally crafted proposed exemptions for similarly situated applicants that contain similar conditions, subject to the Department's periodic reevaluation of the exemption conditions to ensure that they remain appropriately protective for the Department to make the findings required by ERISA section 408(a) and Code section 4975(c)(2).

The Department will consider the individual facts and circumstances of each application, but Section I(j) (formerly section I(k) in the Proposed Amendment) is intended to clearly provide the appropriate starting point for applicants that are preparing an exemption application in connection with Section I(g) ineligibility. Regarding the commenter's reference to the Department's onerous conditions, over the past decade, the Department's experience indicates that QPAM ineligibility under Section I(g) has occurred in most cases due to serious corporate criminal misconduct. The Department believes that it has tailored the conditions of the most recent Section I(g) individual exemptions to appropriately address the potential for significant financial harm to Plans, while providing workable relief. Moreover, if a QPAM is concerned about the usability of a Section I(g) individual exemption, then the QPAM, its Affiliates, and owners of a five (5) percent or more interest may structure their conduct to avoid engaging in transactions that are otherwise legally prohibited or rely on exemptions other than the QPAM Exemption to avoid the consequences that result from Section I(g) ineligibility.

The Department also notes that applicants may request more limited relief than the QPAM Exemption otherwise provides. For example, a QPAM may only need prohibited transaction relief for a particular limited category of transactions, such as an on-going lease that was entered into on behalf of an Investment Fund which is expected to continue past the One-Year Transition Period. In such circumstances, due to the limited nature of the transaction(s) for which relief is sought, applicants should discuss the terms and conditions of prior individual exemptions involving Section I(g) in connection with a request for more limited prohibited transaction relief. The applicant also should include a detailed explanation in its application regarding how Plans will be otherwise protected and why the transaction cannot be unwound before the end of the Transition Period without harm or losses to such Plans.

Finally, the Department reminds any applicant anticipating that it will need relief beyond the end of the One-Year Transition Period to apply to the Department for an individual exemption as soon as practicable. As a fiduciary, the QPAM has obligations with respect to Plans beyond those required by the QPAM Exemption and should approach the Department at the earliest point it appears a conviction will occur, such as when a plea agreement has been entered into—even if the conviction date has not yet been set—to ensure that appropriate steps can be taken by or on behalf of its client Plans ultimately impacted by the QPAM's loss of exemptive relief.

Section I(c)—Involvement in Investment Decisions by a Party in Interest

The Proposed Amendment included modifications to Section I(c) of the QPAM exemption that are consistent with the Department's original intent when granting the exemption. In the 1984 grant notice, the Department stated that an essential premise of the exemption is that broad prohibited transaction relief can be afforded only if the negotiations leading to, and the commitments and investments of, plan assets are the sole responsibility of an independent investment manager. The Department reasoned in the 1984 grant notice that the potential for decision making with regard to plan assets that would inure to the benefit of a party in interest would be increased if exemptive relief were provide in circumstances where the QPAM has less than ultimate discretion over acquisitions for an investment fund that it manages.[54]

The proposed new language in Section I(c) was intended to make clear that a QPAM must not permit a Party in Interest to make decisions regarding Plan investments under the QPAM's control. The Proposed Amendment included in the opening of Section I(c) a statement providing that the terms of the transaction, ''commitments, investment of fund assets, and any corresponding negotiations on behalf of the Investment Fund are the sole responsibility of the QPAM. . . .'' [55] The Department also proposed to add language at the end of Section I(c) stating that the prohibited transaction relief in the exemption applies ''only in connection with an Investment Fund that is established primarily for investment purposes'' and that ''[n]o relief is provided under this exemption for any transaction that has been planned, negotiated, or initiated by a Party in Interest, in whole or in part, and presented to a QPAM for approval because the QPAM would not have sole responsibility with respect to the transaction as required by this section I(c).'' [56] For example, as stated in 1982 proposal for the QPAM Exemption, a plan sponsor that negotiates a transaction and then presents it to a QPAM for approval would not qualify for the relief in the class exemption. The 1982 proposal further states that the relief in the proposed exemption would be available even though the transfer of assets by a plan to a QPAM is subject to general investment guidelines, so long as there is no arrangement, direct or indirect, for the QPAM to negotiate, or engage in, any specific transaction or to benefit any specific person.[57]

The Department received numerous comments regarding the proposed changes to the wording of Section I(c). Some of these commenters indicated their understanding of the Department's view that a QPAM should not act as a rubber stamp to approve transactions designed by the Party in Interest who appointed the QPAM. Similarly, commenters indicated they shared the goal of preventing the QPAM Exemption from being abused, *i.e.,* a QPAM being used to ''sanitize'' a transaction where there is an underlying goal to avoid the restrictions of the prohibited transaction rules. One commenter also indicated that it understood the Department has long maintained that QPAMs should not simply act as ''mere independent approvers'' but should be intimately involved in the negotiation and approval of the transaction. The

[54] 49 FR at 9497.

[55] 87 FR at 45227.

[56] *Id.*

[57] 47 FR at 56947.

commenter believed that this interpretation is widespread in the market and needs no clarification. Another commenter also indicated that the original QPAM Exemption was clear and understood by practitioners—a named fiduciary could not appoint a QPAM to approve a pre-negotiated transaction nor could the appointing fiduciary retain a veto or approval right over any transaction.

Commenters also raised a variety of other general issues and concerns with the proposed changes to Section I(c). One commenter noted that the Department has not identified any evidence of harm necessitating changes to the language of Section I(c). Another commenter suggested that any proposal to make changes to the way various Plan fiduciaries interact with QPAMs should be the subject of a separate, carefully crafted proposal with stakeholder input and regulatory cost analysis. A commenter also asked whether the Department's clarifications were meant to refer to Plan sponsors instead of a Party in Interest with no ability to meaningfully influence a transaction.

The Department has an ongoing interest and responsibility under ERISA section 408(a) and Code section 4975(c)(2) to revisit and update exemptions on an ongoing basis to ensure that that they maintain their protective purpose. Although Section I(a) of the exemption directly addresses Plan sponsors, Section I(c) provides additional protections that also apply to the Plan sponsor. These conditions are intended to work together, not separately, to prevent a Plan sponsor from attempting to influence a transaction. To the extent QPAMs are already fully complying with the Department's expectation of independent judgment, and not acting as mere rubber stamps, appropriate clarifying language should impose no additional burden. It is essential to the achievement of the exemption's aims, however, that the Department's expectations be clear in this regard.

Modifications to Section I(c) are appropriate to ensure the Department's intent is understood by practitioners, QPAMs, and their client Plans. It is also important for QPAMs to be mindful of the requirements of the exemption rather than simply deriving the benefits of calling themselves QPAMs while ignoring the QPAM Exemption's core requirements and protective intent. Moreover, the Department notes that Section I(c) requires the asset manager to act independently, as a general matter, from Plan sponsors and Parties in Interest. Without an overarching compliance-focused approach to its asset management arrangement and Section I(c), the protective purpose of ensuring the QPAM's independence is undermined.

Commenters raised a variety of other topics, such as: (1) the amount of permitted involvement by a Party in Interest/Plan sponsor in investment decisions, including voting proxies; (2) arrangements that involve multiple investment managers; (3) transactions initiated or negotiated by a Party in Interest; (4) sub-advisers and collective investment trusts; (5) pension risk transfers; (6) an Investment Fund established primarily for investment purposes; (7) eliminating all the changes in the Proposed Amendment; and (8) alternatives to the changes in the Proposed Amendment. The Department revised the wording of Section I(c) in this Final Amendment in response to some of these comments, as discussed below. However, the Department reemphasizes that the role of the QPAM under the terms of the exemption is not to act as a mere independent approver of transactions. Rather, the QPAM must have and exercise sole discretion over the commitments and investments of Plan assets and the related negotiations on behalf of the Plan with respect to an Investment Fund that is established primarily for investment purposes for the relief provided under the exemption to apply.

Involvement in Investment Decisions

One commenter opined that Plan sponsors and Plan fiduciaries should be able to have meaningful involvement in the process of negotiating an investment contract's investment guidelines without affecting the ability of the investment manager to rely on the QPAM Exemption. Another commenter requested that the Department clarify that routine monitoring meetings and inquiries by Plan fiduciaries with respect to a manager's trading strategies do not constitute ''planning.'' One commenter also requested clarification that nothing in the Proposed Amendment would prevent the trustees of multiemployer plans from retaining or delegating the right to vote proxies held by the QPAM, or to exercise other similar shareholder rights, even if such proxies or rights relate to investments in a Party in Interest.

The Department notes that routine monitoring of meetings and inquiries by Plan fiduciaries would not be considered ''planning'' for purposes of Section I(c). This type of involvement is consistent with a fiduciary's obligations under ERISA section 404 and the Department's prior guidance regarding investment guidelines that may be provided to the QPAM. For clarity, the Department is changing the word ''because'' to ''to the extent'' in the proposed sentence:

No relief is provided under this exemption for any transaction that has been planned, negotiated, or initiated by a Party in Interest, in whole or in part, and presented to a QPAM for approval because the QPAM would not have sole responsibility with respect to the transaction as required by this Section I(c).

That sentence now reads:

No relief is provided under this exemption for any transaction that has been planned, negotiated, or initiated by a Party in Interest, in whole or in part, and presented to a QPAM for approval to the extent the QPAM would not have sole responsibility with respect to the transaction as required by this Section I(c).

With respect to proxies and exercising other shareholder rights, the Department notes that the QPAM Exemption was never intended to cover transactions in which a Party in Interest is making the decisions pertaining to specific transactions. The possibility that Plan fiduciaries have been relying upon the QPAM Exemption for such transactions highlights one of the reasons the Department proposed changes to Section I(c). The Department would generally consider reliance on the QPAM Exemption in these cases to be an abuse or misuse of the QPAM Exemption.[58] Importantly, as the Department stated in the preamble of the original granted exemption in 1984, the Department ''does not interpret Section I(c) as exempting a subsidiary transaction unless such transaction is itself subject to relief under the class exemption and the applicable conditions are met.'' [59]

Multiple Investment Managers

Commenters indicated that Plan sponsors often hire multiple investment managers to execute the Plan's overall investment strategy with each manager being given certain assets to manage in a particular manner. And since only the Plan sponsor knows the overall strategy, it is natural and beneficial for the Plan sponsor to be able to have ongoing dialogues with their managers without those dialogues disqualifying the manager from serving as a QPAM.

The Department notes that the proposed changes to Section I(c) were not intended to prevent Plan sponsors

[58] Any parties that require more detailed guidance on the applicability of the QPAM Exemption to certain transactions may submit an advisory opinion request to the Department.

[59] 49 FR at 9497.

from having ongoing dialogue with an investment manager. The Department's intent and additional clarification regarding the proposed changes re-emphasize that a Plan sponsor can provide investment guidelines to a QPAM. The natural corollary would be for Plan sponsors to revisit those investment guidelines at appropriate intervals. One of the Department's key points with the proposed changes to Section I(c) is that any direction from a Plan sponsor or other Party in Interest for a QPAM to engage in a particular transaction would be contrary to the intent of Section I(c). A Plan sponsor that utilizes multiple QPAMs, however, may interact with each manager as part of a larger overall investment strategy as long as the QPAMs retain the sole authority to engage in transactions in accordance with the strategy, and there is no direct or indirect arrangement for any QPAM to negotiate, or engage in, any specific transaction or to benefit any specific person.

Initiating, Planning, and Negotiation Transactions

Many commenters raised concerns regarding the use of the word ''initiate'' in the Department's proposed changes to Section I(c). Some commenters expressed concern because Investment Fund transactions in derivatives or other investment products that are developed and pitched to a QPAM by a financial institution acting as a service provider to the QPAM—a common scenario in the derivatives market—could be interpreted as initiated by a Party in Interest. Commenters also indicated that even if a transaction is not of a type that is customarily negotiated, the counterparty Party in Interest would still be involved. A few commenters opined that the reference to a transaction being ''negotiated'' by the Party in Interest and then ''presented to a QPAM for approval'' is sufficient to achieve the Department's objective. Further, a commenter indicated that the proposed amendments mischaracterize the actual application of a QPAM's discretionary authority. This commenter indicated that if not eliminated, the terms ''planned,'' ''negotiated,'' and ''initiated'' should be clarified to address the Department's concerns more directly. For example, if the Department is concerned about the practice of hiring a QPAM for the sole purpose of approving a particular transaction already contemplated and/or negotiated by another Plan fiduciary, the Department should craft language more narrowly aimed at preventing this situation.

The Department notes that whether a particular sales pitch or an offer of an investment product from a Party in Interest would run afoul of the intent of Section I(c), including the proposed changes, depends on the associated facts and circumstances. It would be inappropriate for the Department to embed these facts and circumstances into an exemption condition, because the exemption would become unduly complex and unworkable. As a general matter in this regard, QPAMs should interpret the protective nature of Section I(c) expansively and avoid responding to any sales pitch or offer with respect to a proposed transaction that would call into question whether the QPAM is ultimately solely responsible for planning, negotiating, and initiating the transaction.

In order to further clarify this concept, the Department has added the following sentences to Section I(c): ''In exercising its authority, the QPAM must ensure that any transaction, commitment, or investment of fund assets for which it is responsible are based on its own independent exercise of fiduciary judgment and free from any bias in favor of the interests of the Plan sponsor or other parties in interest. The QPAM may not be appointed or relied upon to uncritically approve transactions, commitments, or investments negotiated, proposed, or approved by the Plan sponsor, or other parties in interest.''

Sub-Advisers and Collective Investment Trusts

A few commenters indicated that the Department's proposed language could be interpreted to restrict the use of sub-advisers by a QPAM, including in the context of collective investment trusts (CITs). Commenters indicated that utilizing sub-advisers to make recommendations for certain investments in which they specialize or possess expertise is important because a QPAM may otherwise be compelled to do its own research before investing Plan assets, even when the QPAM can more readily rely upon a sub-adviser with specialized expertise regarding certain types of assets. Commenters noted that QPAMs regularly delegate certain investment responsibilities to a sub-adviser but retain authority to approve transactions. With respect to CITs, commenters indicated that in order to comply with securities and banking laws, the sponsoring trust company generally retains ultimate investment authority, but typically appoints a sub-adviser who invests the CIT's assets on a day-to-day basis. Commenters felt the proposed revision to Section I(c) would present a structural conundrum for CITs and their providers given the standards imposed by the federal securities laws and OCC regulations. According to commenters, the proposed language requires that the QPAM have the ''sole authority'' over the transaction. Commenters indicated that neither the sponsoring trust company nor sub-adviser have the sole authority, although both are fiduciaries under ERISA and may need to rely on the QPAM Exemption.

The Department expects that a QPAM may rely on the specific expertise of a prudently selected and monitored entity to assist the QPAM in prudently managing Plan assets. Therefore, a QPAM's delegation of certain investment-related responsibilities to a sub-adviser does not, by itself, violate Section I(c), as long as the QPAM retains sole authority with respect to planning, negotiating, and initiating the transactions covered by the QPAM Exemption. A QPAM should not ''more readily'' rely on a sub-adviser that has specialized expertise, in order to engage in a particular transaction, if the reliance means that the QPAM would not have sole authority with respect to planning, negotiating, and initiating the transaction.

Furthermore, parties that participate in arrangements that do not clearly identify which party has the ultimate responsibility and authority to engage in a particular transaction should not assume that the transaction is permitted by the QPAM Exemption. The Department recommends that affected parties involved in such transactions seek an advisory opinion or request other guidance from the Department regarding whether the QPAM Exemption is available for such transactions.

Pension Risk Transfers

One commenter suggested the proposed changes to Section I(c) could render the QPAM Exemption unavailable for pension risk transfers where a Plan purchases an annuity from an insurance company in connection with the termination of the Plan or to annuitize a subset of the Plan's participant population. The commenter did not provide specific details as to what aspects of proposed Section I(c) would potentially create problems for this type of transaction, however. The QPAM Exemption is designed to accommodate a broad range of prudent investment transactions, and the Department does not believe that the exemption poses any special impediment to such transactions as they may relate to pension risk transfers. If

the commenter's concerns remain after it considers the Department's modifications to Section I(c) in the Final Amendment, the affected parties may seek an advisory opinion or request other guidance from the Department regarding whether the QPAM Exemption is available for such transactions.

Fund Established Primarily for Investment Purposes

In connection with the Department's proposed language that the Investment Fund must be established primarily for investment purposes, one commenter requested the Department clarify that this includes a fund that is established for mixed-use purposes that contains an investment component. The commenter indicated the fund may have certain non-investment purposes, such as the payment of benefits and Plan expenses. Another commenter indicated that the QPAM Exemption long has been used by Plans to hire managers, as well as trustees, custodians, and recordkeepers, regardless of the type of Plan (pension, savings, or welfare).

The Department notes that a fund that contains only a minor investment component would not be eligible for the relief provided by the QPAM Exemption. This is true regardless of the Plan type. If a Plan has mixed-use purposes, the Plan sponsor should establish a separate account for any investments held directly by the Plan in order to rely upon the QPAM Exemption for that portion of the Plan's assets. Relatedly, a fund or other pool of Plan assets that contains no investment assets would not be able to rely upon the QPAM Exemption. However, as provided in Section I(c) of this Final Amendment, an Investment Fund that makes distributions and/or engages in other activities that are ancillary to the fund's primary investment purpose will not fail to be an Investment Fund established primarily for investment purposes. The Department provides this additional clarification in the Final Amendment because distributions and other ancillary services are generally necessary in order for investment funds to operate.

Recommended Alternatives

One commenter made a specific recommendation regarding the wording of Section I(c) that would specify that the QPAM ''represents the interest of the Investment Fund.'' The Department accepts this suggested modification in addition to the other modifications discussed above.

Another commenter suggested the Department should issue separate guidance on Section I(c) that makes clear that a QPAM is expected to act prudently on behalf of its Plan clients for any investment opportunity that the QPAM may become aware of and where the QPAM is not conflicted—regardless of how it became aware of the opportunity. The commenter added that as long as the QPAM has the ultimate discretionary authority and responsibility for deciding whether to enter into a given transaction, the QPAM should not be prohibited from transactions merely because such transaction is planned, negotiated, or initiated by a Party in Interest.

The Department believes many of the revisions to Section I(c) in this Final Amendment and related preamble discussion provide the requested guidance. If questions remain regarding the source of investment opportunities in relation to the QPAM's discretionary authority, the Department encourages interested parties to submit an advisory opinion request that details the particular facts and circumstances that raise issues under Section I(c).

Section VI(a)—Asset Management and Equity Thresholds

The QPAM Exemption was originally granted, in part, on the premise that large financial services institutions would be able to withstand improper influence from Parties in Interest. The Department included the asset management and equity thresholds in the exemption to set minimum size thresholds that would help ensure a QPAM would be able to withstand such influence. In 2005, the Department finalized an amendment to the QPAM Exemption that updated the asset management and shareholders' and partners' equity thresholds for registered investment advisers in the QPAM definition in subsection VI(a)(4).[60] In connection with that amendment, the Department indicated that the original thresholds ''may no longer provide significant protections for Plans in the current financial marketplace'' and adjusted the figures based on changes in the Consumer Price Index.[61]

The Department has determined that the same rationale necessitates further updates to the registered investment adviser thresholds and those of other types of QPAMs, such as banks and insurance companies, because they have not been updated since 1984. Therefore, the Department is adjusting all of the thresholds in Section VI(a) based on the original published figures in the 1984 grant notice. This will ensure that changes to the thresholds for all types of financial institutions reflect the same baseline change to the Consumer Price Index (*i.e.,* 1984 vs. 2021).[62]

The Proposed Amendment would have adjusted the $1,000,000 threshold in subsection VI(a)(1) through (3) to $2,720,000 and the assets under management threshold of $85,000,000 and the shareholders' and partners' equity and the broker-dealer net worth thresholds of $1,000,000 in subsection VI(a)(4) to $135,870,000 and $2,000,000, respectively. In this Final Amendment, the Department decided to increase the thresholds in three-year increments beginning in the year 2024 and ending in 2030. The final incremental adjustment will raise the thresholds to the amounts included in the Proposed Amendment. The incrementally adjusted threshold amounts are provided in subsection VI(a)(1) through (4) of the Final Amendment. By publication through notice in the **Federal Register** no later than January 31st every year, the Department will make subsequent annual adjustments for inflation to the Equity Capital, Net Worth, and asset management thresholds in subsection VI(a)(1) through (4) that are rounded to the nearest $10,000.

As a minor ministerial change, the Department proposed to replace the reference to ''Federal Savings and Loan Insurance Corporation'' with ''Federal Deposit Insurance Corporation'' in subsection VI(a)(2), because the Federal Savings and Loan Insurance Corporation was abolished by Congress in 1989, and its responsibilities were transferred to the Federal Deposit Insurance Corporation.[63] The Department received no comments on this ministerial change and retains it in this Final Amendment.

The Department received several comments regarding the proposed asset management and equity thresholds. One commenter noted that the proposed increases may have a material impact on the market for both small and large managers. The commenters stated the sudden increase in the thresholds could force small organizations out of the market, which would prevent small managers and start-up managers from utilizing the QPAM Exemption and put them at a competitive disadvantage.

[60] 70 FR 49305.

[61] Proposed Amendment to PTE 84–14, 68 FR 52419, 52423 (Sept. 3, 2003).

[62] For purposes of these changes, the Department used March 1984 and December 2021 as the relevant dates in the U.S. Bureau of Labor Statistics CPI Inflation Calculator available at: *https://www.bls.gov/data/inflation_calculator.htm.*

[63] *See* Financial Institutions Reform, Recovery, and Enforcement Act of 1989, Public Law 101–73 (1989).

As the Department previously stated, the QPAM Exemption was never intended for small investment managers, and the exemption's minimum asset and equity thresholds are intended to ensure that the fiduciaries managing Plan assets are established institutions that are large enough not to be unduly influenced in their discretionary decision-making process by Parties in Interest. By spreading out the proposed increases occurring with this Final Amendment incrementally from 2024 through 2030, the impact of a sudden increase in the threshold will be greatly reduced. This longer implementation period will provide ample opportunity for QPAMs to prepare and be on notice that the thresholds are increasing in this manner and on an annual basis thereafter. The Department notes that small asset managers or start-ups can apply for individual exemptive relief to use the QPAM Exemption if they are detrimentally impacted by the Final Amendment's increase to the equity and asset thresholds, and the Department will consider those requests on a case-by-case basis. An individual exemption, if granted, would allow the Department to develop conditions for this circumstance that would ensure the QPAM retains the appropriate independence and the means to provide remedies to harmed Plans.

Another commenter stated that changes of such significance should not be undertaken in the absence of an identifiable harm or evidence supporting such harm to Plans, participants, and/or beneficiaries. The Department disagrees and notes that the original intent and protection of the exemption will erode if the asset and equity thresholds are allowed to become irrelevant with the passage of time. What was considered a large institution that could serve the protective purposes of the exemption in 1984 would not be considered sufficiently large by current standards. For the protective nature of the QPAM Exemption to remain effective and relevant, the Department must update the asset and equity thresholds to ensure that they keep pace with financial and economic growth in the marketplace.

A commenter suggested the Department should conduct a survey or issue a request for information designed to gather data necessary to make an informed decision as to whether the thresholds should be increased and, if so, to what extent. It is clear, however, that the asset and equity thresholds have not kept pace with the economic and financial growth of the marketplace, and the Department has undertaken a robust and thorough rulemaking process for this Final Amendment.

Another commenter recommended that at the least, the Department should grandfather QPAMs that met the pre-existing requirements and allow them to continue to rely on the QPAM Exemption. The Department declines to make this modification because allowing entities that fail to meet the thresholds to avail themselves of the relief in the QPAM Exemption would undermine the exemption's core purpose.

The Department received a comment stating that annual indexing of the equity and asset thresholds will create situations where an entity is a QPAM on one day, and not thereafter, leaving its client Plans in a precarious position if the Plans are invested in continuing transactions dependent on the QPAM Exemption. By incrementally increasing the asset and equity thresholds, the Department is effectively putting QPAMs on notice that the thresholds will increase according to a predictable metric (the CPI), which will provide an opportunity to prepare and manage their ERISA assets accordingly before the increases are fully implemented.[64]

Another comment stated that the indexing should only happen once every five years, with a one-year effective date transition. The Department declines to adopt this approach to the indexing. Five-year indexing periods could lead to substantial deficiencies with respect to QPAMs' compliance with the equity and threshold requirements of this exemption. As a general matter, asset managers seeking to rely on this exemption should be constantly aware of all the requirements of this exemption, including the equity and threshold requirements, and take appropriate action in response to the risk of non-compliance, including by not engaging in prohibited transactions or by relying on and complying with alternative exemptions. Further, the current asset and equity thresholds are very outdated, and their ineffectiveness would be exacerbated by waiting an additional five years to increase them.

Finally, a commenter recommended that the Department clarify that the new dollar thresholds published by January 31st annually in the **Federal Register** will not be applicable until January 1st of the following year. The Department has made this clarification in the Final Amendment by providing that each increase in the thresholds will be effective as of the last day of the QPAM's fiscal year in which the increase takes effect. The Department also will include the annual notice of increases on the class exemption section of EBSA's website.[65]

Section VI(u)—Recordkeeping

The Proposed Amendment also included a new recordkeeping requirement in Section VI(t), which would require QPAMs to maintain records for six years demonstrating compliance with this exemption. The Recordkeeping requirement has been redesignated as Section VI(u) in this Final Amendment.[66] The Department proposed this addition to make the QPAM Exemption consistent with other exemptions that generally impose a recordkeeping requirement on parties relying on an exemption and to ensure they will be able to demonstrate, and that the Department will be able to verify, compliance with the exemption conditions.

The Recordkeeping requirement of the Proposed Amendment would require that the records be kept in a manner that is reasonably accessible for examination. The records must be made available, to the extent permitted by law, to any authorized employee of the Department or the Internal Revenue Service or another federal or state regulator; any fiduciary of a Plan invested in an Investment Fund managed by the QPAM; any contributing employer and any employee organization whose members are covered by a Plan invested in an Investment Fund managed by the QPAM; and any participant or beneficiary of a Plan and an IRA Owner invested in an Investment Fund managed by the QPAM.

QPAMs also would be required to make such records reasonably available for examination at their customary location during normal business hours. Participants and beneficiaries of a Plan, IRA owners, Plan fiduciaries, and contributing employers/employee organizations would be able to request only information applicable to their own transactions and not a QPAM's privileged trade secrets or privileged commercial or financial information, or confidential information regarding other individuals. If the QPAM refuses to disclose information to a party other than the Department on the basis that

[64] This includes possibly seeking individual exemption relief in such circumstances.

[65] Available at: *https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/exemptions/class.*

[66] The Department moved the definition of ''Participating In'' that appeared in Section I(g)(3) of the Proposed Amendment into the Definitions and General Rules at Section VI(t) of this Final Amendment.

the information is exempt from disclosure, the Department would require the QPAM to provide a written notice, within 30 days, advising the requestor of the reasons for the refusal and that the Department may request such information. The requestor would then be able to contact the Department if it believes it would be useful for the Department to request the information.

Any failure to maintain the records necessary to determine whether the conditions of the exemption have been met would result in the loss of the relief provided under the exemption only for the transaction or transactions for which such records are missing or have not been maintained. Such failure would not affect the relief for other transactions if the QPAM maintains required records for such transactions.

The Department received several comments opposing the Proposed Amendment's recordkeeping requirement. Some commenters indicated that the specific recordkeeping requirements are unnecessary given the existing recordkeeping requirements under ERISA section 107. Other commenters added that the requirement does not add materially to the protective provisions already in place in the exemption and unnecessarily increases regulatory compliance costs. Commenters also pointed to other status-based exemptions that do not impose any recordkeeping requirement on a transaction-by-transaction basis, while others, like the insurance company general account exemption (PTE 95–60)[67] and INHAM exemption (PTE 96–23)[68] do not have a recordkeeping requirement at all.

Some commenters noted that only the Department (with respect to ERISA Title I plans) and the IRS (with respect to ERISA Title II plans, including IRAs) have the authority to enforce the terms of the QPAM Exemption. Therefore, those commenters argued that requiring that records be made available to employers, unions, and participants, beneficiaries, and IRA owners, raises the risk of unnecessary litigation and could cause QPAMs to increase the fees they charge to Plans as a result. One commenter added that there are practical reasons why having to retain records sufficient for a determination of compliance is unworkable or otherwise not cost effective. For example, a commenter argued that despite the Department's expectation that the recordkeeping requirements would impose a negligible burden, this requirement will, in fact, prove burdensome and costly because QPAMs will need to be able to demonstrate compliance for every transaction and, in some cases, to prove a negative. Another commenter asked for a simplified recordkeeping requirement that would require QPAMs to undertake prudent efforts to maintain accurate records reflecting their QPAM duties and responsibilities while another commenter suggested the Department should modify the Proposed Amendment to require process-based records of compliance rather than transactional records. Another commenter asked for clarification that the six-year recordkeeping requirement does not create any new obligation to document the basis for satisfaction of the exemption conditions. One commenter indicated it is unclear what it means to ''verify'' compliance with the conditions of the QPAM Exemption.

The Department's response to these comments is that these concerns are overstated and inconsistent with how recordkeeping requirements operate in prohibited transaction exemptions. The extent to which transaction-by-transaction records are necessary depends on the facts and circumstances. The Department often includes a recordkeeping requirement in its administrative prohibited transaction exemptions to ensure that the parties relying on an exemption can demonstrate, and the Department can verify, compliance with the exemption's conditions. Given the broad relief provided by this exemption, including a specific recordkeeping requirement is necessary for the Department to verify that the exemption conditions are being satisfied rather than relying on ERISA's general recordkeeping requirement to maintain records. Given the large number and variety of transactions entered into in reliance on the QPAM Exemption, the Department did not intend for this provision to require transaction-by-transaction recordkeeping. Rather, the condition is focused on requiring the QPAM to retain records satisfactory to prove compliance with the applicable conditions for any section of the exemption the QPAM relied upon, such as satisfying the definition of QPAM, and records supporting the limitation on the involvement of Parties in Interest in investment transactions. The QPAM's reliance on specific transactions covered by Sections II through V of the exemption will require it to maintain more detailed records such as, but not limited to, copies of leases, sales agreements, service contracts, audit reports, policies and procedures, and detailed descriptions of real estate. Financial institutions are accustomed to keeping records of their transactions as a part of their regular business practices and generally have recordkeeping systems already in place.

Additionally, a commenter noted that the National Bank visitorial powers provision and the Office of the Comptroller of the Currency (OCC) regulations would prevent Plan investors from accessing the records of national banks and federal savings associations. The commenter asserted that this could lead to an unintended discriminatory effect between these banks and state-chartered banks, which may not have the same available safeguards on the release of a QPAM bank's records. The Department notes that if the OCC regulations, in fact, bar Plan investors from accessing this information, that is no reason to bar others from accessing the records. If the commenter's purported restriction on access to national bank records is meaningful to Plan sponsor fiduciaries, then they are free to choose a QPAM that is not restricted from providing access to such records.

One commenter asked the Department to withdraw the recordkeeping requirement entirely, or if not, to modify it to be consistent with the recordkeeping requirement in PTE 2020–02. As stated above, the Department often includes a recordkeeping condition in administrative prohibited transaction exemptions to ensure compliance with the exemption. The recordkeeping requirement in PTE 2020–02 was developed specifically for that exemption and the specific relief for investment advice provided pursuant to certain conditions.

A commenter also requested that the 30-day window for producing records should be expanded to at least 90 days and a QPAM should have 90 days to provide notice of grounds for non-production. The Department notes that because QPAMs are fiduciaries, the Department is unpersuaded that additional time is necessary or consistent with the QPAM's fiduciary status. The Department believes a longer period would be required only if a QPAM is not already maintaining the records necessary to demonstrate compliance with this condition. To allow a QPAM additional time to produce, or indicate that it is not producing, records would be directly contrary to the purpose of the recordkeeping condition.

[67] As amended and restated at 87 FR 12985, 12996 (Mar. 8, 2022).

[68] As amended and restated at 76 FR 18255 (Apr. 1, 2011).

Other Ministerial Changes

The Department did not receive any comments regarding the ministerial changes in the Proposed Amendment. Therefore, the Department is finalizing the proposed ministerial changes as proposed, which include: (1) changing the headings of each portion of the exemption from ''Part'' to ''Section,'' (2) removing many internal cross-references to definitional provisions and instead capitalizing the terms used in those definitional provisions throughout the exemption,[69] and (3) adding internal references to ''above'' and ''below'' throughout to direct readers where to find certain cross-referenced provisions.

The Department corrected two minor typographical errors by changing: (1) ''assure'' to ''ensure'' in Section V and the related audit provision in Section VI(q), and (2) ''INHAM'' to ''QPAM'' in Section VI(p). All references to ''ERISA'' and the ''Code'' have been updated so that they come before the sections referenced, and references to the term ''employee benefit plan'' have been removed so that the exemption only uses the term ''Plan.'' Finally, the Department has amended the definition of the term ''Control'' in Section VI(e) so that it specifically refers to variations of the word ''control'' used throughout the exemption. Therefore, Section VI(e) now defines the terms ''Controlling,'' ''Controlled by,'' ''under Common Control,'' and ''Controls'' in the same manner as the prior single term ''Control.''

Regulatory Impact Analysis

The Department has examined the effects of the Final Amendment as required by Executive Order 12866,[70] Executive Order 13563,[71] the Congressional Review Act,[72] the Paperwork Reduction Act of 1995,[73] the Regulatory Flexibility Act,[74] section 202 of the Unfunded Mandates Reform Act of 1995,[75] and Executive Order 13132.[76]

Executive Order 12866 (Regulatory Planning and Review), Executive Order 14094 (Modernizing Regulatory Review), and 13563 (Improving Regulation and Regulatory Review)

Under Executive Order 12866 (as amended by Executive Order 14094), the Office of Management and Budget (OMB)'s Office of Information and Regulatory Affairs determines whether a regulatory action is significant and, therefore, subject to the requirements of the executive review by OMB. As amended by Executive Order 14094, section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order. OMB has determined that the Final Amendment is a significant regulatory action under Section 3(f)(1) of Executive Order 12866.

Executive Order 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; the regulation is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitative values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The Department has quantified the impact of the Final Amendment based on the best available data and provides an assessment of its benefits, costs, and transfers below. Based on this assessment, the Department concludes that the Final Amendment's benefits would justify its costs. Pursuant to the Congressional Review Act, OMB has designated the Final Amendment a ''major rule,'' as defined by 5 U.S.C. 804(2).

Need for Regulation

Substantial changes have occurred in the financial services industry since the Department granted the QPAM Exemption in 1984. Today's asset management industry has been marked by industry consolidation and an increasingly global reach. As a result, QPAM affiliations and investment strategies, including those involving Plan assets, have changed significantly since 1984. This Final Amendment updates some of the key elements of the QPAM Exemption to ensure that Plans affected by the exemption remain protected in light of the changes in the industry, and that the QPAM Exemption remains consistent with the original intent.

The Final Amendment addresses ambiguity as to whether foreign convictions are included in the scope of the ineligibility provision under Section I(g). QPAMs today often have corporate or relationship ties to a broad range of entities, some of which are located internationally. Additionally, some global financial service institutions may be headquartered, or have parent entities, in foreign jurisdictions. These entities may have significant control and influence over the operation of all entities within its organizational structure, including those operating as QPAMs. Moreover, the international ties of QPAMs extend to their investment strategies, including those involving Plan assets.

The Final Amendment also expands ineligibility to include QPAMs (and as applicable, an Affiliate or owner of a five (5) percent or more interest) that Participate In Prohibited Misconduct, such as conduct that has resulted in QPAMs entering into an NPA or DPA with a U.S. federal or state prosecutor's office or regulatory agency; a systematic pattern or practice of violating the exemption's conditions; intentionally violating the exemption's conditions in connection with otherwise non-exempt prohibited transactions; or providing materially misleading information to the Department and other regulators in connection with the exemption conditions. The Final Amendment ensures that QPAMs are not able to avoid the conditions related to integrity and ineligibility that are central to the QPAM Exemption by entering into NPAs and DPAs with prosecutors to side-step the consequences that otherwise would result from a Criminal Conviction. Plans may suffer significant

[69] However, for the sake of clarity, cross-references have been retained for the term ''Affiliate'' because it is defined in different ways under Section VI(c) and (d) of the exemption.

[70] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[71] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

[72] 5 U.S.C. 804(2) (1996).

[73] 44 U.S.C. 3506(c)(2)(A) (1995).

[74] 5 U.S.C. 601 *et seq.* (1980).

[75] 2 U.S.C. 1501 *et seq.* (1995).

[76] Federalism, 64 FR 43255 (Aug. 10, 1999).

harm if they are exposed to serious misconduct committed by unscrupulous firms or individuals that ultimately results in an NPA or DPA rather than Criminal Conviction and consequent ineligibility under Section I(g). Likewise, intentionally or systematically violating the exemption conditions exposes Plans to significant potential harm caused by the misconduct of those with influence or control over managing the investment of their assets. In the Department's view, QPAMs, and those in a position to influence or control a QPAM's policies, that repeatedly engage in serious misconduct do not display the requisite standards of integrity necessary to provide the protection intended for Plans that they are responsible for under the exemption.

Through its administration of the individual exemption program, the Department also determined that certain aspects of the QPAM Exemption would benefit from a focus on mitigating potential costs and disruption to Plans that occurs when a QPAM becomes ineligible for the exemptive relief because of ineligibility under Section I(g). The Final Amendment requires QPAMs to provide a One-Year Transition Period to its client Plans to avoid unnecessary disruptions to Plans that could occur upon a Criminal Conviction or for Participating In Prohibited Misconduct. The Transition Period will help bridge the gap between the QPAM Exemption and the Department's administration of its individual exemption program in connection with Section I(g) ineligibility.

The Department believes the changes to Section I(c) in the Final Amendment are needed to clarify and remind QPAMs and Parties in Interest of the level of involvement Parties in Interest may have in investment decisions and prevent possible abuses of the exemption.

The Final Amendment is also needed to update asset management and equity thresholds to current values in the definition of a ''QPAM'' in Section VI(a). Some of the thresholds that establish the requisite independence upon which the QPAM Exemption is based have not been updated since 1984, and the thresholds for registered investment advisers have not been updated since 2005. The amendment will standardize all the thresholds to current values using the Bureau of Labor Statistics Consumer Price Index (CPI).

Finally, the Final Amendment adds a recordkeeping requirement to ensure QPAMs will be able to demonstrate, and the Department will be able to verify, compliance with the exemption conditions. This requirement is similar to a recordkeeping requirement the Department generally includes in its individual Section I(g) exemptions.

Together, the Department believes the Final Amendment is necessary to ensure the QPAM Exemption remains in the interest of and protective of the rights of Plans and their participants and beneficiaries and IRA owners as required by ERISA section 408(a) and Code section 4975(c)(2).

Affected Entities

The Final Amendment affects financial institutions acting as a QPAM, and client Plans of QPAMs, including their participants and beneficiaries.

Qualified Professional Asset Managers (QPAMs)

As discussed above in this preamble, to qualify as a QPAM, the financial institution must be a bank, savings and loan association, insurance company, or a registered investment adviser that meets specified standards regarding financial size. The financial institution must also acknowledge in a Written Management Agreement (WMA) that it is a fiduciary with respect to each Plan that retains it as a QPAM. Before this Final Amendment, the following entities were able to act as a QPAM under the terms of the exemption:

(1) Banks—as defined in section 202(a)(2) of the Investment Advisers Act of 1940, with equity capital in excess of $1,000,000.

(2) Savings and loan associations—the accounts of which are insured by the Federal Deposit Insurance Corporation, with equity capital or net worth in excess of $1,000,000;

(3) Insurance companies—subject to supervision under state law, with net worth in excess of $1,000,000; and

(4) Investment advisers—registered under the Investment Advisers Act of 1940 with total client assets under management in excess of $85,000,000 and either (1) shareholders' or partners' equity in excess of $1,000,000 or (2) payment of liabilities guaranteed by an affiliate, another entity that could qualify as a QPAM, or a broker-dealer with net worth of more than $1,000,000.

As amended, the thresholds in Section VI(a) will be indexed to the CPI, rounded to the nearest $10,000. The amendment will update these thresholds based on the price inflation since 1984. The increases in thresholds will be phased-in incrementally between 2024 and 2030. This Final Amendment increases the thresholds as follows:

(1) Banks—as defined in section 202(a)(2) of the Investment Advisers Act of 1940, with equity capital in excess of $1,570,300 effective as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

(2) Savings and loan associations—the accounts of which are insured by the Federal Deposit Insurance Corporation, with equity capital or net worth in excess of $1,570,300 as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

(3) Insurance companies—subject to supervision under state law, with net worth in excess of $1,570,300 effective as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

(4) Investment advisers—registered under the Investment Advisers Act of 1940 with total client assets under management in excess of $101,956,000 effective as of the last day of the fiscal year ending no later than December 31, 2004, $118,912,000 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $135,868,000 effective as of the last day of the fiscal year ending no later than December 31, 2030. In addition, the investment adviser must either have shareholders' or partners' equity—or payment of liabilities guaranteed by an affiliate, another entity that could qualify as a QPAM, or a broker-dealer with net worth—in excess of $1,570,300 effective as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

The Department will make subsequent annual adjustments for inflation to the equity capital, net worth, and asset management thresholds, rounded to the nearest $10,000, no later than January 31st of each year by publication of a notice in the **Federal Register**.

QPAMs that met the *prior* thresholds, but that otherwise will not meet the new threshold requirements, will also be

affected by the Final Amendment, because they no longer will be able to rely on the QPAM Exemption.[77] The Department proposed introducing the entire increase at the end of the first year after granting the amendment. However, after considering comments received in response to the Proposed Amendment, the Department decided to implement the increase incrementally over three-year periods, which provides Plans and QPAMs with significantly more time to adjust and prepare if the QPAM is unable to continue meeting the updated thresholds.

Several comments on the Proposed Amendment stated that the Department underestimated the number of QPAMs in the economic analysis for the Proposed Amendment, with one commenter remarking that the actual number of QPAMs was likely 10 to 20 times larger than the Department's original estimate of 616 QPAMs.[78] Another commenter estimated that more than 90 percent of investment managers investing Plan assets rely on the QPAM Exemption. They recommended an alternative estimation methodology that involved multiplying the number of investment managers reported on the Form 5500 Schedule C by 90 percent.[79] This results in an estimate of 3,876 QPAMs.[80] After considering these comments, the Department has revised its estimates as described below.

Multiple QPAMs can exist within the same organizational hierarchy. Accordingly, when estimating the effect of this exemption, the Department focused not on the firm level, but rather at each distinct entity within the organizational hierarchy providing services as a QPAM. For example, multiple subsidiaries under a parent company may act as QPAMs in addition to the parent company itself. The methodology suggested by the commenter would count each subsidiary and the parent company itself as if each were acting as separate QPAMs. Therefore, to estimate the number of QPAMs, the Department identified the number of unique entities that provided investment management services in the 2020 Form 5500 Schedule C dataset.[81] This analysis yielded 5,702 unique investment managers.

Small Plans are not required to file a Schedule C; therefore, in order to account for asset managers used by small Plans, the Department looked at the Form 5500 Schedule C that were voluntarily filed by small Plans. Among the 1,267 small Plans that filed a Schedule C, the Department found 10 unique asset managers that were not used by large Plans. Applying this ratio to the universe of small Plans, the Department estimates that 5,153 additional unique QPAMs may be used by small Plans.[82] The Department believes that this adjustment likely overstates the number of unique asset managers servicing the universe of small Plans because it assumes unique asset managers would continue to be found at the same rate for the entire universe, but the Department is using this estimate to derive a conservative estimate for purposes of this analysis. Therefore, based on the foregoing, the Department estimates that 10,855 unique QPAMs could be affected by the Final Amendment.[83]

Several comments expressed concern that the proposal would decrease the number of entities acting as QPAMs due to the costs and risks associated with the proposed requirements to add penalty-free withdrawal and indemnification provisions for QPAMs that become ineligible due to a Section I(g) triggering event. In response, the Department moved these conditions into the transition provision of the Final Amendment so that only QPAMs that experience an ineligibility trigger will be required to agree to these provisions with their client Plans. Based on this revision, the Department expects that the Final Amendment will not have a significant effect on the number of entities acting as QPAMs.

Plans, Participants, Beneficiaries, and IRA Owners

The Final Amendment will affect Plans whose assets are held by an Investment Fund that is managed by a QPAM. The Department does not collect data on Plans that use QPAMs to manage their assets. In the proposal, the Department estimated that a single QPAM would service, on average, 32 client Plans.[84] A few commenters stated that the Department underestimated the number of Plans that have hired a QPAM. Commenters remarked that investment managers may manage assets for hundreds to thousands of Plans, while one commenter stated that the largest investment managers manage assets for between 2,000 and 4,000 client Plans.[85] Another commenter estimated that the average number of contracts per QPAM is 14,180 with a median of 14,500 based on the number of QPAMs that are members of its association.[86]

In response to these comments, the Department conducted further analysis on QPAM-Plan relationships. In its analysis of the 2020 Form 5500, the Department found that the largest QPAMs can have thousands of client Plans, with the largest having 3,158 clients. However, the average number of client Plans per QPAM was significantly lower. Examining the number of unique QPAM-Plan relationships within the Form 5500 universe, the Department estimates that there are 547,546 client Plans with QPAM relationships, resulting in an average of 50 client Plans per QPAM.[87] Additionally, the Department estimates that 215,135 unique Plans have a relationship with a QPAM.[88]

[77] As noted earlier in this preamble, such QPAMs may submit an individual exemption application requesting relief to continue relying upon the QPAM Exemption.

[78] Comment submitted by SIFMA on 11 October 2022. (*See https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07/00009.pdf*).

[79] Comment submitted by the Seward and Kissel. (*See https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07/00025.pdf*).

[80] In the 2020 Form 5500, the Department identified 4,307 unique investment managers providing services under service code 28 (investment management) to Plans. This is estimated as: $4,307 \times 90\% = 3,876$. As discussed later in this section, small Plans do not file the Form 5500 Schedule C, so relying solely on the Form 5500 Schedule C will likely underestimate the number of QPAMs.

[81] The Department included service providers that were listed under service codes 28 (investment management), 51 (investment management fees paid directly by the plan), or 52 (investment management fees paid indirectly by the plan).

[82] If the ratio of 10 unique providers for 1,267 small Plans is held constant for the whole universe of small plans, then that would indicate a further $(10/1,267) \times 652,934 = 5,153$ additional unique QPAMs used exclusively by small Plans.

[83] The number of unique QPAMs is calculated as: 5,702 QPAMs found on the 2020 Form 5500 Schedule C + 5,153 QPAMs estimated as servicing exclusively small Plans = 10,855 QPAMs.

[84] 87 FR at 45220.

[85] Comment submitted by SIFMA on 11 October 2022. (*See https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07/00009.pdf*).

[86] Comment submitted by the American Bankers Association on 6 January 2023. (*See https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07-2/00142.pdf*).

[87] In the 2020 Form 5500, the Department found 64,216 QPAM relationships amongst a total of 87,559 Plans that filed the Form 5500 Schedule C. To estimate the number of total Plans with QPAM relationships, the Department applies this ratio to the entire Plan universe. This assumption implies that small plans have the same number of relationships with QPAMs as the larger plans that file Schedule C. The number of total Plans with QPAM relationships is estimated as: $(64,216/87,559) \times 746,610 = 547,566$ Plan client relationships. This equates to an average of 50 clients per QPAM, calculated as: 547,566 Plan client relationships/10,855 unique QPAMs = 50.44 Plan clients per QPAM, rounded to 50.

[88] In the 2020 Form 5500, the Department found 25,230 unique plans using QPAMs among amongst a total of 87,559 Plans that filed the Form 5500

While this estimate is larger than the Department's estimate for the Proposed Amendment, it is substantially smaller than the estimates provided by the commenters. The Department believes variance in the estimates is likely due to the definition of Investment Fund in the exemption and the various ways Plans may invest through those funds, including as individual investment options for participant-directed plans. The Department does not have sufficient data to differentiate between single and pooled customer funds and/or whether those funds are provided to different types of plans, such as defined benefit plans or defined contribution plans (including individual account plans).

The Department reiterates that the scope of this exemption, and the unit of analysis, is each distinct legal entity. A firm can have multiple distinct legal entities that all act as QPAMs. The number of clients per entity would be expected to be lower than the number of client Plans per firm. The commenters did not clarify the types of Plans or arrangements they were considering in connection with the estimates they provided.

The definition of ''Plan'' also includes IRAs, and therefore, the Final Amendment also affects IRA owners who hire a discretionary asset manager that is a QPAM or invest in a pooled fund that relies upon a QPAM. In 2020, nearly 65 million U.S. taxpayers had an IRA.[89] A survey of U.S. households conducted by the Investment Company Institute found that approximately half of the households with a traditional IRA consulted a professional financial adviser on how to manage income and assets in retirement.[90] The Department does not have data on the proportion of IRAs that rely on a discretionary asset manager; however, the Department assumes that such relationships are rare or that the involvement of a QPAM is through a pooled investment fund managed on a discretionary basis. The Department did not receive any comments concerning the number of IRA owners that would be affected.

Accounting Table

In accordance with OMB Circular A–4, Table 1 summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action in an accounting statement. The Department is unable to quantify all benefits, costs, and transfers of this Final Amendment but has sought, where possible, to describe qualitatively all non-quantified impacts.

Many of the expected benefits to Plans and their participants and beneficiaries stem from provisions in the Final Amendment that will impose minimal or no costs on QPAMs but will benefit them by providing more certainty, protection, and transitional support, such as the provision clarifying that foreign convictions are included in Section I(g), clarification that QPAMs must not permit other Parties in Interest to make decisions regarding Plan investments under the QPAM's control, and the addition of a One-Year Transition Period for Plans after an ineligibility trigger under Section I(g) has occurred.

TABLE 1—ACCOUNTING STATEMENT

Benefits:

Non-Quantified:

- Ensure the QPAM's integrity is enhanced compared to the regulatory baseline before the Final Amendment, which will protect Plans affected by the exemption better than prior Section I(g).
- Provide more clarity, certainty, protection, and transitional support for client Plans of an ineligible QPAM.
- Update the asset management and equity thresholds to ensure that QPAMs are sufficiently large to be able to withstand improper influence from Parties in Interest.

Costs	Estimate	Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($Million/year)	$1.56	2023	7	2024–2033
	1.44	2023	3	2024–2033

Quantified Costs:

- Quantified costs include rule familiarization, the QPAM's adoption of additional protections after an ineligibility trigger occurs, satisfying the exemption's record-keeping requirements, and individual exemption application costs for entities losing eligibility due to Participating In Prohibited Misconduct.

Non-Quantified Costs:

- QPAMs that become ineligible for Participating In Prohibited Misconduct may incur costs associated with indemnifying their client Plans for ''actual'' losses if they move to a new asset manager.
- Some Plans may incur costs if they conduct a request for proposal sooner than they otherwise would have if their asset manager no longer qualified as a QPAM due to the updated equity and asset thresholds in the Final Amendment.

Transfers:

Non-Quantified:

- Client Plans of ineligible QPAMs may choose to transfer assets and revenue away from the ineligible asset managers to its competitors when a QPAM becomes ineligible due to occurrence of a Section I(g) triggering event.

Benefits

The new and amended conditions will benefit Plans and their participants and beneficiaries by providing more clarity, certainty, protection, and transitional support. The heightened standards in this Final Amendment may result in entities being more careful about ensuring that their compliance programs are sufficiently robust to prevent Prohibited Misconduct or Criminal Convictions from occurring. In this respect, the exemption would provide clear guardrails that would make the costs associated with QPAMs

Schedule C. To estimate the number of total Plans with QPAM relationships, the Department applies this ratio to the entire Plan universe. This assumption implies that small plans use QPAMs at the same rate as the larger plans that file Schedule C. the number of unique plans using QPAMs is estimated as (25,230/87,559) × 746,610 = 215,135.

[89] Internal Revenue Service. ''SOI Tax Stats—Accumulation and distribution of Individual Retirement Arrangements (IRA).'' Table 1. (2020). *https://www.irs.gov/statistics/soi-tax-stats-accumulation-and-distribution-of-individual-retirement-arrangements.*

[90] The study found that 67 percent of traditional IRA-owning households have a strategy for managing income and asset in retirement and that 77 percent of those households consulted with a professional financial advisor on how to manage income and assets. The percent of IRA-owning households that consulted with a professional financial advisor is estimated as: 67% × 77% = 52%. (*See* Investment Company Institute. ''The Role of IRAs in US Households' Saving for Retirement, 2022.'' *ICI Research Perspective:* Vol. 29, No. 1. (February 2023). *https://www.ici.org/system/files/2023-02/per29-01_0.pdf.*)

becoming ineligible clearly avoidable. The specific benefits expected to result from the rulemaking are discussed below.

Ineligibility Due to Foreign Criminal Convictions—Subsection I(g)(1)(A) and Subsection VI(r)(2)

One of the primary underlying principles of the QPAM Exemption is that any entity acting as a QPAM, or that is in a position to influence a QPAM's policies, should maintain a high standard of integrity.[91] This principle is called into question when a QPAM, or an entity that may be in a position to influence its policies, is convicted of certain crimes. With this concern in mind, the Department makes entities ineligible for the prohibited transaction relief in the QPAM Exemption as of the date of the trial court judgment for any of the crimes listed in Section VI(r).[92]

The baseline version of the exemption did not explicitly address foreign convictions. Since the initial grant of the QPAM Exemption, the Department has granted ten individual exemption requests from QPAM applicants in connection with a foreign conviction, the first being in 2000.[93] The amended exemption directly references foreign-equivalent crimes, clarifying that a conviction ''by a foreign court of competent jurisdiction or released from imprisonment, whichever is later, as a result of a crime, however denominated by the laws of the relevant foreign government'' will be considered a Criminal Conviction for purposes of ineligibility under Section I(g).

The Department believes this clarification in the Final Amendment aligns the QPAM Exemption with the realities of modern investment practices engaged in by many Plans. Further, it removes all doubt that foreign-equivalent crimes are a basis for ineligibility, providing necessary protections for Plans as required by ERISA section 408(a) and Code section 4975(c)(2). This ultimately provides a benefit to a QPAM's client Plans and their participants and beneficiaries that rely upon QPAMs that are owned by or affiliated with entities operating in foreign jurisdictions by not depriving them of the protection provided by the amendment to this exemption, particularly including the indemnification and penalty-free withdrawal conditions in the Transition Period provisions.

Ineligibility Due to Participating In Prohibited Misconduct—Subsection I(g)(1)(B) and Section VI(s)[94]

To reinforce the Department's premise regarding the integrity standard, the Department is expanding the circumstances that lead to ineligibility. The Final Amendment extends ineligibility under Section I(g)(1)(B) to include QPAMs and their Affiliates and owners of a five (5) percent or more interest that ''Participate In'' Prohibited Misconduct. A more in-depth discussion on how the Department narrowed the scope of entities whose ''Prohibited Misconduct'' could lead to ineligibility in the Final Amendment is provided in an earlier section of this preamble.

This extension of Section I(g) ineligibility will strengthen the protections to Plans and their participants and beneficiaries that rely upon QPAMs. The unamended exemption leaves Plans and their participants and beneficiaries vulnerable to the activities of corporate families with significant compliance failures that pose equal risk of loss to Plan assets. Additionally, the Department expects that this Final Amendment will prevent unfair and unequal treatment of entities and corporate families that have a record of engaging in malfeasance that ultimately may not result in a Criminal Conviction.

Mandatory One-Year Transition Period—Section I(i)

Under the previous and amended text of Section I(g), the immediate ineligibility of a QPAM upon a judgment of conviction may expose Plans to potential costs and losses without the necessary time to make alternative investment arrangements. Before this Final Amendment, the only way to avoid immediate ineligibility after a conviction was for the QPAM to submit an individual exemption application to the Department requesting relief to continue relying upon the QPAM Exemption. The QPAM's client Plans had no additional protections under the baseline version of the exemption to address the immediate loss of the QPAM Exemption.

The Transition Period included in the Final Amendment is designed to benefit client Plans by guarantying transitional relief and protections if they decide to wind-down their arrangements with a QPAM that becomes ineligible. The Transition Period ensures that responsible Plan fiduciaries have the time and ability to choose an alternative discretionary asset manager or investment strategy without incurring undue costs. If Plan fiduciaries decide to retain an ineligible QPAM as a discretionary asset manager, the One-Year Transition Period will provide Plan fiduciaries with time to determine and prepare for any changes that may become necessary for Plan investments.

Additionally, the Transition Period benefits QPAMs by providing additional time for them to request an individual exemption from the Department. This will allow QPAMs to communicate with and assist their client Plans in determining an appropriate path forward for the management of Plan assets consistent with their applicable fiduciary obligations.

Requesting an Individual Exemption—Section I(j)

In addition to providing more certainty to QPAMs and Plans, the Final Amendment also requires QPAMs that seek individual exemption relief to review the Department's most recently granted individual exemptions with the expectation that similar conditions will be required if an exemption is proposed and granted. If an applicant requests the Department to exclude any term or condition from its exemption that is included in a recently issued similar individual exemption, the applicant must accompany such request with a detailed explanation of the reason such change is necessary, in the interest of, and protective of the Plans and their participants and beneficiaries. Applicants also should provide detailed information in their applications quantifying the specific cost in dollar amounts, if any, of the harms Plans would suffer if a QPAM could not rely on the exemption after the Transition Period.

Currently, the Department requests such information from an applicant if it does not include such information in its exemption application requesting extended relief under the QPAM Exemption when the QPAM becomes ineligible. Therefore, this provision will streamline the application process and reduce costs because there will be fewer back-and-forth discussions between the Department and the applicant.

[91] 47 FR at 56947.

[92] Criminal Conviction as defined in Section VI(r) of this Final Amendment.

[93] *See* Prohibited Transaction Exemption (PTE) 2023–13, 88 FR 26336 (Apr. 28, 2023); PTE 2020–01, 85 FR 8020 (Feb. 12, 2020); PTE 2019–01, 84 FR 6163 (Feb. 26, 2019); PTE 2016–11, 81 FR 75150 (Oct. 28, 2016); PTE 2016–10, 81 FR 75147 (Oct. 28, 2016); PTE 2012–08, 77 FR 19344 (March 30, 2012); PTE 2004–13, 69 FR 54812 (Sept. 10, 2004); and PTE 96–62 (''EXPRO'') Final Authorization Numbers 2003–10E, 2001–02E, and 2000–30E, *See https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/exemptions/expro-exemptions-under-pte-96-62.*

[94] Subsection I(g)(1) was proposed as subsection I(g)(3).

Involvement in Investment Decisions by Parties in Interest—Section I(c)

The modification to the language in Section I(c) will benefit Plans and their participants and beneficiaries by ensuring that the Plan is not engaging in harmful prohibited transactions that are orchestrated by a Party in Interest. The Department understands that some Plan fiduciaries, in conjunction with hiring a QPAM, may be engaging in abuses of the exemption. The amended language will help ensure that Plans, their participants and beneficiaries, and IRA owners are not exposed to conflicts of interest that the QPAM Exemption was not designed to address and for which the Department should not provide prohibited transaction relief.

Asset Management and Equity Thresholds—Section VI(a)

As discussed earlier in this document, the Final Amendment updates the asset management and equity thresholds in the exemption's definition of the entities that are eligible to act as a QPAM to account for inflation as measured by the CPI. After an initial phase-in, the thresholds will be updated on an annual basis according to the CPI.

A few commenters expressed concern that the Department did not provide evidence in the Proposed Amendment to support the increase in size thresholds and that the increased thresholds may create a high barrier to entry for financial institutions providing QPAM services. In proposing this update, the Department considered its original intent when granting the QPAM Exemption. The exemption was based on the premise that an asset manager of a certain size would be large enough to withstand improper influence from Parties in Interest (*i.e.,* maintain independence). Between March 1984, when the exemption was published, and April 2023, the CPI increased by 194.4 percent. During this period, the Department did not increase the equity thresholds for banks, savings and loan associations, and insurance companies. The asset management and equity thresholds for registered investment advisers were increased only once during this period.

The Department maintains that while some entities may no longer be able to satisfy the updated asset management and/or equity thresholds, this Final Amendment is necessary for the Department to continue to ensure that QPAMs are indeed large enough to maintain their independence. This change will enhance the protections to Plans and their participants and beneficiaries relying on a QPAM.

Costs

This analysis estimates the additional cost incurred by affected entities because of the Final Amendment. The Department recognizes that financial institutions providing QPAM services are already required to comply with certain regulatory requirements in addition to the conditions to qualify for exemptive relief under the QPAM Exemption, such as those outlined by ERISA's fiduciary duty requirements to the extent applicable, or an individual exemption granted in connection with Section I(g) ineligibility. The Department considers these requirements to be the regulatory baseline. The following analysis considers only the additional costs imposed by the Final Amendment.

The Department estimates that the Final Amendment will impose total costs of $6.8 million in the first year and $0.8 million in each subsequent year. Over 10 years, the costs associated with the amendment will total approximately $11.0 million, annualized to $1.6 million per year (using a seven percent discount rate).[95]

Preliminary Assumptions and Cost Estimate Inputs

The Department assumes that different types of personnel will be responsible for satisfying the requirements in the Final Amendment. To account for the labor costs associated with different types of personnel, the Department estimates the hourly labor costs for each type of personnel. In the analysis below the Department applies the hourly labor costs of $63.45 for clerical personnel, $159.34 for internal legal professionals, $190.63 for financial managers, and $535.85 for outside legal professionals.[96]

The Final Amendment requires QPAMs to distribute various notices to client Plans after an ineligibility trigger, as described below. The Department does not have sufficient data to estimate how many QPAMs will elect to send such notices electronically or by mail. For the purposes of this analysis, the Department estimates that 80 percent of these notices will be delivered by first-class mail at a first-class mail postage rate of $0.68.[97]

Costs Incurred by All QPAMs

The following analysis considers the marginal costs of the amendments on all financial institutions acting as QPAMs. As discussed in the Affected Entities section, the Department estimates that 10,855 financial institutions act as QPAMs and rely on the QPAM Exemption.

Rule Familiarization Costs

The Department expects that QPAMs are likely to rely on outside specialized legal counsel to ensure compliance with the Final Amendment. The specialized legal counsel likely will review the amendment and present updates to multiple clients. On average, the Department estimates that each QPAM will incur a cost equivalent to the cost of consulting with an outside legal professional for one hour. This results in an equivalent cost estimate of $5.82 million in the first year.[98]

Reporting Reliance on the QPAM Exemption—Section I(k)

Section I(k) of the Final Amendment will require QPAMs to report their reliance on the QPAM Exemption by emailing the Department at *QPAM@dol.gov.* The email must include the legal name of the entity and any name the QPAM may be operating under. This one-time cost is expected to result in a minor clerical cost for QPAMs. The Department estimates drafting and sending the email will take a clerical worker employed by each QPAM 15 minutes, on average, resulting in an estimated cost of $0.17 million in the first year.[99] In subsequent years, new QPAMs or QPAMs that change their name will be required to send the notification. The Department does not have data on how many QPAMs will be required to send this notification in subsequent years. For the purposes of this analysis, the Department assumes

[95] The costs would be $12.3 million over a 10-year period, annualized to $1.4 million per year using a three percent discount rate.

[96] Labor costs for clerical personnel, accountants or auditors, internal legal professionals, and financial managers are based off internal Department of Labor calculations based on 2023 labor cost data. For a description of the Department's methodology for calculating wage rates, see *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.* Labor costs for outside legal professionals is calculated as a composite weighted average based on the Laffey Matrix for Wage Rates for the time period 6/01/2022–5/31/2023, *see http://www.laffeymatrix.com/see.html.* The labor cost is estimated as: (40% × $413) + (35% × $508) + (15% × $733) + (10% × $829) = $535.85.

[97] USPS. ''Mailing & Shipping Prices.'' (2024). *https://www.usps.com/business/prices.htm.*

[98] The hour burden is estimated as: 10,855 QPAMs × 1 hour = 10,855 hours. The labor cost of $535.85 is applied for an external legal professional. The equivalent cost is estimated as: 10,855 hours × $535.85 = $5,816,652, rounded to $5.82 million.

[99] The hour burden is estimated as: 10,855 QPAMs × 15 minutes = 2,713.75 hours. The labor cost of $63.45 is applied for a clerical worker. The equivalent cost is estimated as: 10,855 QPAMs × 15 minutes × $63.45 = $172,187, rounded to $0.17 million.

that one percent of QPAMs, or 109 QPAMs, will either be new or have a name change.[100] Accordingly, the reporting requirement is estimated to total 27.3 hours with an equivalent cost of $1,729.[101]

If a QPAM fails to report its reliance on the exemption within 90 days, the QPAM must send a notice to the Department within an additional 90 days that includes its reliance on the exemption or name change and explains the reason(s) for its failure to provide notice. The Department does not have sufficient information to determine the percentage of QPAMs that are likely to fail to report reliance. For the purposes of this analysis, the Department estimates that two percent of QPAMs, or 217 QPAMs in the first year and two QPAMs in subsequent years will fail to report reliance.[102] The Department estimates that preparing the notice will require a legal professional to spend 30 minutes. Based on the foregoing, the Department estimates that the burden is 108.5 hours with an equivalent cost of approximately $17,288 in the first year[103] and one hour with an equivalent cost of approximately $159 in subsequent years.[104] The cost for a clerical professional to draft and send an email notifying the Department of its reliance or name change is included in the cost estimate of sending notice of reliance above.

Recordkeeping—Section VI(u)

Under this new provision, QPAMs will be required to maintain records sufficient to determine whether the conditions of the exemption have been met for a given transaction. QPAMs also will be required to make those records available to the persons identified in Subsection VI(u)(2) for six years. If a QPAM refuses to disclose information to any of the parties listed in Section VI(u) on the basis that information is exempt from disclosure, the QPAM must provide a written notice advising the requestor of the reason for the refusal and that the Department may request such information.

In the Proposed Amendment, the Department posited that QPAMs, as fiduciaries, already maintain records as part of their regular business practices consistent with this requirement. Further, the Department stated that the recordkeeping requirement corresponds to the six-year retention requirement in ERISA section 107. Therefore, the Department estimated that the recordkeeping requirement would impose a negligible burden, because most QPAMs already are maintaining records in accordance with the proposed amendment's recordkeeping requirement.[105]

The Department received several comments that the Department underestimated the cost associated with the recordkeeping requirement in the economic analysis for the Proposed Amendment. Several commenters expressed concern that the requirements in the Proposed Amendment were vague or confusing. In response to these comments, the Department has provided additional guidance on recordkeeping earlier in this preamble to alleviate potential confusion. The additional guidance clarifies that recordkeeping should be based on a ''facts and circumstances'' test. After further consideration, the Department maintains that these requirements are consistent with common business practices for entities relying on the QPAM Exemption.

The Department recognizes that some QPAMs may not be maintaining records that satisfy the requirements of the Final Amendment and accordingly will experience higher marginal costs to comply with this requirement. However, the Department expects that most QPAMs are already fully compliant. The Department estimates that, on average, the additional recordkeeping requirement will require clerical personnel at a QPAM to spend one hour annually resulting in an estimated equivalent cost of approximately $689,000.[106]

The Department does not have data on how often a QPAM might refuse to disclose information to any of the parties listed in Section VI(u); however, the Department believes such instances will be rare. The Department did not receive comments on the frequency or the costs. For the purposes of this analysis, the Department estimates that two percent of QPAMs, or 217 QPAMs, will refuse to disclose requested information annually. The Department estimates that drafting a written notice advising the requestor of the reason for the refusal and that the Department may request such information will require an internal legal professional to spend one hour, which results in an estimated equivalent cost of approximately $35,000.[107]

Additionally, some commenters expressed concern that this requirement would lead to heightened litigation risk from those who request the records, which would further increase costs for QPAMs. This concern fails to account for the fact that a QPAM is a fiduciary with obligations to its client Plans, including their participants and beneficiaries. The Department has included a similar recordkeeping requirement in many administrative prohibited transaction exemptions and is not aware that such requirements have resulted in increased litigation for those entities subject to the requirements. Commenters did not provide data or estimates of the direct cost that might be associated with the purported increased litigation risk. Therefore, the Department believes that such cost will be minimal or nonexistent when compared to the baseline litigation risk associated with being a fiduciary asset manager.

Involvement in Investment Decisions by Parties in Interest—Section I(c)

The Department anticipates that the modifications to Section I(c) will not change the costs of the exemption compared to cost of the baseline QPAM Exemption because the types of transactions that were intended to be excluded by previous Section I(c) are the same types of transactions intended to be excluded by modified Section I(c).

Costs Incurred by QPAMs Losing Eligibility for the Exemption for a Criminal Conviction or Prohibited Misconduct

According to past QPAM Section I(g) individual exemption applicants, the QPAM Exemption serves as one of the most advantageous exemptions for financial institutions that are involved with discretionary asset management. Even if other exemptions are available, financial institutions may seek QPAM

[100] The number of QPAMs is estimated as: 10,855 QPAMs × 1% = 108.6, rounded to 109.

[101] The hour burden is estimated as: 109 QPAMs × 15 minutes = 27.3 hours. The labor cost of $63.45 is applied for a clerical worker. The equivalent cost is estimated as: 109 QPAMs × 15 minutes × $63.45 = $1,729.

[102] The number of QPAMs in the first year is estimated as: 10,855 × 2% = 217.1, rounded to 217. The number of QPAMs in subsequent years is estimated as: 109 QPAMs × 2% = 2.2, rounded to 2.

[103] The number of QPAMs in the first year is 217. The labor cost of $159.34 is applied for an internal legal professional. The equivalent cost is estimated as: 217 QPAMs × 0.5 hours × $159.34 = $17,288, rounded to $17,000.

[104] The hour burden is estimated as: 2 QPAMs × 0.5 hour = 1 hour. The labor cost of $159.34 is applied for an internal legal professional. The equivalent cost is estimated as: 1 hour × $159.34 = $159.34, rounded to $159.

[105] 87 FR at 45224.

[106] The hour burden is estimated as: 10,855 QPAMs × 1 hour = 688,750 hours. The labor cost of $63.45 is applied for clerical personnel. The equivalent cost is estimated as: 10,855 QPAMs × 1 hour × $63.45 = $688,750, rounded to $689,000.

[107] The number of QPAMs is estimated as 10,855 × 2% = 217 QPAMs. The hour burden is estimated as: 217 QPAMs × 1 hour = 217 hours. The labor cost of $159.34 is applied for a legal professional. The equivalent cost is estimated as: 217 QPAMs × 1 hour × $159.34 = $34,577, rounded to $35,000.

status to mitigate risk of exposure to excise taxes under Code sections 4975(a) and (b) for engaging in non-exempt prohibited transactions if they fail to meet the conditions of those exemptions.

Financial Institutions also use QPAM status to attract and maintain client Plans. Although a QPAM that fails to satisfy Section I(g) may continue to operate as an asset manager for Plans, the Department understands that some entities use QPAM status as an indicator of size and/or sophistication to potential client Plans. According to past individual exemption applicants, if an entity is no longer able to represent that it is a QPAM, Plans are less likely to retain the QPAM as their manager, even in situations where the client technically does not need the relief provided by the exemption.

The loss of eligibility for the QPAM Exemption may create perceived or actual costs in the form of lost opportunities for the financial institution. The costs associated with the loss of reliance on the QPAM Exemption are not added costs imposed by this Final Amendment, but rather costs attributable to the criminal behavior of a QPAM or its Affiliate or owner of a five (5) percent or more interest. Such costs are not considered as part of this analysis, which only considers costs that are directly imposed by this amendment.

Estimate of the Number of Financial Institutions Experiencing Ineligibility Due to a Criminal Conviction or Prohibited Misconduct

The Department believes the individual exemptions granted in the past provide the best basis for estimating how many QPAMs will experience an ineligibility trigger in the future. The Department only has data on the number of QPAMs covered by each individual exemption since 2013. As shown in Table 2 below, the Department granted individual exemptions to 65 QPAMs facing ineligibility under current Section I(g) in connection with 14 separate convictions or possible convictions.[108]

The number of QPAMs affected in any given year is a function of the number of convictions covered by Section I(g) and the number of entities within a corporate family operating as QPAMs. As shown by past experience, this number is likely to fluctuate between years. Based on the experience shown in Table 2, the Department estimates that, on average, eight QPAMs each year will lose eligibility due to a Criminal Conviction.[109] As this is an average, the number of affected QPAMs impacted by ineligibility due to a Criminal Conviction could be higher than eight in some years and lower than eight in others.

TABLE 2—PAST CONVICTIONS AND AFFECTED QPAMS*

	Number of convictions	Number of affected QPAMs
2013	1	4
2014	1	3
2015	1	20
2016	6	25
2017	.....	.....
2018	.....	.....
2019	.....	.....
2020	.....	.....
2021	1	13
Total	10	65
Average	1.1	7.2
Estimated Yearly Average** (rounded)	2	8

*The average number of affected QPAMs includes zeros for years without convictions, 2017 through 2020.
**The corresponding calculated averages include decimals; therefore, to err on the side of caution and inclusion the estimated yearly average is rounded to the upper integer.

The Department's expansion of the ineligibility provision to include Prohibited Misconduct under Subsection I(g)(1)(B) and Section VI(s) will likely increase the number of QPAMs that become ineligible under Section I(g). For the Proposed Amendment, the Department estimated that eight additional QPAMs each year would experience ineligibility due to the Prohibited Misconduct provisions, which equals the average annual number of QPAMs that have experienced ineligibility due to a Criminal Conviction. The Final Amendment reduced the scope of entities whose Prohibited Misconduct could cause ineligibility for a QPAM as compared to the Proposed Amendment and as discussed in more detail in an earlier section of the preamble. The Department does not have sufficient data to determine the exact number of QPAMs that will become ineligible due to this change. For the purposes of this analysis, the Department assumes four additional QPAMs will become ineligible.[110]

The Final Amendment also clarifies that Section I(g) applies to foreign

[108] Ineligible QPAMs that request individual exemptions generally request relief for the entire ten-year ineligibility period. However, to engage in a thorough fact-finding process and to verify compliance with certain audit provisions in the individual exemptions, the Department has granted exemptions that include less than ten years of relief in many situations. Ineligible QPAMs then typically apply for an extension of relief even though no additional conviction has occurred. Additionally, in situations where an ineligible QPAM is impacted by a subsequent conviction before the expiration of the ten-year ineligibility period for the initial conviction, the Transition Period would also not be implicated, so there is no additional cost burden associated with subsequent convictions. There was a total of three subsequent convictions after an initial conviction for some entities in 2017, 2018, and 2019.

[109] The Department did not include in this estimate any of the possible QPAMs that have remote relationships with a convicted entity that are identified in the individual exemptions as ''Related QPAMs.'' The Department has never received comments, questions, requests for guidance, or separate individual exemption applications from any entities that would fall into that definition, and therefore, assumes such entities are not operating as QPAMs.

[110] Due to the reduced scope of entities captured by Participating In Prohibited Misconduct, the Department lowered the estimate to four as compared to the estimate of eight in the Proposed Amendment.

convictions that are substantially equivalent to U.S. federal or state crimes that are enumerated in Section I(g) of the exemption. The Department and QPAMs have treated foreign convictions as causing ineligibility under Section I(g) since at least 2000.[111] Therefore, the Department believes that the clarifying reference that includes foreign convictions within the scope of Section I(g) will not change the number of financial institutions losing eligibility.

In total, the Department estimates that 12 QPAMs, on average, will become ineligible due to a Criminal Conviction or Prohibited Misconduct annually. The Department received a few comments confirming that the expansion of ineligibility would increase the number of financial institutions that would lose eligibility; however, the comments did not provide data that directly address the Department's estimates.

Notice to the Department of Prohibited Misconduct or Foreign NPA or DPA of the QPAM and Its Affiliates or Owners

The Department is including a requirement in this Final Amendment that whenever a QPAM, its Affiliates, or owners of a five (5) percent or more interest Participates In Prohibited Misconduct or executes a foreign NPA or DPA, they must notify the Department at *QPAM@dol.gov*. The Department does not have sufficient data to estimate how frequently such Prohibited Misconduct would occur, but the Department assumes it will occur infrequently. For the purposes of this analysis, the Department assumes that four instances of Prohibited Misconduct each year will require such a notice, at a cost of approximately $300.[112]

Mandatory One-Year Transition Period—Section I(i)

The amendment includes a mandatory One-Year Transition Period that the QPAM must provide to its client Plans that begins on the Ineligibility Date. During this period, relief under the QPAM Exemption would only be available for existing client Plans of the QPAM. The Department modeled the Transition Period provisions from the conditions included in the Department's recent individual Section I(g) exemptions.

This Final Amendment does not include the provisions from the Proposed Amendment that would have prevented QPAMs from engaging in new transactions on behalf of existing client Plans during the Transition Period. The Department has not included a similar requirement in past one-year QPAM individual exemptions it has issued, and several commenters expressed concern that this provision would be harmful to Plans that rely on QPAMs. After considering these comments, the Department has removed this restriction in the Final Amendment.

As amended, the Department expects that QPAMs will not incur increased costs as a result of a Criminal Conviction due to the Transition Period provisions because these costs would be equivalent to the costs incurred by QPAMs who have obtained an individual exemption that includes similar conditions. However, an increased cost will be associated with the expansion of the ineligibility provisions. As discussed above, the Department estimates that four additional QPAMs will become ineligible each year due to Participating In Prohibited Misconduct.

Notice to Plans—Subsection I(i)(1)

Within 30 days of the Ineligibility Date, the QPAM must provide notice to the Department and each of its client Plans. The preamble provides more detail regarding the information the QPAM is required to include in this notice.

QPAMs that experience ineligibility and apply for individual exemption relief already are required to provide this type of notice, therefore, the Department is not attributing an incremental burden to this requirement. However, due to the expanded scope of ineligibility, QPAMs that become ineligible due to Participating In Prohibited Misconduct will incur the cost of sending notices to their client Plans.

As discussed in the Affected Entities section above, the Department estimates that each QPAM provides discretionary asset management services to an average of 50 Plans. The Department estimates that a legal professional at each QPAM will spend, on average, 30 minutes preparing the notice, and clerical personnel will spend two minutes preparing each notice to be sent to a Plan by mail, resulting in an equivalent labor cost of approximately $700.[113] Additionally, the Department assumes that notices sent by mail will require two pages of paper each, resulting in a material and postage cost of approximately $100.[114]

The Department believes the cost of sending this notice to the Department will be negligible because the QPAM will have already prepared and sent the notice to client Plans, and the notice to the Department is required to be submitted electronically.

Indemnification

As discussed above, QPAMs will be required to indemnify, hold harmless, and promptly restore actual losses to each client Plan for any damages directly resulting from a QPAM losing eligibility for the exemption due to a Criminal Conviction or Prohibited Misconduct. Damages may include losses and related costs arising from unwinding transactions with third parties and transitioning Plan assets to an alternative asset manager.

When the Department has granted individual exemptions for Section I(g) ineligibility, it has included these additional protections and required QPAMs to ensure that Plans are permitted to withdraw from their asset management arrangement with an ineligible QPAM without penalty and be indemnified and held harmless in the event of future misconduct. Accordingly, the Department has not attributed any incremental burden to this requirement.

However, due to the expanded scope of ineligibility, QPAMs that become ineligible as a result of Participating In Prohibited Misconduct may incur costs associated with indemnifying their client Plans for losses that would occur if they moved to a new asset manager. In the proposal, the Department requested comments on the cost of the indemnification provision. The Department received several comments asserting that the indemnity obligation

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[111] *See* Prohibited Transaction Exemption (PTE) 2023–13, 88 FR 26336 (Apr. 28, 2023); PTE 2020–01, 85 FR 8020 (Feb. 12, 2020); PTE 2019–01, 84 FR 6163 (Feb. 26, 2019); PTE 2016–11, 81 FR 75150 (Oct. 28, 2016); PTE 2016–10, 81 FR 75147 (Oct. 28, 2016); PTE 2012–08, 77 FR 19344 (March 30, 2012); PTE 2004–13, 69 FR 54812 (Sept. 10, 2004); and PTE 96–62 (''EXPRO'') Final Authorization Numbers 2003–10E, 2001–02E, and 2000–30E, *See https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/exemptions/expro-exemptions-under-pte-96-62.*

[112] The Department estimates that preparing and sending each notice will require an in-house legal professional 30 minutes and a clerical staff 5 minutes. The hour burden is estimated as: 4 notices × (30 minutes + 5 minutes) = 2 hour and 20 minutes. The labor cost of $159.34 is applied for an in-house legal professional, and a labor cost of $63.45 is applied for clerical staff. The equivalent cost is estimated as: 4 notices × [(30 minutes × $159.34) + (5 minutes × $63.45)] = $324, rounded to $300.

[113] The hour burden is estimated as: (4 QPAMs × 0.5 hours of professional legal time) + (4 QPAMs × 50 Plans × 80% of notices being mailed × 2/60 hours of clerical personnel time) = 7.3 hours. The labor cost of $159.34 is applied for a legal professional, and the labor cost of $63.45 is applied for clerical personnel. The equivalent cost is estimated as: (4 QPAMs × 0.5 hours of professional legal time × $159.34) + (4 QPAMs × 50 Plans × 80% of notices being mailed × 2/60 hours of clerical personnel time × $63.45) = $657, rounded to $700.

[114] The material and postage cost are estimated as: (4 QPAMs × 50 Plans × 80% of notices being mailed) × [(2 pages × $0.05 per page) + $0.68] = $124, rounded to $100.

will increase the risk and cost associated with being a QPAM, and that these costs will be passed onto Plans in the form of higher fees. The Department did not receive any comments providing data directly addressing the amount of the cost for indemnification.[115]

Costs Incurred by QPAMs Requesting an Individual Exemption—Section I(j)

The Final Amendment retains Section I(j)[116] from the Proposed Amendment, which provides that a QPAM that is ineligible or anticipates that it will become ineligible may apply for an individual exemption from the Department. This individual exemption would allow the QPAM to continue relying on the relief provided in the QPAM Exemption for a longer period than the One-Year Transition Period.

Costs for all QPAMs Seeking an Individual Exemption

The Department estimates that, on average, three individual exemption applications will be submitted to the Department each year. The Department estimates that four QPAMs annually will be covered by each exemption application (12 QPAMs total; with four losing eligibility due to Prohibited Misconduct and eight losing eligibility due to a Criminal Conviction). The Final Amendment instructs applicants that apply for an individual exemption to provide the Department with detailed information quantifying the cost of the harm, if any, its client Plans would suffer if a QPAM could not rely on the QPAM Exemption after the Transition Period. Section I(j) also instructs all applicants to include in their exemption applications the specific dollar amounts of investment losses resulting from foregone investment opportunities that would result from ineligibility and any evidence supporting the proposition that investment opportunities will only be available to client Plans on less advantageous terms. For this requirement, the Department assumes a financial professional will spend four hours preparing this supporting information. Therefore, the Department estimates that for the three applications covering the estimated 12 QPAMs losing eligibility annually, the cost associated with the additional requirement will be approximately $2,300.[117]

Finally, Section I(j) of the Final Amendment provides that if an applicant would like to request the Department to exclude any term or condition from its individual exemption that is included in a recently granted individual exemption, the applicant must provide a detailed statement explaining why the variation is necessary and in the interest of and protective of affected Plans, their participants and beneficiaries, and IRA owners. The Department expects QPAMs that become ineligible due to a Criminal Conviction already will conduct this analysis and thus would not incur incremental costs. Alternatively, if this information is not included in an application, the Department will generally require it before proceeding with a final determination regarding the exemption request.

The Department assumes the four QPAMs that are estimated to become ineligible due to Participating In Prohibited Misconduct would incur incremental costs due to the requirement to review the Department's most recently granted individual exemptions involving Section I(g) ineligibility. To satisfy the requirement, the Department estimates that an outside legal professional will spend three hours drafting this addition to the individual exemption application. Preparing an individual exemption application is specialized work, and the Department assumes that most legal professionals that are retained by QPAMs will have prior experience. Based on the foregoing, the Department estimates that the costs associated with the additional requirement totals approximately $1,600 for the application covering the four ineligible QPAMs due to Participating In Prohibited Misconduct.[118]

Costs for QPAMs That Become Ineligible Due to Prohibited Misconduct

In the Final Amendment, the Department expanded the scope of ineligibility to include Participating In Prohibited Misconduct. This provision could cause additional financial institutions to lose eligibility for the QPAM Exemption and may require them to incur the additional costs associated with preparing and filing an exemption application with the Department.

In the Proposed Amendment, the Department estimated that two additional applicants each year would apply for an individual exemption, each covering four ineligible QPAMs, resulting in a total cost of approximately $30,000,[119] or a per-application cost of approximately $15,000. The Department received one comment stating that the Department underestimated this cost, and that provided an alternative estimate that the cost for filing an individual exemption will total between $250,000 and $500,000.[120] This commenter did not support its estimates with specific information detailing how the cost estimate was derived. However, after considering the comment, the Department has revised its estimate as discussed below.

The Department has limited information on the process for preparing an exemption application. Based on the applications received, the Department believes that each QPAM affected may need to dedicate clerical and in-house legal time to gather information for the application. For this Final Amendment, the Department estimates that gathering the information for the application will require, on average, an in-house legal professional and clerical personnel each to spend 20 hours gathering and preparing information for the application. The Department assumes that the formal exemption application will be prepared by an outside legal professional specializing in such matters who will spend 15 hours, on average, preparing the application. For the four QPAMs becoming ineligible due to Participating In Prohibited Misconduct, the Department estimates that this provision will result in an estimated cost of approximately $26,000.[121]

[115] The Department received several comments addressing the specific costs associated with amending WMAs, as required under the Proposed Amendment. These costs did not directly address indemnification costs but rather contract negotiation and updating the WMAs. The Department moved the proposed requirements for the WMA into the Transition Period provisions in response to commenters and believes the cost to ineligible QPAMs regarding this will generally be captured within the required notices to client Plans after an ineligibility trigger.

[116] Proposed Section I(k) has been redesignated as Section I(j) in the Final Amendment.

[117] The hour burden is estimated as: 3 applications × 4 hours = 12 hours. At an hourly rate of $190.63 is applied for financial professional. The equivalent cost is estimated as: (3 applications × 4 hours × $190.63 financial professional rate) = $2,288, rounded to $2,300.

[118] The hour burden is estimated as: (1 application × 3 hours) = 3 hours. A labor cost of $535.85 is applied for an outside legal professional. The equivalent cost is estimated as: (1 application × 3 hours × $535.85 outside legal professional labor) = $1,608 rounded to $1,600.

[119] 87 FR 45204, pp. 45220.

[120] Comment submitted by SIFMA on 11 October 2022. (*See https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07/00009.pdf*).

[121] The hour burden is estimated as: [4 QPAMs × (20 hours from an in-house legal professional + 20 hours for clerical personnel)] + (1 application × 15 hours from an external legal professional) = 175 hours. The labor cost of $159.34 is applied for an in-house legal professional, a labor cost of $63.45 is applied for clerical personnel, and a labor cost of $535.85 is applied for an outside legal professional. The equivalent cost is estimated as: (4 QPAMs × 20 hours × $159.34) + (4 QPAMs × 20

Continued

While this estimate is higher than the Department's estimate in the Proposed Amendment, it is significantly lower than the estimate provided by the commenter. As previously stated, the commenter did not elaborate on the methodology it used to derive its cost estimate. The Department's analysis only includes the costs directly associated with preparing documentation for the application and preparing the application itself.[122] Additionally, the commenter did not elaborate on the type of entity that would be requesting exemptive relief. Applications may vary in complexity, depending on the nature of the Prohibited Misconduct and the number of QPAMs affected. The Department believes that its updated estimate for the Final Amendment reflects a fair representation of the cost to prepare an exemption application in a typical scenario.

Applicants that receive a final granted individual exemption must prepare and distribute a notice to interested parties. Similarly, each of the four QPAMs will be required to send an objective description of the facts and circumstances upon which the misconduct is based to each client Plan. The Department estimates that approximately 200 notices will be distributed annually, corresponding to an average of 50 client Plans for each of the four QPAMs estimated to be affected by the application. The Department estimates that clerical personnel will spend 10 minutes distributing the notices and objective descriptions, resulting in a labor cost of approximately $2,100.[123] In addition, the Department estimates that material and mailing costs for these notices will total approximately $400.[124]

Costs Incurred by Plans and Participants, Beneficiaries

The Department received several comments stating that the Proposed Amendment would increase Plan expenses. Commenters identified the following as factors that are likely to increase Plan expenses: (1) increased resources devoted to avoiding non-exempt prohibited transactions; (2) disruptions during the Transition Period; (3) increased fees due to the risk of ineligibility, and (4) transition costs associated with replacing an ineligible QPAM.

The Department also received several comments stating that the Proposed Amendment would decrease the investment options available to Plans, specifically regarding a counterparty in a trade who is a Party in Interest. Several commenters expressed concern that the proposed modifications to Section I(c) would limit access to primary investment markets and could limit access to asset classes that are not typically traded on large exchanges, such as asset-backed securities. In response to these comments, the Department did not include many of the proposed modifications in the Final Amendment. Therefore, the Department believes there will be no related costs incurred by Plans and their participants and beneficiaries due to the modifications to Section I(c) in the Final Amendment.

Asset Management and Equity Thresholds—Section VI(a)

As a result of the adjustments to the asset management and equity thresholds in the QPAM definition in Section VI(a), the Department acknowledges that some QPAMs may not meet the new threshold requirements, and, consequently, would no longer be able to rely on the QPAM Exemption. The Department expects Plans that utilize these QPAMs will incur costs due to this transition but does not have sufficient data to estimate the impact.[125]

The Department requested similar data in connection with individual exemption applications when a QPAM becomes ineligible due to convictions covered by Section I(g), but the data provided, and cost identified by applicants has been limited. Additionally, the Department requested comments and data in the Proposed Amendment regarding the number of QPAMs who will potentially become unable to rely upon the QPAM Exemption and the number of Plans and the value of Plan assets that will be impacted by the increase in asset management and equity thresholds.

As discussed in the Benefits section above, several commenters expressed concern that the Department did not provide evidence to support the increase in the asset and equity thresholds. Additionally, commenters noted that the increased thresholds may create a high barrier to entry for financial institutions or would disqualify small financial institutions, which would impose transition costs for client Plans that search for a new investment manager to replace an ineligible QPAM. One commenter noted that the inflation increases would introduce uncertainty regarding a QPAM's eligibility.[126] One commenter noted that a Plan transitioning to a new asset manager would incur costs associated with searching for a new asset manager to replace the QPAM (such as the costs and time required for a request for proposal process; costs associated with consultants to assist or manage the process, legal review and negotiation of a new management agreement, and other due diligence expenses; brokerage and other transaction costs associated with the sale of portfolio investments to accommodate the investment policies and strategy of the new asset manager; the opportunity costs of holding cash pending investment by the new asset manager; and lost investment opportunities in connection with a change of asset manager). Another commenter estimated that a formal request for proposal for a new QPAM would cost between $10,000 and $50,000 with legal fees ranging between $10,000 and $20,000 for a typical asset class or $20,000 to $40,000 for a more specialized strategy.

However, none of the commenters directly addressed the number of QPAMs that will lose eligibility due to the increased thresholds or relatedly, the number of client Plans serviced by those QPAMs. The Department received one comment stating that an incremental increase approach would give smaller investment fiduciaries, who would be most affected by the threshold

hours × $63.45) + (1 application × 15 hours × $535.85) = $25,861, rounded to $26,000.

[122] It is unclear if the commenter was also considering the ongoing costs associated with complying with the individual exemption. For purposes of this portion of the Department's analysis, ongoing costs associated with complying with a granted individual exemption are not included as a cost of filing the exemption application under Section I(j).

[123] The hour burden is estimated as: 4 QPAMs × 50 Plans per QPAM × (10/60) hours = 33.3 hours. A labor cost of $63.45 is applied for clerical personnel The equivalent cost is estimated as: 4 QPAMs × 50 Plans per QPAM × (10/60) hours × $63.45 = $2,116, rounded to $2,100.

[124] The Department further assumes that notices and the descriptions of facts and circumstances will be delivered separately, comprising 15 and 5 pages, respectively. With a printing cost of $0.05 per page and a mailing cost of $0.66 per notice, the Department estimates the mailing cost as 4 QPAMs × 50 Plans per QPAM × 80% of notices mailed × {[(15 × $0.05) + $0.68] + [(5 × $0.05) + $0.68]} = $378, rounded to $400.

[125] Some QPAMs have suggested in the past that there could be costs associated with unwinding transactions that relied on the QPAM Exemption and reinvesting assets in other ways. The loss of QPAM status could also require an asset manager to keep lists of Parties in Interest to its client Plans to ensure the asset manager does not engage in prohibited transactions. However, even without the QPAM Exemption, a wide variety of investments are available that do not involve non-exempt prohibited transactions.

[126] Comment submitted by the Spark Institute on 11 October 2022. (*See https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/public-comments/1210-ZA07/00026.pdf*).

changes, more time to prepare for and respond to threshold changes and minimize the negative impact on these entities.

As discussed in the preamble and after considering these comments, the Department decided to phase in the initial increase to asset and equity thresholds incrementally over an extended period rather than implement the entire increase in a single year in order to reduce the immediate impact on QPAMs and their client Plans. QPAMs and Plans relying on those QPAMs that will lose the ability to rely upon the QPAM Exemption, particularly in the second and third portions of the phase-in period will have time to make needed adjustments.

Although Plans may continue to rely on asset managers who do not satisfy the definition of QPAM, the Department acknowledges that some Plans may choose to hire a different asset manager if their current asset manager is not able to rely on the QPAM Exemption. The Department understands that it is common industry practice to conduct a request for proposal every three to five years, and some Plans may choose to do so sooner than they otherwise would have because of the new threshold requirements. These Plans will incur costs with preparing and reviewing proposals from potential new asset managers. The Department lacks sufficient data to estimate the number of Plans and QPAMs that would be affected by the increased thresholds in the definition of QPAM.

Summary of Costs

The total estimated annual costs associated with the Final Amendment will be approximately $6.8 million in the first year and $0.8 million in subsequent years. Table 3 summarizes the costs for each requirement.

TABLE 3—COST SUMMARY

Requirement	Aggregate cost change (in dollars)	
	First year	*Subsequent year*
All QPAMs:		
Rule Familiarization	$5,816,652	
Reporting Reliance on the QPAM Exemption	172,187	$1,729
Notice of Failure to Report Reliance on the QPAM Exemption	17,288	159
Recordkeeping	688,750	688,750
Refusal to Disclose Requested Information	34,577	34,577
QPAMs Losing Eligibility:		
Notice to Plans	782	782
Notice to the Department of Prohibited Misconduct and Foreign NPA/DPA	340	340
QPAMs Applying for Individual Exemptions:		
Quantification of Costs Plans Will Suffer	2,288	2,288
Review of Past Exemptions	1,608	1,608
Exemption Application	25,861	25,861
Individual Exemption Notices	2,494	2,494
Total Estimated Annual Cost	6,762,827	758,588

Note: *Only quantifiable costs are displayed.*

Transfers

If an asset manager cannot rely on the relief under the QPAM Exemption (*e.g.,* because it is ineligible due to its Participation In Prohibited Misconduct or due to the change in asset or equity thresholds), its client Plans may choose to transfer assets and revenue away from the asset manager to its competitors. From the Plan's perspective, the reduction in assets entrusted to the original asset manager (and associated revenue reduction) are offset by the increase in assets managed by another asset manager or managers (and associated revenue increase). Even if the impact of the switch is minimal or neutral from the point of view of the Plan, it is nevertheless appropriately characterized as a transfer from a societal perspective.[127]

Although the Department does not have sufficient data to quantify the likely size of such revenue transfers, they could have an annual effect that exceeds $200 million due to the significant pool of Plan assets that QPAMs manage. To the extent the Final Amendment results in the movement of assets from asset managers that cannot rely on the exemption to other asset managers, the associated revenue transfers promote the Department's objectives in issuing this amendment to the QPAM Exemption and enhance the security of Plan investments.

In the Proposed Amendment, the Department requested comments on whether a QPAM's client Plans would be likely to move all or some of their assets to an alternative asset manager after a QPAM becomes ineligible due to expansion of the ineligibility provision. The Department did not receive comments directly addressing this issue. The cost of conducting a request for proposal and searching for a new asset manager are discussed in greater detail above, in the Cost section.

Regulatory Alternatives

Section 6(a)(3)(C) of Executive Order 12866 requires the Department to assess the cost and benefits of feasible alternatives for rules that are determined to be ''significant'' under Section 3(f)(1) of the executive order. Therefore, the Department considered several alternatives to the provisions in the Final Amendment that are discussed in this section.

Do not amend the QPAM Exemption—Continue status quo of addressing ineligibility under current Section I(g) and only through administration of the individual exemption program.

The Department considered not expanding the scope of Section I(g) and maintaining its practice of addressing ineligibility under Section I(g) only

[127] Although a QPAM's client Plans could be expected to move some or all of its assets to another asset manager if the QPAM is convicted of an enumerated crime, this discussion does not address these transfers. The Department has long viewed both domestic and foreign convictions as causing ineligibility under the existing exemption. Consequently, the regulatory baseline already includes the impact of such convictions.

through the individual exemption process. However, it is the Department's understanding that its issuance of a subsequently revoked opinion caused uncertainty in the regulated community regarding whether foreign convictions are within the scope of Section I(g) of the QPAM Exemption. This amendment provides clarity on that point. Further, immediate ineligibility under Section I(g) has become a source of uncertainty and potential disruption to Plans. As the financial services industry has become increasingly consolidated, the number of entities becoming ineligible for relief under the QPAM Exemption has grown, prompting more entities to face ineligibility. Through the individual exemption process, client Plans would continue to be exposed to the potential for immediate disruption and transition costs that might otherwise be avoided through this Final Amendment.

The Department decided against this alternative in favor of this amendment, relying on its experience processing individual exemption applications to create a smoother transition between the QPAM Exemption and the individual exemption program so that a QPAM's client Plans have certainty regarding their rights after an ineligibility event occurs.

Amend the QPAM Exemption to expressly exclude foreign convictions.

The Department considered expressly limiting the scope of convictions to only those in a U.S. federal or state trial courts. However, given the increasingly global reach of asset managers and investment strategies, the Department determined such a limitation would leave Plans less protected and be inconsistent with the ERISA section 408(a) and Code section 4975(c)(2) required findings. An affiliated entity's criminal misconduct in a foreign jurisdiction is an important indicator of the integrity of the entire corporate organization and casts doubt on a QPAM's ability to act in a manner that will properly protect Plans and their participants and beneficiaries from the related damages, losses, and other harm that often result from such criminal misconduct.

Amend the QPAM Exemption to require QPAMs to amend Written Management Agreements with up-front terms that apply in the event of ineligibility.

In the proposal, the Department included a requirement for all QPAMs to amend their WMAs with client Plans to include:

(1) A provision providing that in the event the QPAM, its Affiliates, and five percent or more owners engage in conduct resulting in a Criminal Conviction or receipt of a Written Ineligibility Notice, the QPAM would not restrict its client Plan's ability to terminate or withdraw from its arrangement with the QPAM;

(2) A provision requiring the QPAM to indemnify, hold harmless, and promptly restore actual losses to each client Plan for any damages directly resulting from a violation of applicable laws, a breach of contract, or any claim arising out of the failure of such QPAM to remain eligible for relief under the QPAM Exemption as a result of conduct that leads to a Criminal Conviction or Prohibited Misconduct; and

(3) A provision requiring the QPAM to agree not to employ or knowingly engage any individual that Participated In the conduct that is the subject of a Criminal Conviction or Prohibited Misconduct.

In the Proposed Amendment, the Department remarked that these provisions would benefit Plans by providing them with additional certainty that the Plan and its assets will be insulated from losses if a Criminal Conviction or Prohibited Misconduct occurs.

The Department estimated that the cost associated with amending the WMAs would result in a total equivalent cost of $135,540,[128] resulting in an average cost of approximately $220 for each QPAM. Comments on the Proposed Amendment criticized the Department's estimation methods, stating that the Department had significantly underestimated the burden this requirement would impose. For instance, one commenter estimated that the Department's estimate was off at least by a factor of 100. Another commenter estimated that it would cost between $1 billion and $12.3 billion.

In its estimate, the Department assumed that amendments to WMAs would be uniform across client Plans, and accordingly, the Department estimated that the associated costs would be relatively small. However, several commenters disagreed with this assumption, stating that the necessary amendments would differ by the type of relationship and investment strategy. Some commenters noted that such amendments would require QPAMs to open contract negotiations with each QPAM client Plan, potentially leading to a time-consuming process. Other commenters indicated that some QPAMs would incur costs associated with consulting outside counsel on these provisions and contract negotiations. Further, several of the commenters stated that amending necessary contracts would not be possible within the 60-day effective period proposed.

The Department believes that these provisions provide an important protection to Plans, participants, beneficiaries, and IRA owners. Namely, these provisions ensure that Plans and IRA owners can terminate the arrangement or withdraw from a QPAM-managed Investment Fund without penalty, protecting Plans and IRA owners from unnecessary costs when relief under the exemption is lost through no fault of their own. However, based on the feedback from commenters, the Department removed the requirement to amend WMAs. Instead, the Final Amendment requires QPAMs to notify and agree to these provisions with Plans in the Notice to Plans required within 30 days of the Ineligibility Date. The Department determined the approach in the Final Amendment provides the same protection to Plans while significantly reducing the cost burden.

Asset Management and Equity Thresholds

The Department considered two alternatives related to the asset management and equity thresholds, described below.

Amend the QPAM Exemption to remove asset management and equity thresholds.

As an alternative to updating the asset management and equity thresholds, the Department revisited whether such thresholds could be removed entirely from the exemption. The Department determined that this approach would be inconsistent with one of the core concepts upon which the QPAM Exemption was based. In the absence of an appropriate alternative ensuring that a QPAM will remain an independent decision-maker, free from influence of other Plan fiduciaries, the Department is unable to justify the removal of the thresholds.

Update the asset management and equity thresholds to full CPI-adjusted values at once.

The proposal included CPI-adjusted values that would have been fully updated to 2022 values. The Department received a variety of comments regarding the possible unintended impact to QPAMs and their client Plans who would not be able to satisfy such significant increases at once. In response to those concerns, the Department determined that a more appropriate way to update the thresholds is through a phase-in to the proposed values, which is included in this Final Amendment.

[128] 87 FR 45204, pp. 45218.

Amend the QPAM Exemption to include entering into NPAs or DPAs of owners and Affiliates of QPAMs as a possible Section I(g) ineligibility trigger.

In the Proposed Amendment, Section I(g) would have been implicated if the QPAM, its owners of a five (5) percent or more interest, or Affiliates enter into an NPA or DPA and subsequently received a Written Ineligibility Notice from the Department. The approach in the Proposed Amendment was intended to ensure QPAMs could not avoid the consequences that otherwise would result from a Criminal Conviction under Section I(g) by entering into NPAs or DPAs with prosecutors. In this Final Amendment, the Department limited the scope of Prohibited Misconduct to NPAs or DPAs that are entered into with a U.S. Federal or State prosecutor's office or regulatory agency and Prohibited Misconduct that is found in or determined by a court or court-approved settlement.

In the Proposed Amendment, the Department estimated that eight QPAMs would be affected by the ineligibility provisions due to Participating In Prohibited Misconduct.[129] As discussed in the cost section, due to the narrowing of the Prohibited Misconduct provision, the Department estimates that four QPAMs annually may become ineligible due to the reduced scope of entities captured in the Final Amendment rather than the eight QPAMs that were estimated in the Proposed Amendment.

Uncertainty Associated With the Final Amendment

The Department is uncertain regarding the total number of QPAMs and examined multiple alternative estimation methodologies before utilizing the one outlined in this amendment.

The first alternative considered was adding additional service codes from form 5500 data. The Department looked at service providers identified under service code 28 and found that they were also frequently identified under service code 50 and 27 (direct payment from the plan and investment advisory respectively). However, after examining these codes in detail, the Department found them too definitionally dissimilar from investment management and that the firms under these codes seemed less likely to meet the asset and equity thresholds required by the QPAM Exemption. Thus, the Department only included codes 28, 51, and 52.

The Department also examined completely different methodologies for generating the number of QPAMs. One proposed methodology was to use data from the SEC and FDIC to estimate the number of QPAMs. The Department could use the FDIC data to see banks with defined benefit plan or defined contribution plan funds in trustee accounts and could use asset data to estimate the number of entities above and below the asset threshold, but that data was generated at the firm-level. Since a firm can contain multiple distinct entities, all acting as QPAMs, the Department believed that use of this data would lead to a significant undercount of QPAMs.

The Department is also uncertain about the extent to which the changes in asset management and equity thresholds would give rise to new costs because some QPAMs that meet the current thresholds no longer would be able to rely on the exemption if they do not meet the increased thresholds. Some of these small QPAMs may lose this portion of their business. However, there still may be other exemptions that they could use, or they could seek an individual exemption that could allow them to continue offering services.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the Department solicited comments concerning the information collection request included in the Proposed Amendment entitled ''Proposed Amendment to Prohibited Transaction Class Exemption 84–14 (the QPAM Exemption).'' [130] At the same time, the Department also submitted an information collection request to the (OMB), in accordance with 44 U.S.C. 3507(d).

The Department received one comment addressing the audit cost estimates in the paperwork burden analysis of the information collections. Other comments submitted contained information relevant to the costs and administrative burdens attendant to the Proposed Amendment. The Department considered these public comments in connection with making changes to the Final Amendment, analyzing the economic impact of the Proposed Amendment and developing the revised paperwork burden analysis summarized below.

ICRs are available at *RegInfo.gov* (*reginfo.gov/public/do/PRAMain*). Requests for copies of the ICR can be sent to the PRA addressee:

By mail: James Butikofer, Office of Research and Analysis, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210
By email: ebsa.opr@dol.gov

Prohibited Transaction Exemption 84–14, 49 FR 9494 (March 13, 1984), as corrected at 50 FR 41430 (October 10, 1985) and amended at 70 FR 49305 (August 23, 2005) and at 75 FR 38837 (July 6, 2010) (the QPAM Exemption) permits various parties related to Plans to engage in transactions involving Plan assets if, among other conditions, the assets are managed by a QPAM. The following analysis considers the paperwork burden associated with the existing QPAM Exemption as well as the incremental cost associated with the Final Amendment.

Affected Entities

As discussed in the Affected Entities section of the regulatory impact analysis, the Department estimates that there are 10,855 QPAMs. Additionally, the Department estimates that each QPAM, on average, provides services to 50 Plans and that there are 215,135 total Plans with relationships with QPAMs.[131]

QPAM-Sponsored Plans—Policies and Procedures—Section V(b)

The existing information collection requirements of the QPAM Exemption require in-house QPAMs to develop written policies and procedures designed to ensure compliance with the conditions of the exemption. Existing in-house QPAMs will have already prepared their policies and procedures in accordance with the QPAM Exemption. However, some in-house QPAMs may also update their policies and procedures in a given year.

The latest Form 5500 estimates from the year 2020 indicate that there are approximately 50 in-house QPAMs.[132] The Department estimates that the burden associated with preparing policies and procedures will affect ten percent of all in-house QPAMs, including all new in-house QPAMs and some existing in-house QPAMs. Therefore, the Department estimates that about five QPAMs will need to

[129] 87 FR at 45218.

[130] 87 FR 45204.

[131] For more information on how the number of QPAMs, average number of relationships between QPAMs and Plans, and unique number of Plans was estimated, refer to the Affected Entities section of the regulatory impact analysis.

[132] The Department estimated the number of in-house QPAMs by examining Schedule C of the 2020 Form 5500. Small Plans are not required to file the Schedule C. This estimate could underestimate the number of in-house QPAMs with small Plans, but the Department believes that in-house QPAMs with small Plans would be rare. In order for this to occur, an investment manager would have to simultaneously be large enough to qualify as a QPAM and small enough to qualify as a small plan for the Form 5500–SF.

update their policies and procedures each year.[133] The Department estimates that the burden associated with new QPAMs meeting the policies and procedures requirements of the QPAM Exemption will be five hours with an equivalent cost of $797.[134]

QPAM-Sponsored Plans—Independent Audit—Section V(c)

Additionally, the exemption requires in-house QPAMs to engage an independent auditor to conduct an annual exemption audit and issue an audit report to the Plan. The Department estimates that each of the 50 in-house QPAMs will use in-house legal professionals, financial managers, and clerical time to provide documents and respond to questions from the auditor. The Department assumes QPAMs use either a law firm or a consulting firm to conduct the exemption audits, and the Department assumes that the average cost of an exemption audit is $25,000.[135] This results in a total estimated cost of $1,250,000.[136] Additionally, each exemption audit is assumed to require about 5 hours of a legal professional's time, 13 hours of a financial manager's time, and six hours of clerical time for each of the 50 QPAMs to provide needed materials for the audit. This results in a burden estimate of 1,200 hours with an equivalent cost of $182,780.[137]

This results in a per-entity cost of $28,656 for each audit. The Department received one comment on its cost estimate for the audit, noting that legal expenses associated with QPAMs would approach or exceed $100,000. This commenter did not provide additional information to support this estimate.

Property Manager Written Guidelines—Section I(c)

The exemption also contains a requirement for written guidelines when, in certain instances, a property manager acts on behalf of a QPAM. In this case, the QPAM is required to establish and administer the guidelines. Because agreements between an institution and a property manager are customary, the Department estimates that this requirement will impose no additional burden on QPAMs.

Reporting Reliance on the QPAM Exemption—Subsection I(k)

QPAMs will have to report their reliance on the QPAM Exemption via email to *QPAM@dol.gov.* This notification would occur only once for most QPAMs. The information required under subsection I(k) is limited to the legal name of the entity relying upon the exemption and any name the QPAM may be operating under. The Department expects it will take 15 minutes, on average, for each QPAM to both prepare and send this electronic notification. This burden is estimated to amount to 2,713.8 hours with an equivalent cost of $172,187 in the first year.[138] In subsequent years, new QPAMs or QPAMs that change their name will be required to send the notification. The Department does not have data on how many QPAMs will be required to send this notification in subsequent years. For the purposes of this analysis, the Department assumes that one percent of QPAMs, or 109 QPAMs, will either be new or have a name change.[139] Accordingly, this is estimated to amount to 27.3 hours, with an equivalent cost of $1,729.[140]

If a QPAM fails to report its reliance on the exemption within 90 days, the QPAM must send a notice to the Department within an additional 90 days, indicating its reliance on the exemption or name change, as well as an explanation for the failure to provide notice. The Department does not have information on what percent of QPAMs are likely to fail to report reliance. For the purposes of this analysis, the Department estimates that two percent of QPAMs required to report will fail to report reliance each year, or 217 QPAMs in the first year and two QPAMs in subsequent years.[141] The Department estimates that preparing the notice will require a legal professional 30 minutes. The burden is estimated to be 108.5 hours with an equivalent cost of approximately $17,288 in the first year[142] and one hour with an equivalent cost of approximately $159 in subsequent years.[143] The cost for a clerical professional to draft and send an email notifying the Department of its reliance or name change is included in the cost estimate of sending notice of reliance above.

Recordkeeping—Section VI(u)

The amendment adds a new recordkeeping provision that will apply to all 10,855 QPAMs. Due to the fiduciary status of QPAMs and the existing regulatory environment in which they exist, the Department assumes that QPAMs already maintain many of the required records as part of their regular business practices. In addition, the recordkeeping requirements correspond to the six-year period in ERISA sections 107 and 413. The Department expects that the recordkeeping requirement would impose, on average, a burden of one hour per QPAM. Therefore, the Department estimates that the overall hour burden of this recordkeeping requirement for all 10,855 QPAMs will be 10,855 hours with an equivalent cost of $688,750.[144]

If a QPAM refuses to disclose information to any of the parties listed in Section VI(u) on the basis that such information is exempt from disclosure, the QPAM must provide a written notice advising the requestor of the reason for the refusal and that the Department may request such information. The Department does not have data on how often such a refusal is likely to occur. For the purposes of this illustration, the Department

[133] This is estimated as: 50 in-house QPAMs × 10% = 5.

[134] The burden is estimated as follows: (5 QPAMs × 1 hour) = 5 hours. A labor rate of $159.34 is used for legal counsel and applied in the following calculation: (5 QPAMs × 1 hour × $159.34) = $797.

[135] The Department has received information from industry representatives that the cost of a similar annual audit required by PTE 96–23 (the INHAM Exemption) may range from approximately $10,000 to $25,000, depending on asset size and how many years the INHAM has used the auditing firm. Because of the type of audit required for an in-house QPAM, the Department has assumed that the average cost of an exemption audit required by the QPAM Exemption would be $25,000.

[136] Assuming that the average cost of an exemption audit would be $25,000: 50 in-house QPAMs × $25,000 = $1,250,000.

[137] The burden is estimated as follows: (50 × 5 hours) + (50 × 13 hours) + (50 × 6 hours) = 1,200 hours. A labor rate of $159.34 is used for legal counsel, a labor rate of $190.63 is used for a financial professional, and a labor rate of $63.45 is used for a clerical worker. These labor rates are applied in the following calculation: (50 × 5 hours × $159.34) + (50 × 13 hours × $190.63) + (50 × 6 hours × $63.45) = $182,780.

[138] The hour burden is estimated as: 10,855 QPAMs × 15 minutes = 2,713.8 hours. The labor cost of $63.45 is applied for a clerical worker. The equivalent cost is estimated as: 10,855 QPAMs × 15 minutes × $63.45 = $172,187.

[139] The number of QPAMs is estimated as: 10,855 QPAMs × 1% = 108.6, rounded to 109.

[140] The hour burden is estimated as: 109 QPAMs × 15 minutes = 27.3 hours. The labor cost of $63.45 is applied for a clerical worker. The equivalent cost is estimated as: 109 QPAMs × 15 minutes x $63.45 = $1,729.

[141] The number of QPAMs in the first year is estimated as: 10,855 × 2% = 217.1, rounded to 217. The number of QPAMs in subsequent years is estimated as: 109 QPAMs × 2% = 2.2, rounded to 2.

[142] The hour burden is estimated as: 217 QPAMs × 0.5 hour = 108.5 hours. The labor cost of $159.34 is applied for an internal legal professional. The equivalent cost is estimated as: 108.5 hours × $159.34 = $17,288, rounded to $17,000.

[143] The hour burden is estimated as: 2 QPAMs × 0.5 hour = 1 hour. The labor cost of $159.34 is applied for an internal legal professional. The equivalent cost is estimated as: 1 hour × $159.34 = $159.34, rounded to $159.

[144] The hour burden is estimated as: 10,855 QPAMs × 1 hour = 10,855 hours. The labor cost of $63.45 is applied for clerical personnel. The equivalent cost is estimated as: 10,855 QPAMs × 1 hour × $63.45 = $688,750.

estimates that two percent of QPAMs, or 217 QPAMs, will refuse to disclose requested information annually. The Department estimates that drafting a written notice advising the requestor of the reason for the refusal and that the Department may request such information will require an internal legal professional to spend one hour, resulting in a burden of 217 hours with an equivalent cost of approximately $34,577.[145]

Notice to Plans—Subsection I(i)(1)

Within 30 days after the Ineligibility Date, the QPAM must provide notice to the Department and each of its client Plans. The preamble provides more detail on what the QPAM is required to include in this notice. As discussed in the Cost section of the regulatory impact analysis, the Department estimates that 12 QPAMs will lose eligibility each year, eight due to a Criminal Conviction and four due to Participating In Prohibited Misconduct.

As discussed in the Affected Entities section, the Department estimates that each QPAM provides services to 50 Plans, on average. The Department estimates that a legal professional at each ineligible QPAM will spend one hour preparing the notice and two minutes for clerical personnel will spend two minutes preparing each notice to be sent to a Plan by mail, resulting in an hour burden of 22 hours with an equivalent cost of $1,971.[146] Additionally, the Department assumes that notices sent by mail will require two pages of paper each, resulting in a material and postage cost of approximately $374.[147]

The Department believes the cost of sending this notice to the Department will be negligible since the QPAM will already prepare and send the notice to their client Plans and the notice is required to be sent electronically.

Notice to the Department of Prohibited Misconduct and Foreign NPA or DPA

If a QPAM, an Affiliate, or owner of a five (5) percent or more interest in a QPAM Participates in Prohibited Misconduct or enters into a foreign equivalent of an NPA or DPA, the QPAM is required to provide notice to the Department of the agreement. The Department does not have data on how frequently these entities enter into such agreements but assumes it will be infrequent. For the purposes of this analysis, the Department assumes that four instances each year will require such a notice. The Department estimates that this will result in a cost of approximately $340.[148]

Requesting an Individual Exemption—Section I(j)

Participating In Prohibited Misconduct could lead a QPAM to request an individual exemption. The burden for filing an application requesting an individual exemption is included in the ICR for the Exemption Procedure Regulation, which has been approved under OMB Control Number 1210–0060. Instead of amending that ICR, the estimated burden for applications from QPAMs Participating In Prohibited Misconduct is included here.[149]

The Department estimates that there will, on average, be one application each year related to Prohibited Misconduct, affecting four QPAMs. The Department estimates that gathering and preparing the information for the application will take, on average, 20 hours of in-house legal professional labor and 20 hours of clerical personnel labor at each QPAM. The Department assumes that the application will be prepared by an outside legal professional specializing in such matters. The Department estimates that it will require 15 hours, on average, of outside legal professional labor to prepare the application. For the four QPAMs losing eligibility due to Prohibited Misconduct, this will result in an hour burden of 175 hours with an equivalent cost of $25,861.[150]

For applications that reach the stage of publication of a proposed individual exemption in the **Federal Register**, a notice must be prepared and distributed to interested parties. Similarly, if the exemption is ultimately granted, each of these four QPAMs will be required to send an objective description of the facts and circumstances upon which the misconduct is based to each client Plan. The Department estimates that approximately 200 notices will be distributed annually, corresponding to an average of 50 client Plans for each of the four QPAMs estimated to be affected by the application. The Department estimates that it will take 10 minutes for clerical personnel to distribute the notices and objective descriptions, resulting in an hour burden of 33.3 hours with an equivalent cost of approximately $2,116.[151] In addition, material and mailing costs for all of these notices totals approximately $378.[152] The Department estimates that approximately 40 (20 percent of the total number of notices) will be distributed electronically.

Additional Requirement for QPAMs Requesting an Individual Exemption

New Section I(j) indicates that a QPAM that is ineligible or anticipates that it will become ineligible due to an actual or possible Criminal Conviction or Participating In Prohibited Misconduct may apply for an individual exemption from the Department to continue to rely on the relief provided in this exemption for a longer period than the One-Year Transition Period. In such an event, an applicant should review the Department's most recently granted individual exemptions

[145] The number of QPAMs is estimated as 10,855 × 2% = 217 QPAMs. The hour burden is estimated as: 217 QPAMs × 1 hour = 217 hours. The labor cost of $159.34 is applied for a legal professional. The equivalent cost is estimated as: 217 QPAMs × 1 hour × $159.34 = $34,577.

[146] The hour burden is estimated as: (12 QPAMs × 0.5 hours of professional legal time) + (12 QPAMs × 50 Plans × 80% of notices being mailed × 2/60 hours of clerical personnel time) = 22 hours. The labor cost of $159.34 is applied for a legal professional, and the labor cost of $63.45 is applied for clerical personnel. The equivalent cost is estimated as: (12 QPAMs × 0.5 hours of professional legal time × $159.34) + (12 QPAMs x 50 Plans x 80% of notices being mailed x 2/60 hours of clerical personnel time × $63.45) = $1,971.

[147] The material and postage cost are estimated as: (12 QPAMs x 50 Plans × 80% of notices being mailed) × [(2 pages × $0.05 per page) + $0.68] = $374.

[148] If preparing and sending each notice were to require an in-house legal professional 30 minutes and a clerical staff 5 minutes. The hour burden is estimated as: 4 notices × (30 minutes + 5 minutes) = 2 hour and 20 minutes. The labor cost of $159.34 is applied for an in-house legal professional, and a labor cost of $63.45 is applied for clerical staff. The equivalent cost is estimated as: 4 notices × [(30 minutes × $159.34) + (5 minutes × $63.45)] = $340. The Department assumes such notices will be sent electronically and will not create material or postage costs.

[149] In three years when control number 1210–0060 is extended, the increase in requests for individual exemptions will be captured in the historical data used for the renewal and the burden going forward will be captured there.

[150] The hour burden is estimated as: [4 QPAMs × (20 hours from an in-house legal professional + 20 hours for clerical personnel)] + (1 application × 15 hours from an external legal professional) = 175 hours. The labor cost of $159.34 is applied for an in-house legal professional, a labor cost of $63.45 is applied for clerical personnel, and a labor cost of $535.85 is applied for an outside legal professional. The equivalent cost is estimated as: (4 QPAMs × 20 hours × $159.34) + (4 QPAMs × 20 hours × $63.45) + (1 application × 15 hours × $535.85) = $25,861.

[151] The hour burden is estimated as: 4 QPAMs × 50 Plans per QPAM × (10/60) hours = 33.3 hours. A labor cost of $63.45 is applied for clerical personnel The equivalent cost is estimated as: 4 QPAMs × 50 Plans per QPAM × (10/60) hours × $63.45 = $2,116, rounded to $2,100.

[152] The Department further assumes that notices and the descriptions of facts and circumstances will be delivered separately, comprising 15 and 5 pages, respectively. With a printing cost of $0.05 per page and a mailing cost of $0.66 per notice, the Department estimates the mailing cost as 4 QPAMs × 50 Plans per QPAM × 80% of notices mailed × {[(15 × $0.05) + $0.68] + [(5 × $0.05) + $0.68]} = $378.

involving Section I(g) ineligibility. If an applicant requests the Department to exclude any term or condition from its exemption that is included in a recently granted individual exemption, the applicant must include a detailed statement with its exemption application explaining the reason(s) why the variation is necessary and in the interest and protective of affected Plans and their participants and beneficiaries. For the three applications covering the 12 ineligible QPAMs, the burden is estimated to be 9 hours with an equivalent cost of $4,823.[153]

Such applicants also should provide detailed information in their applications quantifying the specific cost or harms in dollar amounts, if any, Plans would suffer if a QPAM could not rely on the exemption after the Transition Period, including the specific dollar amounts of investment losses resulting from foregone investment opportunities and any evidence supporting the proposition that investment opportunities would only be available to Plans on less advantageous terms. All three applications will need to include this information if they submit an exemption application. The Department estimates that it will require four hours of a financial professional's time to prepare such information. Therefore, for the three applications covering the estimated 12 QPAMs losing eligibility annually, the cost associated with the additional requirement results in an hour burden of 12 hours with an equivalent cost of $2,288.[154]

Summary

Based on the foregoing, the PRA burden associated with the information collection requirements contained in the QPAM Exemption are summarized below:

Agency: DOL–EBSA.

Type of Review: Revision.

Title of Collection: Plan Asset Transactions Determined by Independent Qualified Professional Asset Managers under Prohibited Transaction Exemption 1984–14.

OMB Control Number: 1210–0128.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 10,855.

Estimated Number of Annual Responses: 23,093.

Frequency of Response: Annual or as needed.

Estimated Total Annual Burden Hours: 15,353.

Estimated Total Annual Burden Cost: $1,250,752.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[155] imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities.[156] Unless an agency determines that a regulation or amendment will not have a significant economic impact on a substantial number of small entities, section 604 of the RFA requires the agency to present a final regulatory flexibility analysis of the Final Amendment.

The Department emphasizes that the QPAM Exemption was always premised on the QPAM being an entity of sufficient size to withstand undue influence from Parties in Interest. The Department clearly makes this point in the preamble to 1982 QPAM proposal where it stated that the minimum capital and funds-under-management standards are intended to ensure that the eligible fiduciaries managing the accounts or investment funds are established institutions which are large enough to discourage the exercise of undue influence upon their decision-making processes by parties in interest.[157]

This is consistent with the Department's past actions. When the exemption was granted, the Department declined to reduce or delete the asset and equity thresholds as requested by some commenters.[158] Furthermore, when the Department raised the thresholds for investment advisers in 2005, it stated that the thresholds had ''not been revised since 1984 and may no longer provide significant protections for plans in the current financial marketplace.'' [159]

As discussed in greater detail below, the Department lacks data to be able to identify how many asset managers providing services to Plans fall below the SBA size thresholds and above the QPAM eligibility thresholds. However, given the nature of the QPAM Exemption and based on the premise of the entity being large enough to remain independent, the requirements of this Final Amendment are applicable to all entities, regardless of size.

On September 16, 2022, the Department published a supplementary Initial Regulatory Flexibility Analysis explaining the possible impact on small entities of the amended exemption.[160]

The Department has considered the comments submitted to the Department as well as the information discussed in hearings conducted by the Department to update this analysis. Specifically, the Department responded to the following comments in this analysis:

- Several commenters on the Proposed Amendment stated that the Department underestimated the number of QPAMs in the supplementary Initial Regulatory Flexibility Analysis for the Proposed Amendment. In response to these comments, the Department has revised its methodology to estimate the number of QPAMs leading to an increase in the estimate of QPAMs.
- A few commenters stated that the Department underestimated the number of Plans that have hired a QPAM. In response to these comments, the Department has revised its estimates of the number of QPAM–Plan relationships.
- The Department received several comments that the Department underestimated the cost associated with the recordkeeping requirement in the supplementary Initial Regulatory Flexibility Analysis for the Proposed Amendment. In response to these comments, the Department has provided additional guidance on recordkeeping earlier in this preamble to alleviate potential confusion.

There were no comments filed by the SBA's Office of Advocacy.

Despite the importance of a QPAM being sufficiently large to withstand undue influence from parties in interest, the Department has determined that the Final Amendment could have a significant impact on a substantial number of small entities in an abundance of caution, because it does not have sufficient information to determine it would not. Therefore, the Department presents its Final Regulatory Flexibility Analysis below.

Need for and Objectives of the Amendment

Substantial changes have occurred in the financial services industry since the

[153] The hour burden is estimated as: (3 applications × 3 hours) = 9 hours. A labor cost of $535.85 is applied for an outside legal professional. The equivalent cost is estimated as: (3 application × 3 hours × $535.85 outside legal professional labor) = $4,823.

[154] The hour burden is estimated as: 3 applications × 4 hours = 12 hours. At an hourly rate of $190.63 is applied for financial professional. The equivalent cost is estimated as: (3 applications × 4 hours × $190.63 financial professional rate) = $2,288.

[155] 5 U.S.C. 601 *et seq.* (1980).

[156] 5 U.S.C. 551 *et seq.* (1946).

[157] 47 FR 56945, 56947 (Dec. 21, 1982).

[158] *See* 49 FR at 9502.

[159] *See* Proposed Amendment, 68 FR 52419, 52423 (Sept. 3, 2003).

[160] 87 FR 56912.

Department granted the QPAM Exemption in 1984. These changes include industry consolidation and an increasingly global reach for financial services institutions, both in their affiliations and in their investment strategies.

The baseline version of the QPAM Exemption is ambiguous regarding whether foreign convictions are included in the scope of the ineligibility provision under Section I(g). Today, QPAMs often have corporate or relationship ties to a broad range of entities, some of which are located internationally. Additionally, some global financial service institutions are headquartered or have parent entities that reside in foreign jurisdictions. These entities may have significant control and influence over the operation and management of all entities within a large financial institution's organizational structure, including those entities operating as QPAMs. Additionally, the international ties of QPAMs come not just from their affiliations and parent entities, but also their investment strategies, including those involving Plan assets.

The Department is also concerned about QPAMs that engage in significant misconduct of a similar type and nature as the conduct that might lead to a Criminal Conviction,[161] but ultimately does not result in a conviction. Under the baseline version of the exemption, a QPAM could theoretically avoid the conditions related to integrity and ineligibility under Section I(g) by entering into an NPA or DPA with prosecutors, which would allow it to side-step the consequences that otherwise would result from a Criminal Conviction. Plans may suffer significant harm if they are exposed to serious misconduct committed by a QPAM, its Affiliates, or owners of a five (5) percent or more interest that ultimately results in a an NPA or DPA rather than a Criminal Conviction and consequent ineligibility under Section I(g).

Likewise, intentionally or systematically violating the conditions of the exemption exposes Plans to significant potential harm at the hands of those with influence or control over their assets. In the Department's view, QPAMs that repeatedly engage in these types of serious misconduct do not display the requisite standards of integrity necessary to warrant their eligibility for the broad relief provided in the QPAM Exemption.

Through its administration of the individual exemption program, the Department also determined that certain aspects of the QPAM Exemption would benefit from a focus on mitigating potential costs and disruption to Plans when a QPAM becomes ineligible for the exemptive relief due to Section I(g). The Final Amendment would reduce the harmful impact on Plans by requiring QPAMs that become ineligible to allow their client Plans to withdraw from their arrangement with the QPAM penalty-free and indemnify their client Plans for certain losses during a One-Year Transition Period to avoid unnecessary disruptions to Plans when a QPAM becomes ineligible due to a Criminal Conviction or Participation In Prohibited Misconduct. The Transition Period will help bridge the gap between the QPAM Exemption and the Department's administration of its individual exemption program in connection with Section I(g) ineligibility.

The Final Amendment also is needed to update asset management and equity thresholds to current values in the definition of QPAM in Section VI(a). Some of the thresholds that establish the requisite independence upon which the QPAM Exemption is based have not been updated since 1984, and the thresholds for registered investment advisers have not been updated since 2005. The amendment will standardize all the thresholds to current values using the CPI.

Finally, the Final Amendment is needed to add a standard recordkeeping requirement to ensure QPAMs will be able to demonstrate, and the Department will be able to verify, compliance with the exemption conditions.

As a whole, the changes to the QPAM Exemption in this Final Amendment are necessary to ensure it remains in the interest of and protective of the rights of Plans and their participants and beneficiaries as required by ERISA section 408(a) and Code section 4975(c)(2).

Affected Small Entities

Qualified Professional Asset Managers (QPAMs)

To qualify as a QPAM, financial institutions must meet equity capital, net worth, and/or asset under management requirements. The Final Amendment will update these thresholds based on the price inflation since 1984, incrementally phasing in the thresholds from the Proposed Amendment over the period between 2024 and 2030. This Final Amendment increases the thresholds as follows:

(1) Banks—as defined in section 202(a)(2) of the Investment Advisers Act of 1940, with equity capital in excess of $1,570,300 as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

(2) Savings and loan associations—the accounts of which are insured by the Federal Deposit Insurance Corporation, with equity capital or net worth in excess of $1,570,300 effective as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

(3) Insurance companies—subject to supervision under state law, with net worth in excess of $1,570,300 effective as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

(4) *Investment advisers*—registered under the Investment Advisers Act of 1940 with total client assets under management in excess of $101,956,000 effective as of the last day of the fiscal year ending no later than December 31, 2024, $118,912,000 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $135,868,000 effective as of the last day of the fiscal year ending no later than December 31, 2030. In addition, the investment adviser must either have shareholders' or partners' equity— or payment of liabilities guaranteed by an affiliate, another entity that could qualify as a QPAM, or a broker-dealer with net worth— in excess of $1,570,300 effective as of the last day of the fiscal year ending no later than December 31, 2024, $2,140,600 effective as of the last day of the fiscal year ending no later than December 31, 2027, and $2,720,000 effective as of the last day of the fiscal year ending no later than December 31, 2030.

The Department will make subsequent annual adjustments for inflation to the equity capital, net worth, and asset management thresholds, rounded to the nearest $10,000, no later than January 31 of each year by publication in the **Federal Register**.

As discussed in the Affected Entities section above, the Department estimates that there are 10,855 QPAMs. The Department does not know how many

[161] The term ''Criminal Conviction'' is defined in Section VI(r) of this Final Amendment.

QPAMs fit the SBA's small entity definition for the finance and insurance sector. SBA outlines size standards to determine whether an entity is a small entity. The size standards and NAICS codes are summarized in the table below.

TABLE 4—SBA SIZE THRESHOLDS AND NAICS CODES BY POTENTIAL QPAM TYPE

Entity type	NAICS codes	SBA size threshold	
		Receipts in millions of dollars	Assets in millions of dollars
Investment Banks	523150	47.0	.....
Commercial Banks	522110	.....	$850
Savings and Loan Associations	522180	.....	850
Insurance Companies	524113	47.0	.....
Investment Advisers	523940	47.0	.....

The Department lacks sufficient data to identify how many of the estimated asset managers providing services to Plans fall below the SBA size thresholds and are above the QPAM eligibility thresholds. However, the Department believes some small entities that meet the SBA's definition could be significantly impacted by the Final Amendment to the QPAM Exemption.

For example, some smaller QPAMs may no longer be able to rely upon the exemption due to the increases in the asset and equity thresholds in the definition of ''QPAM'' in Section VI(a) of the Final Amendment. After considering public comments and testimony at the public hearing regarding the Proposed Amendment, the Department has decided to implement the proposed increase in thresholds incrementally between 2024 and 2030 to reduce the potential impact on small entities. Additionally, to the extent that Plans that are small entities are more likely to hire a QPAM that is a small entity, the Final Amendment could also impact them by reducing the market of available QPAMs.

Plans, Participants, Beneficiaries, and IRA Owners

The Final Amendment will affect Plans whose assets are held by an Investment Fund that is managed by a QPAM. The Department does not collect data on Plans that use QPAMs to manage their assets. As discussed in the Affected Entities section of the regulatory impact analysis above, the Department estimates that a single QPAM services, on average, 50 client Plans, resulting in an estimate of 547,566 total client Plan relationships. The Department estimates that 483,350 of these relationships are with small Plans.[162] Additionally, the Department estimates that 215,135 unique Plans have a relationship with a QPAM, of which 189,905 are assumed to be small Plans.[163]

Impacts of the Rule

In analyzing compliance costs associated with the Final Amendment, the Department considers the QPAM's existing compliance costs as the regulatory baseline. This includes ERISA's fiduciary duty requirements (to the extent applicable), requirements under the prior version of the QPAM Exemption, typical requirements in the individual exemption process, and individual exemptions granted in connection with Section I(g) ineligibility. The Department does not expect that the Final Amendment will lead to more than a modest increase to the existing costs associated with QPAM ineligibility and individual exemption requests related to Criminal Convictions. The Department is uncertain, however, regarding the number of QPAMs that would become ineligible under the expansion of the ineligibility provision related to Participating In Prohibited Misconduct. The Department also is uncertain about the extent to which the changes to asset management and equity thresholds in the Final Amendment will cause new costs for a small, unknown number of QPAMs that would lose their eligibility to rely on the exemption because they do not meet the increased thresholds. In order to mitigate such costs, the Department has phased-in the increase in the equity and asset thresholds in three-year increments beginning in 2024 and ending in 2030.

As discussed above, the Department lacks information and data to estimate the number of small QPAMs that would no longer be able to rely upon the exemption due to the expansion of the ineligibility provision related to Participating In Prohibited Misconduct or due to the increased size thresholds. The Department expects that small QPAMs remaining able to rely upon the amended QPAM Exemption will experience a similar impact as larger entities. Accordingly, the following analysis considers the cost that each QPAM is estimated to incur, depending on whether that QPAM loses the ability to rely upon the QPAM Exemption.

Although the Department has provided a cost analysis below, the heightened standards in this Final Amendment may result in entities being more diligent in compliance. Further, the Final Amendment will provide clear guardrails that would make the costs associated with QPAMs becoming ineligible under Section I(g) more clearly avoidable.

Preliminary Assumptions and Cost Estimate Inputs

The Department assumes that different types of personnel will be responsible for satisfying the requirements in the Final Amendment. To account for the labor costs associated with different types of personnel, the Department estimates the hourly labor costs for each type of personnel. In the analysis below, the Department applies the hourly labor costs of $63.45 for clerical personnel, $159.34 for internal legal professionals, $190.63 for financial managers, and $535.85 for outside legal professionals.[164]

[162] In the 2020 Form 5500, the Department found 64,216 QPAM relationships amongst a total of 87,559 Plans that filed the Form 5500 Schedule C. Small Plans are not required to file Schedule C. The number of client-Plan relationships for small Plans is estimated as: 547,566 − 64,216 = 483,350.

[163] In the 2020 Form 5500, the Department found 25,230 Plans that used QPAM service providers of 87,559 Plans that filed the Form 5500 Schedule C. Small Plans are not required to file Schedule C. The number of client-Plan relationships for small Plans is estimated as: 215,135 − 25,230 = 189,905.

[164] Labor costs for clerical personnel, accountants or auditors, internal legal professionals, and financial managers are based off internal Department of Labor calculations based on 2023 labor cost data. For a description of the Department's methodology for calculating wage rates, see *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/*

The Final Amendment requires QPAMs to distribute various notices to client Plans in certain situations, as described below. The Department does not have sufficient data to estimate how often QPAMs will elect to send such notices electronically or by mail. For the purposes of this analysis, the Department estimates that 80 percent of these notices will be delivered by first-class mail. The Department assumes the postage cost associated with sending notices through first-class mail is $0.66.[165]

Costs Incurred by All QPAMs

Rule Familiarization Costs

The Department expects that QPAMs are likely to rely on outside specialized legal counsel to ensure compliance with the Final Amendment. On average, the Department estimates that each QPAM will incur a cost equivalent to the cost of consulting with an outside legal professional for one hour. This results in an average cost of $536 per entity in the first year.[166]

Reporting Reliance on the QPAM Exemption—Subsection I(k)

The Department believes that the one-time requirement to report reliance on the QPAM Exemption via email to *QPAM@dol.gov* will result in a minor additional clerical cost. The information required under subsection I(k) is limited to the legal name of the entity relying upon the exemption and any name the QPAM may be operating under. This notification would occur only once for most QPAMs. In subsequent years, new QPAMs or QPAMs that change their name will be required to send the notification. The Department expects it will take one hour, on average, for each QPAM to prepare and send this electronic notification. This cost is estimated to be approximately $63 per entity either upon enactment of the Final Amendment, origination of a new QPAM, or a name change.[167]

If a QPAM fails to report their reliance on the exemption within 90 days, the Final Amendment provides the QPAM with an additional 90 days to send the notice to the Department. This notice must include an explanation for the QPAM's failure to provide timely notice. The Department estimates that preparing the notice will require a legal professional to spend 30 minutes on average resulting in a cost estimate of $80 per entity upon the effective date of the Final Amendment, origination of a new QPAM, or a name change.[168] The Department includes the cost for a clerical professional to draft and send an email notifying the Department of its reliance or name change in the cost estimate.

Recordkeeping—Section VI(u)

The Final Amendment includes a new recordkeeping provision that will apply to all QPAMs. Due to the fiduciary status of QPAMs and the existing regulatory environment, the Department assumes that QPAMs already maintain such records as part of their regular business practices. In addition, the recordkeeping requirements correspond to the six-year record retention period in ERISA section 107. The Department recognizes that some QPAMs may not be keeping records that satisfy the requirements and accordingly will experience a larger marginal cost for this requirement. However, the Department expects that most QPAMs are already fully compliant. The Department estimates that, on average, the additional recordkeeping requirements will require a QPAM's clerical personnel to spend one hour, resulting in a per-QPAM cost of $63.[169]

If a QPAM refuses to disclose information to any of the parties listed in Section VI(u), on the basis that information is exempt from disclosure, the QPAM must provide a written notice advising the requestor of the reason for the refusal and that the Department may request such information. The Department does not have sufficient data to estimate how often such a refusal is likely to occur; however, the Department believes such instances will be rare. In the case when a QPAM refuses to disclose the information, the Department estimates that an internal legal professional will spend one hour, resulting in a per-QPAM cost of $159.[170]

Costs Incurred by QPAMs Losing Eligibility for the Exemption for a Criminal Conviction or Prohibited Misconduct

In the regulatory impact analysis, the Department estimated that eight QPAMs would lose eligibility due to Criminal Convictions and four QPAMs would lose eligibility due to Prohibited Misconduct each year. The Department does not have sufficient data to estimate how many QPAMs losing eligibility are small entities. The following analysis examines the per-entity cost of a typical QPAM losing eligibility. The Department does not expect the cost for small and large QPAMs losing eligibility to be significantly different.

Notice to the Department of Prohibited Misconduct and Foreign NPAs or DPAs

If the QPAM, its Affiliates, or owners of a five percent or more interest in a QPAM Participates in Prohibited Misconduct or enters into a foreign equivalent of an NPA or DPA, the QPAM must notify the Department of the agreement. The Department assumes that this notice will require a legal professional to spend 30 minutes producing the notice and a clerical worker five minutes to send the notice, resulting in a per-entity cost of $85.[171]

Mandatory One-Year Transition Period—Section I(i)

As amended, the Department expects that the costs incurred by a QPAM during the Transition Period would be equivalent to the costs incurred by a QPAM obtaining an individual exemption. However, there will be an increased cost associated with the expansion of the ineligibility provisions. As discussed above, the Department estimates that four additional QPAMs will become ineligible each year due to Prohibited Misconduct.

Notice to Plans—Subsection I(i)(1)

Within 30 days after the Ineligibility Date, the QPAM must provide notice to the Department and each of its client Plans. The preamble provides more detail on the information the QPAM is required to include in this notice.

QPAMs that experience ineligibility and apply for individual exemption relief are already required to provide

technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf. Labor costs for outside legal professionals is calculated as a composite weighted average based on the Laffey Matrix for Wage Rates for the time period 6/01/2022–5/31/2023, see *http://www.laffeymatrix.com/see.html.* The labor cost is estimated as: (40% × $413) + (35% × $508) + (15% × $733) + (10% × $829) = $535.85.

[165] *See* USPS. ''Mailing & Shipping Prices.'' (2023). *https://www.usps.com/business/prices.htm.*

[166] The labor cost of $535.85 is applied for an external legal professional. The cost burden is estimated as: 1 hour × $535.85 = $535.85, rounded to $536.

[167] The labor rate of $63.45 is applied for a clerical worker. The cost is estimated as: (15/60) hours × $63.45 = $15.86, rounded to $16.

[168] The labor rate of $159.34 is applied for an internal legal professional. The cost is estimated as: 0.5 hour × $159.34 = $79.67, rounded to $80.

[169] The labor rate of $63.45 is applied for a clerical professional. The cost is estimated as: 1 hour × $63.45 = $63.45, rounded to $63.

[170] The labor rate of $159.34 is applied for an internal legal professional. The cost is estimated as: 1 hour × $159.34 = $159.34, rounded to $159.

[171] If preparing and sending each notice were to require an in-house legal professional 30 minutes and a clerical staff 5 minutes. The hour burden is estimated as: 1 notices × (30 minutes + 5 minutes) = 35 minutes. The labor cost of $159.34 is applied for an in-house legal professional, and a labor cost of $63.45 is applied for clerical staff. The cost is estimated as: (30 minutes × $159.34) + (5 minutes × $63.45) = $85. The Department assumes such notices will be sent electronically and will not create material or postage costs.

this type of notice. Therefore, the Department has attributed no incremental burden to this requirement for QPAMs that become ineligible due to a Criminal Conviction. However due to the expanded scope of ineligibility, QPAMs that become ineligible due to Participating In Prohibited Misconduct will incur costs to send notices to their client Plans.

The Department estimates that a legal professional will spend 30 minutes preparing the notification for each QPAM, and clerical staff will spend two minutes preparing and distributing the notifications by mail. Additionally, the Department assumes that each notice will require two sheets of paper. The total incremental cost related to ineligibility for Participating in Prohibited Misconduct is $196 per entity, including mailing expenses.[172]

The cost to send this notice to the Department will be negligible because it is required to be sent electronically, and the QPAM will have already prepared and sent the notice to its client Plans.

Indemnification

As discussed above, the Final Amendment requires QPAMs to agree to indemnify, hold harmless, and promptly restore actual losses to each client Plan for any damages directly resulting from a QPAM losing eligibility for the exemption due to a Criminal Conviction or Prohibited Misconduct. Damages may include losses and related costs arising from unwinding transactions with third parties, transitioning Plan assets to an alternative asset manager, and exposure to excise taxes under Code section 4975.

When the Department has granted individual exemptions regarding section I(g) ineligibility, it has required applicants to comply with additional protections for their plan and IRA clients that allow them to withdraw from the asset management arrangement without penalty and indemnify and hold them harmless in the event future misconduct occurs. Accordingly, in this analysis, no incremental burden is attributed to this requirement for QPAMs that become ineligible due to a Criminal Conviction.

However due to the expanded scope of ineligibility, QPAMs that become ineligible due to Participating In Prohibited Misconduct may incur costs associated with indemnifying their client Plans for losses that would occur if they moved to a new asset manager. In the Proposed Amendment, the Department requested comments on the costs of the indemnification provisions. The Department received several comments noting that the indemnity obligation will increase the risk and cost associated with being a QPAM and that these costs will be passed onto Plans in higher fees. The Department, however, did not receive any comments directly addressing the amount of the indemnification costs, and the Department does not have sufficient information and data to estimate these costs.[173]

Costs Incurred by QPAMs Requesting an Individual Exemption—Section I(j)

The amendment adds Section I(j), which states that a QPAM that is ineligible or anticipates that it will become ineligible may apply for an individual exemption from the Department. This individual exemption would allow the QPAM to continue relying on the relief provided in the QPAM Exemption for a longer period than the One-Year Transition Period.

Costs for all QPAMs Seeking an Individual Exemption

The Department estimates that, on average, QPAMs will submit three applications annually. In these three applications, the Department estimates that 12 QPAMs annually will become ineligible, with four losing eligibility due to Prohibited Misconduct and eight losing eligibility due to a Criminal Conviction.

The Final Amendment will require all QPAMs to include in their exemption applications the specific dollar amounts of investment losses resulting from foregone investment opportunities and any evidence supporting the proposition that investment opportunities would only be available to client Plans on less advantageous terms. For this requirement, the Department assumes a financial professional will spend four hours preparing the report, resulting in a per-application cost of $763, and a per-entity cost of $191.[174]

If an applicant requests the Department to exclude any term or condition from its exemption that is included in a recently granted individual exemption, the applicant must include a detailed statement with its exemption application explaining the reason(s) why the variation is necessary and in the interest and protective of affected Plans, their participants and beneficiaries, and IRA owners. While the Department is including this requirement in the Final Amendment, it expects that applicants who are ineligible due to Criminal Conduct already are conducting this analysis and thus would not incur an incremental cost.

QPAMs that become ineligible due to Participating In Prohibited Misconduct will incur incremental costs due to the requirement to review the Department's most recently granted individual exemptions involving Section I(g) ineligibility. The Department estimates that an outside legal professional would spend three hours reviewing past individual exemptions and draft this addition to the individual exemption application, resulting in a per-application cost of $1,600.[175] The Department estimates that each application would cover four QPAMs, resulting in a per-entity cost of $402.

Due to the expanded scope of ineligibility to include Participating In Prohibited Misconduct, additional financial institutions may lose eligibility for the QPAM Exemption and may seek an individual exemption. These entities would incur the additional costs of filing the application.

For this Final Amendment, the Department estimates that gathering the information for the application will require, on average, an in-house legal professional and clerical personnel to spend 10 hours each gathering and preparing information for the application at each QPAM. The Department assumes that the application will be prepared by an outside legal professional specializing in such matters. Once it receives information from the affected QPAMs, the Department estimates that an outside legal professional will spend 15 hours preparing the application. For the four QPAMs losing eligibility due to Prohibited Misconduct, this will result

[172] The labor cost of $159.34 is applied for a legal professional, and the labor cost of $63.45 is applied for clerical personnel. The equivalent cost is estimated as: (0.5 hours of professional legal time × $159.34) + (50 Plans × 80% of notices being mailed × 2/60 hours of clerical personnel time × $63.45) = $165. The material and postage cost are estimated as: (50 Plans × 80% of notices being mailed) × [(2 pages × $0.05 per page) + $0.68] = $31. The total cost is estimated to be $196 ($165 + $31).

[173] The Department received several comments addressing the specific costs associated with amending WMAs, as required under the Proposed Amendment. These costs did not directly address indemnification costs but rather contract negotiation and updating the WMAs. The Department moved the proposed requirements for the WMA into the Transition Period provisions in response to commenters and believes the cost to ineligible QPAMs regarding this will generally be captured within the required notices to client Plan after an ineligibility trigger.

[174] An hourly rate of $190.63 is applied for financial professional. The equivalent cost is estimated as: (4 hours × $190.63 financial professional rate) = $763.

[175] A labor cost of $535.85 is applied for an outside legal professional. The equivalent cost is estimated as: (3 hours × $535.85 outside legal professional labor) = $1,608.

in a per-application cost of $26,000 [176] or a per-QPAM cost of $6,465.

For applications that are published as proposed exemptions, the QPAM must prepare and distribute a notice to interested persons. Similarly, if the exemptions are ultimately granted, each of these four QPAMs will be required to send an objective description of the facts and circumstances upon which the misconduct is based to each client Plan. The Department estimates four QPAMs will be required to notify interested parties and client Plans under these circumstances, with each QPAM having an average of 50 client Plans. The Department estimates that clerical personnel will spend 10 minutes to distribute the notices and objective descriptions, resulting in a per-QPAM cost of $264 [177] In addition, material and mailing costs for these notices totals approximately $94.[178]

Costs Incurred by Plans and Participants and Beneficiaries

As a result of the adjustments to the asset management and equity thresholds to the QPAM definition in Section VI(a), the Department acknowledges some QPAMs may not meet the new threshold requirements, and, consequently, would no longer be able to rely on the QPAM Exemption. The Department expects QPAMs and Plans that utilize these QPAMs to incur costs due to this transition, but it lacks sufficient data to estimate the impact.[179] The Department has requested similar data in connection with individual exemption applications following convictions covered by Section I(g), but the data provided by applicants and costs identified by them has been limited. The Department requested comments on these costs in the Proposed Amendment but did not receive comments identifying specific costs that would be incurred due to a possible transition to a new QPAM by small or large entities.

Summary of Costs

The Department estimates that the total, per-entity, estimated incremental annual costs associated with the amendment will range between $854 and $10,282 in the first year and between $318 and $9,746 in subsequent years. Table 5 summarizes the per entity costs for each requirement and the estimated annual costs associated with the amendment for QPAMs to comply with the exemption, QPAMs who trigger the conditions associated with Participating In Prohibited Misconduct, and QPAMs that become ineligible due to a Criminal Conviction.

TABLE 5—INCREMENTAL COST SUMMARY ASSOCIATED WITH AMENDMENTS, PER ENTITY

Requirement	Cost for QPAMs to comply with exemption	Cost for QPAMs with prohibited misconduct *(estimated 4 per year)*	Cost for QPAMs with a conviction *(estimated 8 per year)*
Rule Familiarization	$536	$536	$536
Reporting Reliance on the QPAM Exemption [1]	$16	$16	$16
Notice of Failure To Report Reliance [2]	$80	$80	$80
Recordkeeping	$63	$63	$63
Notice of Refusal To Disclose Requested Information	$159	$159	$159
Notice of Prohibited Misconduct or Foreign NPA/DPA [3]	.....	$85	.....
Notice to Plans of Ineligibility	.....	$196	.....
Requesting an Individual Exemption Costs: [4]			
Preparation Labor Cost	.....	$6,465	.....
Notices Distribution	.....	$622	.....
Additional Requirement—Criminal Conviction	.....	.....	$191
Additional Requirement—Prohibited Misconduct	.....	$593	.....
First Year Total Estimated Annual Cost	$854	$8,815	$1,045
Cost as a Percentage of Equity Capital or Net Worth Threshold Effective December 31, 2024 [5]	*0.05%*	*0.65%*	*0.07%*
Subsequent Years Total Estimated Annual Cost [1]	$318	$9,746	$509
Cost as a Percentage of Equity Capital or Net Worth Threshold Effective December 31, 2024 [5]	*0.02%*	*0.62%*	*0.03%*

Notes: Only quantifiable costs are displayed.

[1] Most entities will only need to provide this notice once, either upon the effective date of the Final Amendment or when first relying on the QPAM Exemption. Entities will also need to provide the notice after a name change.

[2] Entities will only need to provide this notice after failing to report its reliance on the exemption within the allotted time.

[3] Entities will only need to provide such a notice if the QPAM, its Affiliates, or owners of a five (5) percent or more interest Participate In Prohibited Misconduct or execute a foreign equivalent of a non-prosecution or deferred prosecution agreement.

[4] One individual exemption application associated with ineligible QPAMs (caused by Prohibited Misconduct) are estimated each year, affecting 4 QPAMs. This cost reflects the total cost of the application divided by the number of QPAMs.

[176] The hour burden is estimated as: [4 QPAMs × (20 hours from an in-house legal professional + 20 hours for clerical personnel)] + (1 application × 15 hours from an external legal professional) = 175 hours. The labor cost of $159.34 is applied for an in-house legal professional, a labor cost of $63.45 is applied for clerical personnel, and a labor cost of $535.85 is applied for an outside legal professional. The equivalent cost is estimated as: (4 QPAMs × 20 hours × $159.34) + (4 QPAMs × 20 hours × $63.45) + (1 application × 15 hours × $535.85) = $25,861, rounded to $26,000.

[177] A labor cost of $63.45 is applied for clerical personnel The equivalent cost is estimated as: 50 Plans per QPAM × (10/60) hours × $63.45 = $264.

[178] The Department further assumes that notices and the descriptions of facts and circumstances will be delivered separately, comprising 15 and 5 pages, respectively. With a printing cost of $0.05 per page and a mailing cost of $0.68 per notice, the Department estimates the mailing cost as 50 Plans per QPAM × 80% of notices mailed × {[(15 × $0.05) + $0.68] + [(5 × $0.05) + $0.68]} = $94.

[179] Some QPAMs have suggested in the past that there could be costs associated with unwinding transactions that relied on the QPAM Exemption and reinvesting assets in other ways. The loss of QPAM status could also require an asset manager to keep lists of Parties in Interest to its client Plans to ensure the asset manager does not engage in prohibited transactions. However, even without the QPAM Exemption, a wide variety of investments are available that do not involve non-exempt prohibited transactions.

[5] Banks, savings and loan associations, insurance companies, and investment advisers each have different size threshold requirements, as discussed in more detail in the Affected Entities Section of the regulatory impact analysis. However, the size threshold requirements for each entity type include either an equity capital or net worth requirement. Effective no later than December 31, 2024, the equity capital and net worth requirements will be $1,570,300. For subsequent years, this estimate does not reflect future increases in equity capital and net worth threshold requirements. As these thresholds increase, the Department expects that the cost as a percentage of equity capital or net worth will decrease.

On January 1, 2025, each entity type will be required to have either equity capital or net worth exceeding $1,570,300. Table 5 shows the per entity cost as a percent of this equity capital or net worth threshold. While some entities face additional size threshold requirements, this measure can provide insight into the magnitude of costs faced by small QPAMs. This demonstrates that the smallest asset managers able to qualify for the QPAM Exemption, who are not facing ineligibility, are estimated to incur costs amounting to 0.05 percent of this threshold in the first year and 0.02 percent in subsequent years. The incremental costs incurred by the few QPAMs facing ineligibility due to Prohibited Misconduct or a Criminal Conviction are higher but remain below one percent of the threshold.

As discussed in the Affected Entities section, the Department lacks sufficient data to identify how many of the estimated asset managers providing services to Plans fall below the SBA's small business size thresholds and are above the QPAM eligibility thresholds. Table 6 shows the estimated cost as a percent of the SBA size threshold, in terms of annual receipts for investment banks, insurance companies and investment advisers and in terms of assets under management for commercial banks and savings and loans associations. For most QPAMs, the cost to comply with the Final Amendment is expected to amount to less than 0.01 percent of the respective SBA threshold. The few QPAMs facing ineligibility due to Prohibited Misconduct or a Criminal Conviction may incur costs around 0.02 percent of the respective SBA threshold. The table also shows the estimated cost relative to 50 percent and 10 percent of the SBA threshold for receipts and assets. Even for entities with receipts or assets amounting to 10 percent of the SBA threshold, the costs associated with the Final Amendment account for less than 0.5 percent of the SBA threshold.

TABLE 6—INCREMENTAL COST ASSOCIATED WITH AMENDMENTS, AS A PERCENT OF THE SBA SIZE STANDARD

Size standard	SBA threshold		50% of SBA threshold		10% of SBA threshold	
	$47.0 Million in receipts [1] (%)	$850 Million in assets [2] (%)	$23.5 Million in receipts [1] (%)	$425 Million in assets [2] (%)	$4.7 Million in receipts [1] (%)	$85.0 Million in assets [2] (%)
First Year Total Estimated Annual Cost						
Compliance With the Exemption	0.002	[3]	0.004	[3]	0.018	0.001
QPAMs With Prohibited Misconduct	0.022	0.001	0.044	0.002	0.219	0.012
QPAMs With a Conviction	0.002	[3]	0.004	[3]	0.022	0.001
Subsequent Years Total Estimated Annual						
Compliance With the Exemption	0.001	[3]	0.001	[3]	0.007	[3]
QPAMs With Prohibited Misconduct	0.021	0.001	0.041	0.002	0.207	0.011
QPAMs With a Conviction	0.001	[3]	0.002	[3]	0.011	0.001

[1] The entities subject to this SBA size threshold include investment banks, insurance companies, and investment advisers.
[2] The entities subject to this SBA size threshold include commercial banks and savings and loan associations.
[3] Less than 0.001%.

In summary, the Department lacks data on how QPAMs are distributed relative to the measures of size used by the SBA. However, due to the equity capital and net worth thresholds to qualify for the QPAM exemption, the Department expects that most QPAMs will be on the higher end of the receipts or assets distribution. Based on the analysis above, the Department does not expect the costs associated with the Final Amendment to represent a significant percentage of annual receipts or assets under management of QPAMs.

Regulatory Alternatives

This section of the Final Regulatory Flexibility Act analysis addresses alternatives the Department considered when developing the Final Amendment. The Department evaluates these alternatives and discusses how the alternatives would have affected small entities qualitatively and quantitatively where possible. A more in-depth discussion of the regulatory alternatives is included in the regulatory impact analysis above.

Do Not Amend the QPAM Exemption

The Department considered not expanding the scope of Section I(g) and maintaining its practice of addressing ineligibility under Section I(g) only through the individual exemption process. In considering whether to amend the QPAM Exemption, the Department compared the marginal costs imposed on QPAMs to the marginal benefits experienced by Plans. The Department decided against this alternative in favor of this Final Amendment, relying on its experience processing individual exemption applications to create a smoother transition between the QPAM Exemption and the individual exemption program so that a QPAM's client Plans have certainty regarding their rights after an ineligibility event occurs.

While QPAMs, including small QPAMs, will experience increased costs associated with the Final Amendment, for most QPAMs, these costs are expected to be small compared to the size thresholds required for an investment manager to qualify as a QPAM. This is demonstrated in Table 5 above.

Amend the QPAM Exemption to require QPAMs to amend Written Management Agreements with up-front terms that apply in the event of ineligibility.

In the Proposed Amendment, the Department included a requirement for all QPAMs to amend their WMAs with client Plans to include:

(1) A provision providing that in the event the QPAM, its Affiliates, and five percent or more owners engage in conduct resulting in a Criminal Conviction or receipt of a Written

Ineligibility Notice, the QPAM would not restrict its client Plan's ability to terminate or withdraw from its arrangement with the QPAM;

(2) A provision requiring the QPAM to indemnify, hold harmless, and promptly restore actual losses to each client Plan for any damages directly resulting from a violation of applicable laws, a breach of contract, or any claim arising out of the failure of such QPAM to remain eligible for relief under the QPAM Exemption as a result of conduct that leads to a Criminal Conviction or Prohibited Misconduct; and

(3) A provision requiring the QPAM to agree not to employ or knowingly engage any individual that Participated In the conduct that is the subject of a Criminal Conviction or Prohibited Misconduct.

As discussed in greater detail above in the preamble, the Department believes that these provisions provide an important protection to Plans, participants, beneficiaries, and IRA owners. However, based on the feedback from commenters, the Department has removed the requirement to amend WMAs. Instead, the Final Amendment requires QPAMs to notify and agree to these provisions with Plans in the Notice QPAMs must send to Plans within 30 days after the Ineligibility Date. The Department determined the approach in the Final Amendment provides the same protection to Plans while significantly reducing the cost burden for large and small QPAMs to amend their WMAs.

Asset Management and Equity Thresholds

The Department considered two alternatives related to the asset management and equity thresholds, described below.

Amend the QPAM Exemption to remove asset management and equity thresholds.

As an alternative to updating the asset management and equity thresholds, the Department revisited whether such thresholds could be removed entirely from the exemption. Removing thresholds would allow more small investment managers to qualify for relief under the exemption. However, the Department determined that this approach would be inconsistent with one of the core concepts upon which the QPAM Exemption was based. In the absence of an appropriate alternative ensuring that a QPAM will remain an independent decision-maker, free from the influence of other Plan fiduciaries, the Department is unable to justify the removal of the thresholds.

Update the asset management and equity thresholds to full CPI-adjusted values at once.

The Proposed Amendment included CPI-adjusted values that would have been fully updated to 2022 values. The Department received a variety of comments regarding the possible unintended impact to QPAMs and their client Plans who would not be able to satisfy such significant increases at once. This could have resulted in smaller QPAMs losing relief and caused significant disruption and cost to those small QPAMs and their client Plans.

In order to minimize the impact of an immediate increase in the asset and equity thresholds on small QPAMs who may lose QPAMs status, the Department determined that the most appropriate method to update the thresholds in the Final Amendment is to increase them in three-year increments beginning in 2024 and ending in 2030. This approach will limit the disruption an uncertain number of small QPAMs could experience if they lose their eligibility to rely on the exemption due to the increased thresholds by providing them with an extended period to adjust their business models.

Steps the Agency Has Taken To Minimize the Impacts on Small Entities

The Department's decision to update the asset management and equity thresholds could have a significant impact on some small QPAMs that no longer qualify to use the exemption. As discussed in the Regulatory Alternatives section, to reduce the impact on small QPAMs, the thresholds were adjusted in three-year increments to give small QPAMs time to make decisions and adjust.

Some small QPAMs may lose the QPAM portion of their business. Others may adapt. There still may be other exemptions that these QPAMs could use to service their Plan clients, or they could seek an individual exemption that could allow them to continue offering QPAM services, depending upon the facts and circumstances presented to the Department in the exemption application.

Duplicate, Overlapping, or Relevant Federal Rules

The Department has attempted to avoid duplication of requirements. The required policies and procedures and exemption audit are unique to the circumstances of the particular transactions covered by the exemption and do not replicate any other requirements by state or federal regulations. The exemption permits respondents to satisfy the requirements for written guidelines between the QPAM and property manager with documents that are already in existence due to ordinary and customary business practices, provided such documents contain the required disclosures.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 requires each federal agency to prepare a written statement assessing the effects of any federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by state, local, and tribal governments, in the aggregate, or by the private sector.[180] For purposes of the Unfunded Mandates Reform Act, as well as Executive Order 12875, this Final Amendment does not include any federal mandate that the Department expects would result in such expenditures by state, local, or tribal governments, or the private sector.[181]

Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires adherence by federal agencies to specific criteria in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government.[182] Federal agencies promulgating regulations that have federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final rule.

In the Department's view, this Final Amendment will not have federalism implications because it would not have direct effects on the states, on the relationship between the national government and the states, nor on the distribution of power and responsibilities among various levels of government. The Department welcomed input from affected states regarding this assessment in the Proposed Amendment but received no comments.

General Information

The attention of interested persons is directed to the following:

[180] 2 U.S.C. 1501 *et seq.* (1995).

[181] Enhancing the Intergovernmental Partnership, 58 FR 58093 (Oct. 28, 1993).

[182] Federalism, 64 FR 153 (Aug. 4, 1999).

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) and/or Code section 4975(c)(2) does not relieve a fiduciary, or other Party in Interest with respect to a Plan or IRA, from certain other provisions of ERISA and the Code, including but not limited to any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge their duties respecting the Plan solely in the interests of the participants and beneficiaries of the Plan. Additionally, the fact that a transaction is the subject of an exemption does not affect the requirements of Code section 401(a), including that the Plan must operate for the exclusive benefit of the employees of the employer maintaining the Plan and their beneficiaries;

(2) In accordance with ERISA section 408(a) and Code section 4975(c)(2), and based on the entire record, the Department finds that this exemption is administratively feasible, in the interests of Plans, their participants and beneficiaries, and IRA owners, and protective of the rights of participants and beneficiaries of the Plan and IRA owners;

(3) The Final Amendment to the QPAM Exemption is applicable to a particular transaction only if the transaction satisfies the conditions specified in the exemption; and

(4) The Final Amendment to the QPAM Exemption is supplemental to, and not in derogation of, any other provisions of ERISA and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

PTE 84–14

PTE 84–14 is amended to read as follows:

Section I—General Exemption

The restrictions of ERISA section 406(a)(1)(A) through (D) and the taxes imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (D), shall not apply to a transaction between a Party in Interest with respect to a Plan and an Investment Fund (as defined in Section VI(b)) in which the Plan has an interest, and which is managed by a Qualified Professional Asset Manager (QPAM) (as defined in Section VI(a)), if the following conditions are satisfied:

(a) At the Time of the Transaction (as defined in Section VI(i)), the Party in Interest, or its Affiliate (as defined in Section VI(c)), does not have the authority to—

(1) Appoint or terminate the QPAM as a manager of the Plan assets involved in the transaction, or

(2) Negotiate on behalf of the Plan the terms of the management agreement with the QPAM (including renewals or modifications thereof) with respect to the Plan assets involved in the transaction;

Notwithstanding the foregoing, in the case of an Investment Fund in which two or more unrelated Plans have an interest, a transaction with a Party in Interest with respect to a Plan will be deemed to satisfy the requirements of this Section I(a) if the assets of the Plan managed by the QPAM in the Investment Fund, when combined with the assets of other Plans established or maintained by the same employer (or Affiliate thereof described in Section VI(c)(1) below) or by the same employee organization, and managed in the same Investment Fund, represent less than ten (10) percent of the assets of the Investment Fund;

(b) The transaction is not described in—

(1) Prohibited Transaction Exemption 2006–16 (71 FR 63786; October 31, 2006) (relating to securities lending arrangements) (as amended or superseded),

(2) Prohibited Transaction Exemption 83–1 (48 FR 895; January 7, 1983) (relating to acquisitions by plans of interests in mortgage pools) (as amended or superseded), or

(3) Prohibited Transaction Exemption 82–87 (47 FR 21331; May 18, 1982) (relating to certain mortgage financing arrangements) (as amended or superseded);

(c) The terms of the transaction, commitments, and investment of fund assets, and any associated negotiations are determined by the QPAM (or under the authority and direction of the QPAM) which represents the interests of the Investment Fund. Either the QPAM, or (so long as the QPAM retains full fiduciary responsibility with respect to the transaction) a property manager acting in accordance with written guidelines established and administered by the QPAM, makes the decision on behalf of the Investment Fund to enter into the transaction, provided that the transaction is not part of an agreement, arrangement, or understanding designed to benefit a Party in Interest. In exercising its authority, the QPAM must ensure that any transaction, commitment, or investment of fund assets for which it is responsible is based on its own independent exercise of fiduciary judgment and free from any bias in favor of the interests of the plan sponsor or other parties in interest. The QPAM may not be appointed or relied upon to uncritically approve transactions, commitments, or investments negotiated, proposed, or approved by the plan sponsor, or other parties in interest. The prohibited transaction relief provided under this exemption applies only in connection with an Investment Fund that is established primarily for investment purposes. No relief is provided under this exemption for any transaction that has been planned, negotiated, or initiated by a Party in Interest, in whole or in part, and presented to a QPAM for approval to the extent the QPAM would not have sole responsibility with respect to the transaction as required by this Section I(c);

(d) The Party in Interest dealing with the Investment Fund is neither the QPAM nor a person Related to the QPAM;

(e) The transaction is not entered into with a Party in Interest with respect to any Plan whose assets are managed by the QPAM, when combined with the assets of other Plans established or maintained by the same employer (or Affiliate thereof described in subsection VI(c)(1) below) or by the same employee organization, and managed by the QPAM, represent more than twenty (20) percent of the total client assets managed by the QPAM at the time of the transaction; and

(f) At the Time of the Transaction, and at the time of any subsequent renewal or modification thereof that requires the consent of the QPAM, the terms of the transaction are at least as favorable to the Investment Fund as the terms generally available in arm's length transactions between unrelated parties.

(g) *Integrity.*

(1) *Ineligibility due to a Criminal Conviction or Prohibited Misconduct.* Subject to the Ineligibility Date provision set forth in Section I(h), a QPAM is ineligible to rely on this exemption for 10 years following:

(A) A Criminal Conviction, as defined in Section VI(r), of the QPAM or any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM; or

(B) The QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM Participates In Prohibited Misconduct as defined in Section VI(s) and VI(t); or

(2) *Notice to the Department regarding Participation In Prohibited Misconduct.* The QPAM must submit a notice to the Department at *QPAM@dol.gov* if the QPAM, any Affiliate (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM, Participates In Prohibited Misconduct as defined in Section VI(s) and VI(t), or enters into an agreement with a foreign government, however denominated by the laws of the relevant foreign government, that is substantially equivalent to a non-prosecution agreement (NPA) or deferred prosecution agreement (DPA) described in section VI(s)(1). The notice must be sent within 30 calendar days after the Ineligibility Date for the Prohibited Misconduct as determined pursuant to Section (I)(h)(2) below or the execution date of the substantially-equivalent foreign NPA or DPA, and the notice must include a description of the Prohibited Misconduct or the substantially-equivalent foreign NPA or DPA and the name of and contact information for the QPAM.

(h) *Ineligibility Date.* A QPAM shall become ineligible:

(1) as of the ''Conviction Date,'' which is the date of the judgment of the trial court (or the date of the judgment of any court in a foreign jurisdiction that is the equivalent of a U.S. federal or state trial court), regardless of whether that judgment is appealed; or

(2) (A) as of the date on or after June 17, 2024 that the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM executes a non-prosecution agreement, or a deferred prosecution agreement described in Section VI(s)(1); or

(B) as of the date on or after June 17, 2024 that a final judgment (regardless of whether the judgment is appealed) or a court-approved settlement is ordered by a Federal or State criminal or civil court in connection with determining that the QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM has engaged in Prohibited Misconduct as defined in Section VI(s)(2) and VI(t).

A person will become eligible to rely on this exemption again only upon a subsequent judgment reversing such person's conviction or civil judgment, the effective date of any individual prohibited transaction exemption it receives that expressly permits the relief in this exemption, or the expiration of the 10-year ineligibility period.

(i) *One-Year Transition Period Due to Ineligibility* (One-Year Transition Period or Transition Period). Any QPAM that becomes ineligible under subsection I(g)(1) must provide a Transition Period for its client Plans. Relief is available for transactions (including past transactions) under this exemption during the Transition Period for a maximum period of one year after the Ineligibility Date, provided that the QPAM complies with each condition of the exemption throughout the one-year period (including those additional conditions specified in this subsection (i)). The relief is available during the Transition Period under this exemption only for the QPAM's client Plans that had a pre-existing Written Management Agreement required under subsection VI(a) with the QPAM on the Ineligibility Date. A QPAM must ensure that it manages Plan assets prudently and loyally during the Transition Period. During the Transition Period, the QPAM must comply with the following additional conditions:

(1) Within 30 days after the Ineligibility Date, the QPAM must provide notice to the Department at *QPAM@dol.gov* and each of its Client Plans stating:

(A) Its failure to satisfy subsection I(g)(1) and the resulting initiation of this One-Year Transition Period;

(B) That during the Transition Period, the QPAM:

(i) Agrees not to restrict the ability of a client Plan to terminate or withdraw from its arrangement with the QPAM;

(ii) Will not impose any fees, penalties, or charges on client Plans in connection with the process of terminating or withdrawing from an Investment Fund managed by the QPAM except for reasonable fees, appropriately disclosed in advance, that are specifically designed to: (a) prevent generally recognized abusive investment practices, or (b) ensure equitable treatment of all investors in a pooled fund in the event such withdrawal or termination may have adverse consequences for all other investors, provided that such fees are applied consistently and in a like manner to all such investors;

(iii) Agrees to indemnify, hold harmless, and promptly restore actual losses to the client Plans for any damages that directly result to them from a violation of applicable laws, a breach of contract, or any claim arising out of the conduct that is the subject of a Criminal Conviction or Prohibited Misconduct of the QPAM, an Affiliate (as defined in Section VI(d)), or an owner, direct or indirect, of a five (5) percent or more interest in the QPAM. Actual losses specifically include losses and costs arising from unwinding transactions with third parties and from transitioning Plan assets to an alternative asset manager as well as costs associated with any exposure to excise taxes under Code section 4975 as a result of a QPAM's inability to rely upon the relief in the QPAM Exemption; and

(iv) Will not employ or knowingly engage any individual that Participated In the conduct that is the subject of a Criminal Conviction or Prohibited Misconduct, regardless of whether the individual is separately convicted in connection with the criminal conduct.

(C) An objective description of the facts and circumstances upon which the Criminal Conviction or Prohibited Misconduct is based, written with sufficient detail to fully inform the client Plan's fiduciary of the nature and severity of the conduct so that the fiduciary can satisfy its duties of prudence and loyalty under section 404 of ERISA (29 U.S.C. 1104), as applicable, with respect to hiring, monitoring, evaluating, and retaining the QPAM in a non-QPAM capacity;

(2) As of the Ineligibility Date under Section I(h), the QPAM must not employ or knowingly engage any individual that Participated In the conduct that is the subject of a Criminal Conviction or that Participated In Prohibited Misconduct causing ineligibility of the QPAM under subsection I(g)(1); and

(3) After the One-Year Transition Period expires, and if the Criminal Conviction is not reversed on appeal, the entity may not rely on the relief provided in this exemption until the expiration of the 10-year ineligibility period unless it obtains an individual exemption permitting it to continue relying upon this exemption.

(j) *Requests for an Individual Exemption.* A QPAM that is ineligible or anticipates that it will become ineligible due to an actual or possible Criminal Conviction or Participating In Prohibited Misconduct as defined in Sections VI(r) and VI(s) may apply for an individual exemption from the Department to continue to rely on the relief provided in this exemption for a longer period than the One-Year Transition Period. An applicant should review the Department's most recently granted individual exemptions involving Section I(g) ineligibility with the expectation that similar conditions will be required of the applicant, if the Department proposes and grants a requested exemption. To that end, if an applicant requests the Department to exclude any term or condition from its

exemption that is included in a recently granted individual exemption, the applicant must include a detailed statement with its exemption application explaining the reason(s) why the proposed variation is necessary and in the interest and protective of affected Plans, their participants and beneficiaries, and individuals for whose benefit a Plan described in Code section 4975(e)(1)(B) or (C) is established (IRA owners). The Department will review such requests consist with the requirements of ERISA section 408(a) and Code section 4975(c)(2). Such applicants also should provide detailed information in their applications quantifying the specific cost or harms in dollar amounts, if any, their client Plans would suffer if the QPAM could not rely on the exemption after the Transition Period, including the specific dollar amounts of investment losses resulting from foregone investment opportunities and any evidence supporting the proposition that investment opportunities would be available to client Plans on less advantageous terms. An applicant should not construe the Department's acceptance of an individual exemption application as a guarantee that the Department will grant an individual exemption. A QPAM that submits an individual exemption application must ensure that it manages Plan assets prudently and loyally during the Transition Period in accordance with section 404 of ERISA (29 U.S.C. 1104), as applicable.

(k) Any QPAM that relies upon this exemption must notify the Department via email at *QPAM@dol.gov.* Each QPAM that relies upon the exemption must report the legal name of each business entity relying upon the exemption in the email to the Department and any name the QPAM may be operating under. This notification needs to be reported only once unless there is a change to the legal name or operating name(s) of the QPAM relying upon the exemption or the QPAM no longer is relying on the exemptive relief provided in the exemption. The QPAM must provide notice to the Department within ninety (90) calendar days of its reliance on the exemption or a change to its legal or operating name. If the QPAM inadvertently fails to provide notice to the Department within the initial 90 calendar day period, it may notify the Department of its reliance on the exemption or name change and failure to report without losing the relief provided by this exemption. This notice must be provided within an additional 90 calendar days along with an explanation for the QPAM's failure to provide notice. A QPAM may notify the Department if it is no longer relying upon this exemption at any time.

Section II—Specific Exemption for Employers

The restrictions of ERISA sections 406(a), 406(b)(1), and 407(a) and the taxes imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (E), shall not apply to:

(a) The sale, leasing, or servicing of Goods or the furnishing of services, to an Investment Fund managed by a QPAM by a Party in Interest with respect to a Plan having an interest in the fund, if—

(1) The Party in Interest is an employer any of whose employees are covered by the Plan or is a person who is a Party in Interest by virtue of a relationship to such an employer (described in Section VI(c) below),

(2) The transaction is necessary for the administration or management of the Investment Fund,

(3) The transaction takes place in the ordinary course of a business engaged in by the Party in Interest with the general public,

(4) The amount attributable in any taxable year of the Party in Interest to transactions engaged in with an Investment Fund pursuant to this Section II(a) does not exceed one (1) percent of the gross receipts derived from all sources for the prior taxable year of the Party in Interest, and

(5) The requirements of Sections I(c) through (g) above are satisfied with respect to the transaction.

(b) The leasing of office or commercial space by an Investment Fund maintained by a QPAM to a Party in Interest with respect to a Plan having an interest in the Investment Fund, if—

(1) The Party in Interest is an employer any of whose employees are covered by the Plan or is a person who is a Party in Interest by virtue of a relationship to such an employer (described in Section VI(c) below);

(2) No commission or other fee is paid by the Investment Fund to the QPAM or to the employer, or to an Affiliate of the QPAM or employer (as defined in Section VI(c) below), in connection with the transaction;

(3) Any unit of space leased to the Party in Interest by the Investment Fund is suitable (or adaptable without excessive cost) for use by different tenants;

(4) The amount of space covered by the lease does not exceed fifteen (15) percent of the rentable space of the office building, integrated office park, or of the commercial center (if the lease does not pertain to office space);

(5) In the case of a Plan that is not an eligible individual account plan (as defined in ERISA section 407(d)(3)), immediately after the transaction is entered into, the aggregate fair market value of employer real property and employer securities held by the Investment Funds of the QPAM in which the Plan has an interest does not exceed ten (10) percent of the fair market value of the assets of the Plan held in those Investment Funds. In determining the aggregate fair market value of employer real property and employer securities as described herein, a Plan shall be considered to own the same proportionate undivided interest in each asset of the Investment Fund or funds as its proportionate interest in the total assets of the Investment Fund(s). For purposes of this requirement, the term ''employer real property'' means real property leased to, and the term ''employer securities'' means securities issued by an employer any of whose employees are covered by the Plan or a Party in Interest of the Plan by reason of a relationship to the employer described in ERISA section 3(14)(E) or (G); and

(6) The requirements of Sections I(c) through (g) above are satisfied with respect to the transaction.

Section III—Specific Lease Exemption for QPAMs

The restrictions of ERISA section 406(a)(1)(A) through (D), 406(b)(1) and (2), and the taxes imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (E), shall not apply to the leasing of office or commercial space by an Investment Fund managed by a QPAM to the QPAM, a person who is a Party in Interest of a Plan by virtue of a relationship to such QPAM described in ERISA section 3(14)(G), (H), or (I), or a person not eligible for the General Exemption of Section I above by reason of Section I(a), if—

(a) The amount of space covered by the lease does not exceed the greater of 7,500 square feet or one (1) percent of the rentable space of the office building, integrated office park, or of the commercial center in which the Investment Fund has the investment;

(b) The unit of space subject to the lease is suitable (or adaptable without excessive cost) for use by different tenants;

(c) At the Time of the Transaction, and at the time of any subsequent renewal or modification thereof that requires the consent of the QPAM, the terms of the transaction are not more

favorable to the lessee than the terms generally available in arm's length transactions between unrelated parties; and

(d) No commission or other fee is paid by the Investment Fund to the QPAM, any person possessing the disqualifying powers described in Section I(a), or any Affiliate of such persons (as defined in Section VI(c) below), in connection with the transaction.

Section IV—Transactions Involving Places of Public Accommodation

The restrictions of ERISA section 406(a)(1)(A) through (D) and 406(b)(1) and (2) and the taxes imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (E), shall not apply to the furnishing of services and facilities (and Goods incidental thereto) by a place of public accommodation owned by an Investment Fund managed by a QPAM to a Party in Interest with respect to a Plan having an interest in the Investment Fund, if the services and facilities (and incidental Goods) are furnished on a comparable basis to the general public.

Section V—Specific Exemption Involving QPAM-Sponsored Plans

The relief in Sections I, III, or IV above from the applicable restrictions of ERISA section 406(a), section 406(b)(1) and (2), and the taxes imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (E), shall apply to a transaction involving the assets of a Plan sponsored by the QPAM or an Affiliate (as defined in Section VI(c)) of the QPAM if:

(a) The QPAM has discretionary authority or control with respect to the Plan assets involved in the transaction;

(b) The QPAM adopts Written Policies and Procedures that are designed to ensure compliance with the conditions of the exemption;

(c) An independent auditor, who has appropriate technical training or experience and proficiency with ERISA's fiduciary responsibility provisions and so represents in writing, conducts an Exemption Audit on an annual basis. Following completion of the Exemption Audit, the auditor shall issue a written report to the Plan presenting its specific findings regarding the level of compliance with: (1) the Written Policies and Procedures adopted by the QPAM in accordance with Section V(b) above, and (2) the objective requirements of this exemption. The written report shall also contain the auditor's overall opinion regarding whether the QPAM's program complied with: (1) the Written Policies and Procedures adopted by the QPAM, and (2) the objective requirements of the exemption. The Exemption Audit and the written report must be completed within six months following the end of the year to which the audit relates; and

(d) The transaction meets the applicable requirements set forth in Sections I, III, or IV above.

Section VI—Definitions and General Rules

For purposes of this exemption:

(a) The term ''Qualified Professional Asset Manager'' or ''QPAM'' means an Independent Fiduciary which is—

(1) A bank, as defined in section 202(a)(2) of the Investment Advisers Act of 1940 that has the power to manage, acquire or dispose of assets of a Plan, which bank has, as of the last day of its most recent fiscal year, Equity Capital in excess of $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2024, substitute $1,570,300 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2027, substitute $2,140,600 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2030, substitute $2,720,000 for $1,000,000; or

(2) A savings and loan association, the accounts of which are insured by the Federal Deposit Insurance Corporation that has made application for and been granted trust powers to manage, acquire or dispose of assets of a Plan by a State or Federal authority having supervision over savings and loan associations, which savings and loan association has, as of the last day of its most recent fiscal year, Equity Capital or Net Worth in excess of $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2024, substitute $1,570,300 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2027, substitute $2,140,600 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2030, substitute $2,720,000 for $1,000,000; or

(3) An insurance company which is qualified under the laws of more than one State to manage, acquire, or dispose of any assets of a Plan, which company has, as of the last day of its most recent fiscal year, Net Worth in excess of $1,000,000 and which is subject to supervision and examination by a State authority having supervision over insurance companies. Effective as of the last day of the fiscal year ending no later than December 31, 2024, substitute $1,570,300 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2027, substitute $2,140,600 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2030, substitute $2,720,000 for $1,000,000; or

(4) An investment adviser registered under the Investment Advisers Act of 1940 that has total client assets under its management and control in excess of $85,000,000 as of the last day of its most recent fiscal year, and either (A) Shareholders' or Partners' Equity in excess of $1,000,000, or (B) payment of all of its liabilities including any liabilities that may arise by reason of a breach or violation of a duty described in ERISA sections 404 and 406 is unconditionally guaranteed by—(i) A person with a relationship to such investment adviser described in subsection VI(c)(1) below if the investment adviser and such Affiliate have Shareholders' or Partners' Equity, in the aggregate, in excess of $1,000,000; or (ii) A person described in (a)(1), (a)(2) or (a)(3) of Section VI above; or (iii) A broker-dealer registered under the Securities Exchange Act of 1934 that has, as of the last day of its most recent fiscal year, Net Worth in excess of $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2024, substitute $101,956,000 for $85,000,000 and $1,346,000 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2027, substitute $118,912,000 for $85,000,000 and $1,694,000 for $1,000,000. Effective as of the last day of the fiscal year ending no later than December 31, 2030, substitute $135,868,000 for $85,000,000 and $2,040,000 for $1,000,000;

Provided that such bank, savings and loan association, insurance company, or investment adviser has acknowledged in a ''Written Management Agreement'' that it is a fiduciary with respect to each Plan that has retained the QPAM.

(5) By publication through notice in the **Federal Register**, the Department will make subsequent annual adjustments for inflation to the Equity Capital, Net Worth, and asset management thresholds in subsection VI(a)(1) through (4), rounded to the nearest $10,000, no later than January 31 of each year. The adjustments will be effective as of the last day of the fiscal year in which the increase takes effect, ending no later than December 31 of such fiscal year.

(b) An ''Investment Fund'' includes single customer and pooled separate accounts maintained by an insurance company, individual trusts and common, collective or group trusts maintained by a bank, and any other

account or fund to the extent that the disposition of its assets (whether or not in the custody of the QPAM) is subject to the discretionary authority of the QPAM.

(c) For purposes of Section I(a) and Sections II and V above, an ''Affiliate'' of a person means—

(1) Any person directly or indirectly, through one or more intermediaries, Controlling, Controlled by, or under Common Control with the person;

(2) Any corporation, partnership, trust or unincorporated enterprise of which such person is an officer, director, ten (10) percent or more partner (except with respect to Section II this figure shall be five (5) percent), or highly compensated employee as defined in Code section 4975(e)(2)(H) (but only if the employer of such employee is the Plan sponsor); and

(3) Any director of the person or any employee of the person who is a highly compensated employee, as defined in Code section 4975(e)(2)(H), or who has direct or indirect authority, responsibility or control regarding the custody, management or disposition of Plan assets involved in the transaction. A named fiduciary (within the meaning of ERISA section 402(a)(2)) of a Plan with respect to the Plan assets involved in the transaction and an employer any of whose employees are covered by the Plan will also be considered Affiliates with respect to each other for purposes of Section I(a) above if such employer or an Affiliate of such employer has the authority, alone or shared with others, to appoint or terminate the named fiduciary or otherwise negotiate the terms of the named fiduciary's employment agreement.

(d) For purposes of Section I(g) above an ''Affiliate'' of a person means—

(1) Any person directly or indirectly through one or more intermediaries, Controlling, Controlled by, or under Common Control with the person;

(2) Any director of, Relative of, or partner in, any such person;

(3) Any corporation, partnership, trust or unincorporated enterprise of which such person is an officer, director, or a five percent or more partner or owner; and

(4) Any employee or officer of the person who—

(A) Is a highly compensated employee (as defined in Code section 4975(e)(2)(H) or officer (earning ten (10) percent or more of the yearly wages of such person); or

(B) Has direct or indirect authority, responsibility, or control regarding the custody, management or disposition of Plan assets.

(e) The terms ''Controlling,'' ''Controlled by,'' ''under Common Control with,'' and ''Controls'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(f) The term ''Party in Interest'' means a person described in ERISA section 3(14) and includes a ''disqualified person,'' as defined in Code section 4975(e)(2).

(g) The term ''Relative'' means a relative as that term is defined in ERISA section 3(15), or a brother, a sister, or a spouse of a brother or sister.

(h) A QPAM is ''Related'' to a Party in Interest for purposes of Section I(d) above if, as of the last day of its most recent calendar quarter: (i) The QPAM owns a ten (10) percent or more Interest in the Party in Interest; (ii) a person Controlling, or Controlled by, the QPAM owns a twenty (20) percent or more Interest in the Party in Interest; (iii) the Party in Interest owns a ten (10) percent or more Interest in the QPAM; or (iv) a person Controlling, or Controlled by, the Party in Interest owns a twenty (20) percent or more Interest in the QPAM. Notwithstanding the foregoing, a Party in Interest is ''Related'' to a QPAM if: (i) A person Controlling, or Controlled by, the Party in Interest has an ownership Interest that is less than twenty (20) percent but greater than ten (10) percent in the QPAM and such person exercises Control over the management or policies of the QPAM by reason of its ownership Interest; (ii) a person Controlling, or Controlled by, the QPAM has an ownership Interest that is less than twenty (20) percent but greater than ten (10) percent in the Party in Interest and such person exercises Control over the management or policies of the Party in Interest by reason of its ownership Interest. For purposes of this definition:

(1) The term ''Interest'' means with respect to ownership of an entity—

(A) The combined voting power of all classes of stock entitled to vote or the total value of the shares of all classes of stock of the entity if the entity is a corporation,

(B) The capital interest or the profits interest of the entity if the entity is a partnership, or

(C) The beneficial interest of the entity if the entity is a trust or unincorporated enterprise; and

(2) A person is considered to own an ''Interest'' if, other than in a fiduciary capacity, the person has or shares the authority—

(A) To exercise any voting rights or to direct some other person to exercise the voting rights relating to such interest, or

(B) To dispose or to direct the disposition of such interest.

(i) ''At the Time of the Transaction'' means the date upon which the transaction is entered into. In addition, in the case of a transaction that is continuing, the transaction shall be deemed to occur until it is terminated. If any transaction is entered into on or after December 21, 1982, or a renewal that requires the consent of the QPAM occurs on or after December 21, 1982, and the requirements of this exemption are satisfied at the time the transaction is entered into or renewed, respectively, the requirements will continue to be satisfied thereafter with respect to the transaction. Notwithstanding the foregoing, this exemption shall cease to apply to a transaction exempt by virtue of Section I or Section II above at such time as the percentage requirement contained in Section I(e) is exceeded, unless no portion of such excess results from an increase in the assets transferred for discretionary management to a QPAM. For this purpose, assets transferred do not include the reinvestment of earnings attributable to those Plan assets already under the discretionary management of the QPAM. Nothing in this paragraph shall be construed as exempting a transaction entered into by an Investment Fund which becomes a transaction described in ERISA section 406 or Code section 4975 while the transaction is continuing, unless the conditions of this exemption were met either at the time the transaction was entered into or at the time the transaction would have become prohibited but for this exemption.

(j) The term ''Goods'' includes all things which are movable or which are fixtures used by an Investment Fund but does not include securities, commodities, commodities futures, money, documents, instruments, accounts, chattel paper, contract rights, and any other property, tangible or intangible, which, under the relevant facts and circumstances, is held primarily for investment.

(k) For purposes of subsection VI(a)(1) and (2) above, the term ''Equity Capital'' means stock (common and preferred), surplus, undivided profits, contingency reserves, and other capital reserves.

(l) For purposes of subsection VI(a)(2), (3), and (4) above, the term ''Net Worth'' means capital, paid-in and contributed surplus, unassigned surplus, contingency reserves, group contingency reserves, and special reserves.

(m) For purposes of subsection VI(a)(4) above, the term ''Shareholders' or Partners' Equity'' means the equity

shown in the most recent balance sheet prepared within the two years immediately preceding a transaction undertaken pursuant to this exemption, in accordance with generally accepted accounting principles.

(n) The term ''Plan'' refers to an employee benefit plan described in ERISA section 3(3) and/or a plan described in Code section 4975(e)(1).

(o) For purposes of Section VI(a) above, the term ''Independent Fiduciary'' means a fiduciary managing the assets of a Plan in an Investment Fund that is independent of and unrelated to the employer sponsoring such Plan. For purposes of this exemption, the fiduciary will not be deemed to be independent of and unrelated to the employer sponsoring the Plan if such fiduciary directly or indirectly Controls, is Controlled by, or is under Common Control with the employer sponsoring the Plan. Notwithstanding the foregoing: (1) for the period from December 21, 1982, through November 3, 2010, a QPAM managing the assets of a Plan in an Investment Fund will not fail to satisfy the requirements of this section solely because such fiduciary is the employer sponsoring the Plan or directly or indirectly Controls, is Controlled by, or is under Common Control with the employer sponsoring the Plan; and (2) effective after November 3, 2010 a QPAM acting as a manager for its own Plan or the Plan of an Affiliate (as defined in subsection VI(c)(1) above) will be deemed to satisfy the requirements of this section if the requirements of Section V above are met.

(p) An ''Exemption Audit'' of a Plan must consist of the following:

(1) A review of the Written Policies and Procedures adopted by the QPAM pursuant to Section V(b) above for consistency with each of the objective requirements of this exemption (as described in Section VI(q) below);

(2) A test of a representative sample of the Plan's transactions during the audit period that is sufficient in size and nature to afford the auditor a reasonable basis:

(A) To make specific findings regarding whether the QPAM is in compliance with (i) the Written Policies and Procedures adopted by the QPAM pursuant to Section VI(q) below and (ii) the objective requirements of this exemption, and

(B) To render an overall opinion regarding the level of compliance of the QPAM's program with subsection VI(p)(2)(A)(i) and (ii) above;

(3) A determination as to whether the QPAM has satisfied the definition of a QPAM under the exemption; and

(4) Issuance of a written report describing the steps performed by the auditor during the course of its review and the auditor's findings.

(q) For purposes of Section VI(p), the Written Policies and Procedures must describe the following objective requirements of this exemption and the steps adopted by the QPAM to ensure compliance with each of these requirements:

(1) The definition of a QPAM in Section VI(a);

(2) The requirement of Sections V(a) and I(c) regarding the discretionary authority or control of the QPAM with respect to the Plan assets involved in the transaction, in negotiating the terms of the transaction and with respect to the decision on behalf of the Investment Fund to enter into the transaction;

(3) For a transaction described in Section I above:

(A) That the transaction is not entered into with any person who is excluded from relief under Section I(a), Section I(d), or Section I(e) above;

(B) That the transaction is not described in any of the class exemptions listed in Section I(b) above;

(4) If the transaction is described in Section III above:

(A) That the amount of space covered by the lease does not exceed the limitations described in Section III(a) above, and

(B) That no commission or other fee is paid by the Investment Fund as described in Section III(d) above.

(r) ''Criminal Conviction'' occurs when a QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM:

(1) is convicted in a U.S. federal or state court or released from imprisonment, whichever is later, as a result of any felony involving abuse or misuse of such person's Plan position or employment, or position or employment with a labor organization; any felony arising out of the conduct of the business of a broker, dealer, investment adviser, bank, insurance company or fiduciary; income tax evasion; any felony involving the larceny, theft, robbery, extortion, forgery, counterfeiting, fraudulent concealment, embezzlement, fraudulent conversion, or misappropriation of funds or securities; conspiracy or attempt to commit any such crimes or a crime in which any of the foregoing crimes is an element; or any crime that is identified or described in ERISA section 411; or

(2) is convicted by a foreign court of competent jurisdiction or released from imprisonment, whichever is later, as a result of a crime, however denominated by the laws of the relevant foreign government, that is substantially equivalent to an offense described in(r)(1) above (excluding convictions and imprisonment that occur within a foreign country that is included on the Department of Commerce's list of ''foreign adversaries'' that is codified in 15 CFR 7.4, as amended).

(s) ''Prohibited Misconduct'' means when a QPAM, any Affiliate thereof (as defined in Section VI(d)), or any owner, direct or indirect, of a five (5) percent or more interest in the QPAM:

(1) Enters into a non-prosecution (NPA) or deferred prosecution agreement (DPA) on or after June 17, 2024 with a U.S. federal or state prosecutor's office or regulatory agency, where the factual allegations that form the basis for the NPA or DPA would have constituted a crime described in Section VI(r) if they were successfully prosecuted; or

(2) Is found or determined in a final judgment, or court-approved settlement by a Federal or State criminal or civil court that is entered on or after June 17, 2024 in a proceeding brought by the Department, the Department of Treasury, the Internal Revenue Service, the Securities and Exchange Commission, the Department of Justice, the Federal Reserve Bank, the Office of the Comptroller of the Currency, the Federal Depository Insurance Corporation, the Commodities Futures Trading Commission, a state regulator, or state attorney general to have Participated In one or more of the following categories of conduct irrespective of whether the court specifically considers this exemption or its terms:

(A) engaging in a systematic pattern or practice of conduct that violates the conditions of this exemption in connection with otherwise non-exempt prohibited transactions;

(B) intentionally engaging in conduct that violates the conditions of this exemption in connection with otherwise non-exempt prohibited transactions; or

(C) providing materially misleading information to the Department, the Department of Treasury, the Internal Revenue Service, the Securities and Exchange Commission, the Department of Justice, the Federal Reserve Bank, the Office of the Comptroller of the Currency, the Federal Depository Insurance Corporation, the Commodities Futures Trading Commission, a state regulator or a state attorney general in

connection with the conditions of the exemption.

(t) ''Participate In,'' ''Participates In,'' ''Participating In,'' ''Participated In,'' and ''Participation In'' all refer not only to active participation in Prohibited Misconduct, but also to knowing approval of the conduct, or knowledge of such conduct without taking active steps to prohibit such conduct, including reporting the conduct to the appropriate compliance personnel.

(u) The QPAM maintains the records necessary to enable the persons described in subsection (u)(2) below to determine whether the conditions of this exemption have been met with respect to a transaction for a period of six years from the date of the transaction in a manner that is reasonably accessible for examination. No prohibited transaction will be considered to have occurred solely due to the unavailability of such records if they are lost or destroyed due to circumstances beyond the control of the QPAM before the end of the six-year period.

(1) No party, other than the QPAM responsible for complying with this Section VI(u), will be subject to the civil penalty that may be assessed under ERISA section 502(i) or the excise tax imposed by Code section 4975(a) and (b), if applicable, if the records are not maintained or available for examination as required by this Section VI(u) below.

(2) Except as provided in subsection (3) or precluded by 12 U.S.C. 484 (regarding limitations on visitorial powers for national banks), and notwithstanding any provisions of ERISA section 504(a)(2) and (b), the records are reasonably available at their customary location during normal business hours for examination by:

(A) Any authorized employee of the Department or the Internal Revenue Service or another state or federal regulator,

(B) Any fiduciary of a Plan invested in an Investment Fund managed by the QPAM,

(C) Any contributing employer and any employee organization whose members are covered by a Plan invested in an Investment Fund managed by the QPAM, or

(D) Any participant or beneficiary of a Plan invested in an Investment Fund managed by the QPAM.

(3) None of the persons described in subsection (2)(B) through (D) above are authorized to examine records regarding an Investment Fund that they are not invested in, privileged trade secrets or privileged commercial or financial information of the QPAM, or information identifying other individuals.

(4) Should the QPAM refuse to disclose information to a person described in subsection (2)(A) through (D) above on the basis that the information is exempt from disclosure, the QPAM must provide a written notice advising the requestor of the reasons for the refusal and that the Department may request such information by the close of the thirtieth (30th) day following the request.

(5) A QPAM's failure to maintain the records necessary to determine whether the conditions of this exemption have been met will result in the loss of the relief provided under this exemption only for the transaction or transactions for which such records are missing or have not been maintained. Such failure does not affect the relief for other transactions if the QPAM maintains required records for such transactions in compliance with this Section VI(u).

Signed at Washington, DC, this 18th day of March, 2024.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2024–06059 Filed 4–2–24; 8:45 am]

BILLING CODE 4510–29–P

FEDERAL REGISTER

Vol. 89 Wednesday,

No. 65 April 3, 2024

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1806–P]

RIN 0938–AV32

Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This rulemaking proposes to update the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPF), which include psychiatric hospitals and excluded psychiatric units of an acute care hospital or critical access hospital. This rulemaking also proposes to revise the patient-level adjustment factors, the Emergency Department adjustment, and the payment amount for electroconvulsive therapy. These proposed changes would be effective for IPF discharges occurring during the fiscal year beginning October 1, 2024 through September 30, 2025 (FY 2025). In addition, this proposed rule seeks to adopt a new quality measure and modify reporting requirements under the IPF Quality Reporting Program beginning with the FY 2027 payment determination. Furthermore, this proposed rule solicits comments through Requests for Information (RFIs) regarding potential future revisions to the IPF PPS facility-level adjustments and regarding the development of a standardized IPF Patient Assessment Instrument.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 28, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1806–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1806–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1806–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Nick Brock (410) 786–5148, for information regarding the inpatient psychiatric facilities prospective payment system (IPF PPS).

Kaleigh Emerson (470) 890–4141, for information regarding the inpatient psychiatric facilities quality reporting program (IPFQR).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

Addendum A to this proposed rule summarizes the proposed FY 2025 Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) payment rates, outlier threshold, cost of living adjustment factors for Alaska and Hawaii, national and upper limit cost-to-charge ratios, and adjustment factors. In addition, Addendum B to this proposed rule shows the complete listing of ICD–10 Clinical Modification and Procedure Coding System codes, the FY 2025 IPF PPS comorbidity adjustment, and electroconvulsive therapy procedure codes. The A and B Addenda are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

Tables setting forth the FY 2025 Wage Index for Urban Areas Based on Core-Based Statistical Area Labor Market Areas, the FY 2025 Wage Index Based on CBSA Labor Market Areas for Rural Areas, and a county-level crosswalk of the FY 2024 CBSA Labor Market Areas to the FY 2025 CBSA Labor Market Areas are available exclusively through the internet, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html.*

I. Executive Summary

A. Purpose

This proposed rule would update the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during fiscal year (FY) 2025, (beginning October 1, 2024 through September 30, 2025). We are proposing to adopt the Core-Based Statistical Area (CBSA) Labor Market Areas for the IPF PPS wage index as defined in the Office of Management and Budget (OMB) Bulletin 23–01. In addition, this rule includes a proposal to refine the patient-level adjustment factors and increase the payment amount for electroconvulsive therapy (ECT) treatments. We are not proposing changes to the facility-level adjustment factors for FY 2025; however, this proposed rule presents the results of our latest analysis and includes a request for information relating to those results. This rule also includes a clarification of the eligibility criteria for an IPF to be approved to file all-inclusive cost reports. In addition, this proposed rule includes a request for information regarding the creation of a patient assessment instrument (PAI) as mandated by Section 4125 of the Consolidated Appropriations Act (CAA), 2023 (hereafter referred to as CAA, 2023) (Pub. L. 117–328). Lastly, this proposed rule discusses quality measures and reporting requirements under the Inpatient Psychiatric

Facilities Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions

1. Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)

For the IPF PPS, we are:

- Proposing to revise the patient-level IPF PPS adjustment factors and increase the ECT per treatment payment amount.
- Proposing to update the IPF PPS wage index to use the CBSAs defined within OMB Bulletin 23–01.
- Clarifying the eligibility criteria for an IPF to be approved to file all-inclusive cost reports. Only a government-owned or tribally owned facility will be able to satisfy these criteria and will be eligible to file its cost report using an all-inclusive rate or no charge structure.
- Soliciting comments to inform elements to be included in the IPF patient assessment instrument, which the CAA, 2023 requires the Centers for Medicare & Medicaid Services (CMS) to develop for FY 2028.
- Soliciting comments to inform future refinements to the IPF PPS facility-level adjustment factors.
- Making technical rate setting updates: The IPF PPS payment rates are adjusted annually for inflation, as well as statutory and other policy factors. This rule proposes to update:

++ The IPF PPS Federal per diem base rate from $895.63 to $874.93.

++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to $857.89.

++ The ECT payment per treatment from $385.58 to $660.30.

++ The ECT payment per treatment for providers who failed to report quality data to $647.45.

++ The labor-related share from 78.7 percent to 78.8 percent.

++ The wage index budget neutrality factor to 0.9998. This proposed rule would apply a refinement standardization factor of 0.9514.

++ The fixed dollar loss threshold amount from $33,470 to $35,590, to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.

2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

For the IPFQR Program, we are proposing to:

- Adopt the 30-Day Risk-Standardized All-Cause Emergency Department (ED) Visit Following an IPF Discharge measure beginning with the FY 2027 payment determination; and
- Modify reporting requirements to require IPFs to submit patient-level data on a quarterly basis.

We also refer readers to our RFI in which we solicit comments to inform elements to be included in the IPF patient assessment instrument, which the CAA, 2023 requires the Centers for Medicare & Medicaid Services (CMS) to develop and implement for Rate Year (RY) 2028.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2025 IPF PPS payment update	The overall economic impact of this proposed rule is an estimated $70 million in increased payments to IPFs during FY 2025.
FY2025 IPFQR Program update	The overall economic impact of the IPFQR Program proposals in this proposed rule is an estimated increase of 800 hours of information collection burden resulting in a cost increase of $41,696.

II. Background

A. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department of Health and Human Services (the Secretary) develop a per diem payment perspective system (PPS) for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. ''Excluded psychiatric unit'' means a psychiatric unit of an acute care hospital or of a Critical Access Hospital (CAH), which is excluded from payment under the Inpatient Prospective Payment System (IPPS) or CAH payment system, respectively. These excluded psychiatric units will be paid under the IPF PPS.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as ''the Affordable Care Act'') added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled ''Reference to Establishment and Implementation of System,'' refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY.

Section 1886(s)(2)(A)(ii) of the Act required the application of an ''other adjustment'' that reduced any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for fiscal year Beginning October 1, 2019 final rule, for the RY beginning in 2019,

section 1886(s)(3)(E) of the Act required that the other adjustment reduction be equal to 0.75 percentage point; that was the final year the statute required the application of this adjustment. Because FY 2021 was a RY beginning in 2020, FY 2021 was the first year section 1886(s)(2)(A)(ii) of the Act did not apply since its enactment.

Sections 1886(s)(4)(A) through (D) of the Act require that for RY 2014 and each subsequent RY, IPFs that fail to report required quality data with respect to such a RY will have their annual update to a standard Federal rate for discharges reduced by 2.0 percentage points. This may result in an annual update being less than 0.0 for a RY, and may result in payment rates for the upcoming RY being less than such payment rates for the preceding RY. Any reduction for failure to report required quality data will apply only to the RY involved, and the Secretary will not consider such reduction in computing the payment amount for a subsequent RY. Additional information about the specifics of the current IPFQR Program is available in the FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for fiscal year Beginning October 1, 2019 (FY 2020) final rule (84 FR 38459 through 38468).

Section 4125 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), which amended section 1886(s) of the Act, requires CMS to revise the Medicare prospective payment system for psychiatric hospitals and psychiatric units. Specifically, section 4125(a) of the CAA, 2023 added section 1886(s)(5)(A) of the Act to require the Secretary to collect data and information, as the Secretary determines appropriate, to revise payments under the IPF PPS. CMS discussed this data collection last year in the FY 2024 IPF PPS final rule, as CMS was required to begin collecting this data and information not later than October 1, 2024. As discussed in that rule, the Agency has already been collecting data and information consistent with the types set forth in the CAA, 2023 as part of our extensive and years-long analyses and consideration of potential payment system refinements. We refer readers to the FY 2024 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update (FY 2024 IPF PPS) final rule (88 FR 51095 through 51098) where we discussed existing data collection and requested information to inform future IPF PPS revisions.

In addition, section 1886(s)(5)(D) of the Act, as added by section 4125(a) of the CAA, 2023 requires that the Secretary implement revisions to the methodology for determining the payment rates under the IPF PPS for psychiatric hospitals and psychiatric units, effective for RY 2025 (FY 2025). The revisions may be based on a review of the data and information collected under section 1886(s)(5)(A) of the Act. As discussed in section III.C of this FY 2025 IPF PPS proposed rule, we are proposing revisions to the IPF PPS patient-level adjustment factors based on a review of cost and claims data.

Section 4125(b) of the CAA, 2023 amended section 1886(s)(4) of the Act by inserting a new subparagraph (E), which requires IPFs participating in the IPFQR Program to collect and submit to the Secretary standardized patient assessment data, using a standardized patient assessment instrument, for RY 2028 (FY 2028) and each subsequent rate year. IPFs must submit such data with respect to at least the admission and discharge of an individual, or more frequently as the Secretary determines appropriate. For IPFs to meet this new data collection and reporting requirement for RY 2028 and each subsequent rate year, the Secretary must implement a standardized patient assessment instrument that collects data with respect to the following categories: functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and comorbidities; impairments; and other categories as determined appropriate by the Secretary. This patient assessment instrument must enable comparison of such patient assessment data that IPFs submit across all such IPFs to which such data are applicable.

Section 4125(b) of the CAA, 2023 further amended section 1886(s) of the Act by adding a new subparagraph (6) that requires the Secretary to implement revisions to the methodology for determining the payment rates for psychiatric hospitals and psychiatric units (that is, payment rates under the IPF PPS), effective for RY 2031 (FY 2031), as the Secretary determines to be appropriate, to take into account the patient assessment data described in paragraph (4)(E)(ii).

To implement and periodically update the IPF PPS, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these documents, we refer readers to the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html?redirect=/InpatientPsychFacilPPS/*.

B. Overview of the IPF PPS

On November 15, 2004, we published the RY 2005 IPF PPS final rule in the **Federal Register** (69 FR 66922). The RY 2005 IPF PPS final rule established the IPF PPS, as required by section 124 of the BBRA and codified at 42 CFR part 412, subpart N. The RY 2005 IPF PPS final rule set forth the Federal per diem base rate for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006) and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described previously and certain patient- and facility-level payment adjustments for characteristics that were found in the regression analysis to be associated with statistically significant per diem cost differences, with statistical significance defined as p less than 0.05. A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the RY 2005 IPF PPS final rule (69 FR 66933 through 66936).

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, and comorbidities, as well as adjustments to reflect higher per diem costs at the beginning of a patient's IPF stay and lower costs for later days of the stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and an adjustment for the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for outlier cases, interrupted stays, and a per treatment

payment for patients who undergo ECT. During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

C. Annual Requirements for Updating the IPF PPS

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology. Therefore, in the RY 2005 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

The RY 2005 final rule (69 FR 66922) implemented the IPF PPS. In developing the IPF PPS, and to ensure that the IPF PPS can account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. That regression analysis is described in detail in our RY 2004 IPF proposed rule (68 FR 66923; 66928 through 66933) and our RY 2005 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In the RY 2005 IPF final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

On May 6, 2011, we published a final rule in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)'' (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer to be effective on October 1st. When proposing changes in IPF payment policy, a proposed rule is issued in the spring, and the final rule in the summer to be effective on October 1st. For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 42 CFR 412.428. Beginning October 1, 2012, we finalized that we would refer to the 12-month period from October 1 through September 30 as a ''fiscal year'' (FY) rather than a RY (76 FR 26435). Therefore, in this final rule we refer to rules that took effect after RY 2012 by the FY, rather than the RY, in which they took effect.

The most recent IPF PPS annual update was published in a final rule on August 2, 2023 in the **Federal Register** titled, ''Medicare Program; FY 2024 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update'' (88 FR 51054), which updated the IPF PPS payment rates for FY 2024. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2023 IPF PPS Rate Update final rule (87 FR 46846) in accordance with our established policies.

III. Provisions of the Proposed Regulations

A. Proposed FY 2025 Market Basket Update and Productivity Adjustment for the IPF PPS

1. Background

Originally, the input price index used to develop the IPF PPS was the Excluded Hospital with Capital market basket. This market basket was based on 1997 Medicare cost reports for Medicare-participating inpatient rehabilitation facilities (IRFs), IPFs, long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although ''market basket'' technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term ''market basket,'' as used in this document, refers to an input price index.

Since the IPF PPS inception, the market basket used to update IPF PPS payments has been rebased and revised to reflect more recent data on IPF cost structures. We last rebased and revised the IPF market basket in the FY 2024 IPF PPS rule, where we adopted a 2021-based IPF market basket, using Medicare cost report data for both Medicare participating freestanding psychiatric hospitals and psychiatric units. We refer readers to the FY 2024 IPF PPS final rule for a detailed discussion of the 2021-based IPF PPS market basket and its development (88 FR 51057 through 51081). References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656).

2. Proposed FY 2025 IPF Market Basket Update

For FY 2025 (beginning October 1, 2024 and ending September 30, 2025), we are proposing to update the IPF PPS payments by a market basket increase factor with a productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Consistent with historical practice, we are proposing to estimate the market basket update for the IPF PPS based on the most recent forecast available at the time of rulemaking from IHS Global Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and productivity adjustment. For the proposed rule, based on IGI's fourth quarter 2023 forecast with historical data through the third quarter of 2023, the 2021-based IPF market basket increase factor for FY 2025 is 3.1 percent.

Section 1886(s)(2)(A)(i) of the Act requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the

term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP. However, as mentioned previously, the data and methods are unchanged. We refer readers to *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* In addition, in the FY 2022 IPF final rule (86 FR 42611), we noted that effective with FY 2022 and forward, CMS changed the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (a RY that coincides with a FY) and each subsequent RY. For this proposed rule, based on IGI's fourth quarter 2023 forecast, the proposed productivity adjustment for FY 2025 (the 10-year moving average of TFP for the period ending FY 2025) is projected to be 0.4 percent. Accordingly, we are proposing to reduce the 3.1 percent IPF market basket increase by this 0.4 percentage point productivity adjustment, as mandated by the Act. This results in a proposed FY 2025 IPF PPS payment rate update of 2.7 percent ($3.1 - 0.4 = 2.7$). We are also proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 IPF market basket increase and productivity adjustment for the final rule.

We solicit comment on the proposed IPF market basket increase and productivity adjustment for FY 2025.

3. Proposed FY 2025 IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We are proposing to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2021-based IPF market basket, we are proposing to continue to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of the Capital-Related relative importance from the 2021-based IPF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the labor-related share based on the 2021-based IPF market basket, we refer readers to the FY 2024 IPF PPS final rule (88 FR 51078 through 51081).

The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2021) and FY 2025. Based on IGI's fourth quarter 2023 forecast of the 2021-based IPF market basket, the sum of the FY 2025 relative importance moving average of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services is 75.7 percent. We are proposing, consistent with prior rulemaking, that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs is 6.8 percent of the 2021-based IPF market basket for FY 2025, we are proposing to take 46 percent of 6.8 percent to determine a labor-related share of Capital-Related costs for FY 2025 of 3.1 percent. Therefore, we are proposing a total labor-related share for FY 2025 of 78.8 percent (the sum of 75.7 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs). We are also proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 labor-related share for the final rule. For more information on the labor-related share and its calculation, we refer readers to the FY 2024 IPF PPS final rule (88 FR 51078 through 51081).

Table 1 shows the proposed FY 2025 labor-related share and the final FY 2024 labor-related share using the 2021-based IPF market basket relative importance.

TABLE 1: FY 2025 Proposed IPF Labor-Related Share and FY 2024 IPF Labor-Related Share

	Relative importance, proposed labor-related share FY 2025[1]	Relative importance, labor-related share FY 2024[2]
Wages and Salaries	53.6	53.4
Employee Benefits	14.1	14.2
Professional Fees: Labor-Related	4.7	4.7
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair Services	1.2	1.2
All Other Labor-Related Services	1.5	1.5
Subtotal	75.7	75.6
Labor-related portion of Capital-Related (.46)	3.1	3.1
Total Labor-Related Share	78.8	78.7

1. Based on the 4th quarter 2023 IHS Global Inc. forecast of the 2021-based IPF market basket.
2. Based on the 2nd quarter 2023 IHS Global Inc. forecast of the 2021-based IPF market basket.

We solicit comment on the proposed labor-related share for FY 2025.

B. Proposed Revisions to the IPF PPS Rates for FY Beginning October 1, 2024

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the RY 2005 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget Neutral Federal per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the RY 2005 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (October 1, 2005), and this amount was used in the payment model to establish the budget neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. The information concerning this standardization can be found in the RY 2005 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget neutrality adjustment appears in the RY 2005 IPF PPS final rule (69 FR 66932 through 66933) and in the RY 2007 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be $575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and 42 CFR 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget neutral Federal per diem base rate and the ECT payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html.*

As discussed in section III.B.2 of this proposed rule, we are proposing to revise the patient-level adjustment factors and increase the ECT payment amount for FY 2025. Section 1866(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, requires that revisions to the IPF PPS adjustment factors must be made budget-neutrally. Therefore, as discussed in section III.F of this proposed rule, we are proposing to apply a standardization factor to the FY 2025 base rate that takes these refinements into account to keep total IPF PPS payments budget neutral.

2. Proposed Increase in the Electroconvulsive Therapy (ECT) Payment per Treatment

a. Background

In the RY 2005 IPF PPS final rule (69 FR 66951), we analyzed the costs of IPF stays that included ECT treatment using the FY 2002 MedPAR data. based on comments we received on the RY 2005

IPF PPS proposed rule. Consistent with the comments we received about ECT, our analysis and review indicated that cases with ECT treatment are substantially more costly than cases without ECT treatment. Based on this analysis, in that final rule we finalized an additional payment for each ECT treatment furnished during the IPF stay. This ECT payment per treatment is made in addition to the per diem and outlier payments under the IPF PPS. To receive the payment per ECT treatment, IPFs must indicate on their claims the revenue code and procedure code for ECT (Rev Code 901; procedure code 90870) and the number of units of ECT, that is, the number of ECT treatments the patient received during the IPF stay.

To establish the ECT per treatment payment, we used the pre-scaled and pre-adjusted median cost for procedure code 90870 developed for the Hospital Outpatient Prospective Payment System (OPPS), based on hospital claims data. We explained in the RY 2005 IPF PPS final rule that we used OPPS data because after a careful review and analysis of IPF claims, we were unable to separate out the cost of a single ECT treatment (69 FR 66922). We used the unadjusted hospital claims data under the OPPS because we did not want the ECT payment under the IPF PPS to be affected by factors that are relevant to OPPS, but not specifically applicable to IPFs. The median cost was then standardized and adjusted for budget neutrality. We also adjusted the ECT rate for wage differences in the same manner that we adjust the per diem rate.

Since the ECT payment rate was established in the RY 2005 IPF PPS rule, it has been updated annually by application of each year's market basket, productivity adjustment, and wage index budget neutrality factor to the previous year's ECT payment rate (referred to as our ''standard methodology'' in this section). While the ECT payment rate has been updated each year by these factors, we have not recalculated the ECT payment per treatment based on more recent cost data since the establishment of the IPF PPS.

b. Proposed Increase to the Electroconvulsive Therapy Payment per Treatment

For this FY 2025 IPF PPS proposed rule, we analyzed data in both the IPF PPS and the OPPS. In the IPF PPS setting, our analysis of recent IPF PPS data indicates that IPF costs have increased for stays that include ECT treatments. As discussed in the next paragraph, our analysis of these costs leads us to consider whether the current payment per treatment for ECT is aligned with the additional costs associated with stays that include ECT treatments. We began by analyzing IPF stays with ECT treatment using the CY 2022 Medicare Provider and Analysis Review (MedPAR) data. IPF stays with ECT treatment comprised about 1.7 percent of all stays, which is a decrease from the FY 2002 MedPAR data discussed in the RY 2005 IPF PPS final rule, where stays with ECT treatment were 6.0 percent of all IPF stays. A total of 288 IPF facilities had stays with ECT treatment in 2022, with an average 6.7 units of ECT per stay. We compared the total cost for stays with and without ECT treatment, and found that IPF stays with ECT treatment were approximately three times more costly than IPF stays without ECT treatment ($44,687.50 per stay vs. $15,432.30 per stay). Most of the variance in cost was due to differences in the IPF length of stay (LOS) (28.00 days for stays with ECT treatment vs. 13.43 days for stays without ECT treatment). We note that the IPF PPS makes additional per diem payments for longer lengths of stay, which makes the total payment larger for a longer stay. However, we also observed that there are differences in the per-day cost for stays with and without ECT. We calculated the average cost per day for stays with and without ECT treatment and found that stays with ECT treatment have an average cost per day of $1,595.76, while stays without ECT treatment have an average cost per day of $1,149.51.

Furthermore, as we discuss in section III.C.3.d.(2) of this proposed rule, our latest regression analysis includes a control variable to account for the presence of ECT during an IPF stay. That control variable indicates that, holding all other patient-level and facility-level factors constant, there is a statistically significant increase in cost per day for IPF stays that include ECT, further demonstrating that resource use is higher for IPF stays with ECT than those without ECT. As we previously noted in the RY 2005 IPF PPS final rule (69 FR 66922), IPF claims and cost data are not sufficiently granular to identify the per-treatment cost of ECT. Therefore, we examined the difference in ancillary costs for IPF stays with and without ECT treatment. In the CY 2022 MedPAR data, the ancillary costs per IPF stay with ECT treatment were $7,116.85 higher than ancillary costs per IPF stay without ECT treatment. The ancillary costs were calculated as follows: for each ancillary department (for example, drugs or labs), the charges were multiplied by the department-level CCR, and those department-level costs were summed across departments for each stay. The average ancillary costs per stay were calculated accordingly for stays with and without ECT treatment, revealing that average ancillary costs per day are three times higher for stays with ECT treatment: $99.36 for stays without ECT treatment versus $301.77 for stays with ECT treatment. Accounting for differences in length of stay between stays with and without ECT, the average additional ancillary cost per ECT unit was approximately $849.72.

Application of our standard methodology for updating the ECT payment would result in an FY 2025 payment of $377.54 per ECT treatment (based on the FY 2024 ECT payment amount of $385.58, increased by the market basket update of 2.7 percent and reduced by the FY 2025 wage index budget neutrality factor of 0.9998 and a refinement standardization factor of 0.9536, which is the standardization factor that would account for all other proposed refinements without increasing the ECT per treatment). As we noted above, this ECT payment would be added to the per diem and any applicable outlier payments for the entire stay. CMS considered this rate in proposing to adjust the ECT per treatment rate. However, the analysis of ancillary costs for IPF stays with ECT treatment suggested that a further increase to the current ECT payment amount per treatment could better align IPF PPS payments with the increased costs of furnishing ECT. The ancillary cost data show that costs for furnishing ECT have risen by a factor greater than the standard methodology for updating the rate would adjust for.

It continues to be the case that, as we discussed in the RY 2005 IPF PPS final rule, current IPF cost and claims data are not sufficiently granular to identify the per-treatment cost of ECT. We believe that using the costs in the OPPS setting are the most accurate for purposes of updating the ECT per treatment rate because we believe this treatment requires comparable resources when performed in outpatient and inpatient settings. Thus, we analyzed the most recent OPPS cost information to consider changes to the ECT payment per treatment for FY 2025.

The original methodology for determining the ECT payment per treatment was based on the median cost for procedure code 90870 developed for the OPPS, as discussed in the RY 2005 IPF PPS final rule (69 FR 66951). Since that time, the OPPS has adopted certain changes to its methodology for calculating costs. In the CY 2013 OPPS/ASC final rule with comment period (77

FR 68259 through 68270), CMS finalized a methodology for developing the relative payment weights for Ambulatory Payment Classifications using geometric mean costs instead of median costs. We explained that geometric means better capture the range of costs associated with providing services, including those cases where very efficient hospitals have provided services at much lower costs. While medians and geometric means both capture the impact of uniform changes, that is, those changes that influence all providers, only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis, allowing us to detect changes in the cost of services earlier.

We believe the rationale for using geometric mean cost in the OPPS setting as the underpinning methodology for establishing payments applies equally to the costs of providing ECT on a per treatment basis under the IPF PPS. Therefore, in considering changes for the IPF PPS ECT payment per treatment for FY 2025, we compared the costs observed in the IPF setting to the geometric mean cost for an ECT treatment posted as part of the CY 2024 OPPS/ASC update, which is based on CY 2022 outpatient hospital claims. Although we are proposing to increase the ECT payment with reference to the CY 2024 OPPS ECT geometric mean cost for FY 2025, we are not proposing to adopt the OPPS rate (which is distinct from the geometric mean cost) for the ECT payment per treatment for FY 2025 because the final OPPS rates include policy decisions and payment rate updates that are specific to the OPPS. We intend to continue to monitor the costs associated with ECT treatment and may propose adjustments in the future as needed.

The pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost for ECT is $675.93. Comparatively, the FY 2024 IPF ECT payment rate was $385.58 (88 FR 51054). As discussed in the prior paragraphs, our analysis of updated ancillary cost data indicates that the IPF PPS ECT payment rate per treatment, when updated according to the standard methodology alone, has not kept pace with the cost of furnishing the treatment in the IPF setting. As we stated previously, we believe this treatment requires comparable resources when performed in outpatient and inpatient settings. Therefore, we are proposing to use the pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost of $675.93 as the basis for the IPF PPS ECT payment per treatment in FY 2025, as discussed below. We are proposing to update $675.93 by the FY 2025 IPF PPS payment rate update of 2.7 percent (3.1 percent IPF market basket increase, reduced by the 0.4 percentage point productivity adjustment), and the wage index budget neutrality factor of 0.9998 for FY 2025, in alignment with our current standard methodology.

To account for budget neutrality, as discussed in section III.F of this proposed rule, we are proposing to apply a refinement standardization factor to the FY 2025 IPF PPS Federal per diem base rate and to the ECT payment amount per treatment to account for this proposed change to the ECT payment amount per treatment and all proposed changes to the patient-level adjustment factors and to the ED adjustment factor for FY 2025. We note that this proposed increase to the ECT per treatment amount would be associated with a minor decrease to the IPF Federal per diem base rate as a result of the refinement standardization factor (0.9514 instead of 0.9536). We estimate that this change would increase payments for IPFs that provide ECT, and would decrease payments for IPFs that do not provide ECT. However, the decrease in payments associated with this change would be no more than approximately 0.2 percent, which would be offset by various other proposed changes such as the proposed wage index changes, proposed revisions to the IPF PPS patient-level adjustments, and the proposed market basket increase for FY 2025.

We note that we have monitored the provision of ECT through analysis of claims data since the beginning of the IPF PPS, and have not observed any indicators that payment is inappropriately incentivizing the provision of ECT to IPF patients. We intend to continue monitoring the provision of ECT through further analysis of IPF PPS claims data.

A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule. We welcome comments regarding our analysis, including any comments that could inform our understanding of where ECT costs are allocated in cost reports in order to potentially inform improved collection of data on ECT treatment costs in the IPF setting. We also welcome comments on whether it may be appropriate to collect additional ECT-specific costs on the hospital cost report. Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 Federal per diem base rate and ECT payment per treatment for the FY 2025 IPF PPS final rule.

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries to bill for ECT services, as described in our Medicare Claims Processing Manual, Chapter 3, Section 190.7.3 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*). There were no changes to the ECT procedure codes used on IPF claims in the final update to the ICD–10–PCS code set for FY 2024. Addendum B to this proposed rule shows the ECT procedure codes for FY 2025 and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

3. Proposed Update of the Federal per Diem Base Rate and Electroconvulsive Therapy Payment per Treatment

The current (FY 2024) Federal per diem base rate is $895.63 and the ECT payment per treatment is $385.58. For the proposed FY 2025 Federal per diem base rate, we applied the payment rate update of 2.7 percent,—that is, the proposed 2021-based IPF market basket increase for FY 2025 of 3.1 percent reduced by the proposed productivity adjustment of 0.4 percentage point—the proposed wage index budget neutrality factor of 0.9998 (as discussed in section III.D.1 of this proposed rule), and a proposed refinement standardization factor of 0.9514 (as discussed in section III.F of this proposed rule) to the FY 2024 Federal per diem base rate of $895.63, yielding a proposed Federal per diem base rate of $874.93 for FY 2025. As discussed in section III.B.2 of this proposed rule, we are proposing to increase the ECT payment per treatment for FY 2025 in addition to our routine updates to the rate. We applied the proposed 2.7 percent payment rate update, the proposed 0.9998 wage index budget neutrality factor, and the proposed 0.9514 refinement standardization factor to the proposed payment per treatment based on the CY 2024 OPPS geometric mean cost of $675.93, yielding a proposed ECT payment per treatment of $660.30 for FY 2025.

Section 1886(s)(4)(A)(i) of the Act requires that for RY 2014 and each subsequent RY, in the case of an IPF that fails to report required quality data with respect to such RY, the Secretary will reduce any annual update to a standard Federal rate for discharges during the RY by 2.0 percentage points. Therefore, we are applying a 2.0 percentage point reduction to the annual update to the Federal per diem

base rate and the proposed ECT payment per treatment as follows:

- For IPFs that fail to report required data under the IPFQR Program, we would apply a 0.7 percent payment rate update—that is, the proposed IPF market basket increase for FY 2025 of 3.1 percent reduced by the proposed productivity adjustment of 0.4 percentage point for an update of 2.7 percent, and further reduced by 2.0 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act. We would also apply the proposed refinement standardization factor of 0.9514 and the proposed wage index budget neutrality factor of 0.9998 to the FY 2024 Federal per diem base rate of $895.63, yielding a proposed Federal per diem base rate of $857.89 for FY 2025.
- For IPFs that fail to report required data under the IPFQR Program, we would apply the proposed 0.7 percent annual payment rate update, the proposed 0.9514 refinement standardization factor, and the proposed 0.9998 wage index budget neutrality factor to the proposed payment per treatment based on the CY 2024 OPPS geometric mean cost of $675.93, yielding a proposed ECT payment per treatment of $647.45 for FY 2025.

We are proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 Federal per diem base rate and ECT payment per treatment for the FY 2025 IPF final rule.

C. Proposed Updates and Revisions to the IPF PPS Patient-Level Adjustment Factors

1. Overview of the IPF PPS Adjustment Factors and Proposed Revisions

The current (FY 2024) IPF PPS payment adjustment factors were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, we refer readers to the RY 2005 IPF PPS final rule (69 FR 66935 through 66936).

For FY 2025, we are proposing to implement revisions to the methodology for determining payment rates under the IPF PPS. As we noted earlier in this FY 2025 IPF PPS proposed rule, section 1886(s)(5)(D) of the Act, as added by section 4125(a) of the CAA, 2023 requires that the Secretary implement revisions to the methodology for determining the payment rates under the IPF PPS for psychiatric hospitals and psychiatric units, effective for RY 2025 (FY 2025). The revisions may be based on a review of the data and information collected under section 1886(s)(5)(A) of the Act. Accordingly, we are proposing to revise the patient-level IPF PPS payment adjustment factors as discussed in section III.C.4. of this proposed rule, effective for FY 2025. We have developed proposed adjustment factors based on a regression analysis of IPF cost and claims data, which is discussed in greater detail in the following sections of this proposed rule. The primary sources of this analysis are CY 2019 through 2021 MedPAR files and Medicare cost report data (CMS Form 2552–10, OMB No. 0938–0050) [1] from the FY 2019 through 2021 Hospital Cost Report Information System (HCRIS). For each year (2019 through 2021), if a provider did not have a Medicare cost report for that year, we used the provider's most recent available Medicare cost report prior to the year for which a Medicare cost report was missing, going back to as early as 2018. Section III.C.3 of this proposed rule discusses the development of the proposed revised case-mix adjustment regression.

2. History of IPF PPS Cost and Claims Analyses

In the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we briefly discussed past analyses and areas of interest for future refinement, about which we previously solicited comments. CMS also released a technical report posted to the CMS website [2] accompanying the rule, summarizing these analyses. In that same proposed rule, we described the results of the agency's latest analysis of the IPF PPS and solicited comments on certain topics from the report. We summarized the considerations and findings related to our analyses of the IPF PPS adjustment factors in the FY 2023 IPF PPS final rule (46864 through 46865).

In the FY 2024 IPF PPS proposed rule (88 FR 21269 through 21272), we requested information from the public to inform revisions to the IPF PPS required by the CAA, 2023. Specifically, we sought information about which data and information would be most appropriate and useful for the purposes of refining IPF PPS payments. We requested information related to the specific types of data and information mentioned in the CAA, 2023. We also solicited comments on the reporting of ancillary charges, such as labs and drugs, on IPF claims. Lastly, we presented and solicited comments on the latest results of our analysis of social drivers of health (SDOH).

In response to the requests for information, commenters offered a number of suggestions for further analysis, including recommendations to consider adjusting payment for patients with sleep apnea, violent behavior, and patients that transfer from an acute care unit. We discuss the analysis conducted and our findings, as related to patient-level adjustment factors, in section III.C.3 of this proposed rule.

The primary goal in refining the IPF PPS payment adjustment factors is to pay each IPF an appropriate amount for the efficient delivery of care to Medicare beneficiaries. The system must be able to account adequately for each IPF's case-mix to allow for both fair distribution of Medicare payments and access to adequate care for those beneficiaries who require more costly care. As required by section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, proposed revisions to the IPF PPS adjustment factors must be budget neutral. As discussed in section III.F of this proposed rule, we are applying a refinement standardization factor to the proposed IPF PPS payment rates to maintain budget neutrality for FY 2025.

3. Development of the Proposed Revised Case-Mix Adjustment Regression

To ensure that the IPF PPS continues to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and both patient and facility characteristics to identify those characteristics associated with statistically significant cost differences. We discuss the results of this regression analysis in section III.C.3.e. of this proposed rule. We further discuss proposed revisions to the IPF PPS patient-level adjustment factors based on this regression analysis in section III.C.4 of this proposed rule.

As discussed in greater detail in section III.C.3.c. of this proposed rule, we computed a per diem cost for each Medicare inpatient psychiatric stay, including routine operating, ancillary, and capital components using information from the CY 2019 through CY 2021 MedPAR files and data from the 2019 through 2021 Medicare cost reports, backfilling with Medicare cost reports from the most recent prior year when necessary.

We began with a 100 percent sample of the CY 2019 through CY 2021 MedPAR data files, which contain a

[1] *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202206-0938-017.*

[2] *https://www.cms.gov/files/document/technical-report-medicare-program-inpatient-psychiatric-facilities-prospective-payment-system.pdf.*

total of 1,111,459 stays from 1,684 IPFs. As discussed in section III.C.3.b. of this proposed rule, we applied several data restrictions and exclusions to obtain the set of data used for our regression analysis. The MedPAR data files used for this regression analysis contain a total of 806,611 stays from 1,643 IPFs, which reflect the removal of 41 providers and 304,848 stays with missing or erroneous data. To include as many IPFs as possible in the regression, we used the cost report information for each provider corresponding to the year of claims, when available, and substituted the most recent prior available cost report information for routine cost and ancillary cost to charge ratios if the corresponding year's data was not available.

a. Data Sources

For the regression analysis, we chose to use a combined set of CY 2019 through 2021 MedPAR data. Our analysis showed that using a combined set of data from multiple years yields the most stable and consistent result. When we looked at the results for each year individually, we found that some DRGs and comorbidity categories were not statistically significant due in part to small sample size. In addition, during FY 2020, the U.S. healthcare system undertook an unprecedented response to the Public Health Emergency (PHE) declared by the Secretary of the Department of Health and Human Services on January 31, 2020 in response to the outbreak of respiratory disease caused by a novel (new) coronavirus that has been named ''SARS CoV 2'' and the disease it causes, which has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19''). We believe the aggregated three-year regression serves to smooth the impact of changes in utilization driven by the COVID–19 PHE, as well as significant changes in staffing and labor costs that commenters noted in response to the FY 2023 and FY 2024 IPF PPS proposed rules. As discussed earlier in this proposed rule, we used 2019 through 2021 Medicare cost report data to retain as many records as possible for analysis.

We also used several other data sources to identify the IPF population for analysis and to construct variables in the regression model:

- *Provider of Services (POS) File:* The POS file contains facility characteristics including name, address, and types of services provided.
- *Provider Specific Data for Public Use Files for the IPF PPS:* The Provider Specific File (PSF) contains data used to calculate COLA factors and identify the Core-Based Statistical Area (CBSA). CBSA is used to match providers with corresponding wage index data, which is used to adjust the calculation of the Federal per diem base rate to account for geographic differences in costs.
- *Common Working File (CWF) Inpatient Claims Data:* The CWF contains data regarding ECT treatments provided during an IPF stay.

Among the 1,643 providers included in the regression analysis sample, the majority had their most recent Medicare cost report information corresponding to the year of the MedPAR data file. Specifically, for the CY 2019 MedPAR data file, 99.5 percent (1,551 providers) used FY 2019 Medicare cost reports, and 0.5 percent (8 providers) used FY 2018 Medicare cost reports. For CY 2020, 99.7 percent (1,523 providers) used FY 2020 Medicare cost reports, and 0.3 percent (5 providers) used FY 2019 Medicare cost reports. For CY 2021, 97.6 percent (1,435 providers) used FY 2021 Medicare cost reports, and 2.4 percent (35 providers) used FY 2020 Medicare cost reports. This approach allowed us to use the most current and relevant cost report data, ensuring the robustness and accuracy of our analysis.

b. Trims and Assumptions

To identify the IPF population for analysis, we matched MedPAR records to facility-level information from Medicare cost reports, the POS file, and the PSF. We included MedPAR stays that met the following criteria:

- Hospital CMS Certification Number (CCN) contains ''40,'' ''41,'' ''42,'' ''43,'' or ''44'' in the third and fourth position or a special unit code of ''S'' or ''M'' for psychiatric unit or psychiatric unit in a critical access hospital.
- Beneficiary primary payer code is equal to ''Z'' or blank, indicating Medicare is the primary payer.
- Group Health Organization (GHO) paid code is equal to zero or blank, indicating that a GHO has not paid the facility for the stay.
- National Claims History (NCH) claim type code is equal to ''60,'' an inpatient claim.
- Number of utilization days was greater than zero.

To promote the accuracy and completeness of data included in the regression model, we completed a series of trimming steps to remove missing and outlier data. Before any trims or exclusions were applied, there were 1,684 providers in the MedPAR data file. First, we matched facilities from the MedPAR dataset to the most recent Medicare cost report file available from CY 2018 to CY 2021, and excluded facilities that did not have a Medicare cost report available from 2018 to 2021. If facilities had more than one Medicare cost report in a given year, we used the Medicare cost report representing the longest time span. We identified 1 provider in CY 2019, 5 providers in CY 2020, and 4 providers in CY 2021 that had no available Medicare cost report information. In total, we excluded data from 5 unique providers that had no available Medicare cost report information from CY 2019 to CY 2021.

Next, we trimmed facilities with extraordinarily high or low costs per day. We removed facilities with outlier routine per diem costs, defined as those falling outside of the range of the mean logarithm of routine costs per diem plus or minus 3.00 standard deviations. We also removed stays with outlier total per diem costs, defined as those falling outside the range of the mean per diem cost by facility type (psychiatric hospitals and psychiatric units) plus or minus 3.00 standard deviations. The average and standard deviations of the total per diem cost (routine and ancillary costs) were computed separately for stays in psychiatric hospitals and psychiatric units because we did not want to systematically exclude a larger proportion of cases from one type of facility. In applying these trims across all three data years used in our regression model, there were 104 providers with routine per diem costs outside 3.00 standard deviations from the mean, and 47 providers with total per diem costs outside 3.00 standard deviations from the mean. Specifically, this includes 24 providers in CY 2019, 41 providers in CY 2020, and 39 providers in CY 2021 excluded for outlier routine per diem costs. We identified 25 providers in CY 2019, 1 provider in CY 2020, and 21 providers in CY 2021 that we excluded for outlier total per diem costs. In total, we excluded data from 23 unique providers with outlier routine per diem costs and 8 unique providers with outlier total per diem costs.

We also removed stays at providers without a POS file or PSF. There were 5 providers without a POS file or PSF during the period CY 2019 to CY 2021; therefore, we are excluding data from these 5 providers. Only 1 unique provider was entirely excluded with no POS file or PSF from CY 2019 to CY 2021. Additionally, 1 provider was excluded because no stays had one of the recognized IPF PPS DRGs assigned.

In summary, the application of these data preparation steps resulted in excluding 5 providers because they did not have a cost report available from 2018 to 2021, 23 providers with routine per diem costs outside 3.00 standard

deviations from the mean, and 8 providers with total per diem costs outside 3.00 standard deviations from the mean. We also excluded 1 provider without a POS file or PSF, 1 provider with no stays with IPF PPS DRGs, and 3 providers based on IPF stays restrictions. In total, the exclusion of these 41 providers resulted in the removal of 304,848 stays from our original total of 1,111,459 stays.

We considered trimming stays from facilities where 95 percent or more of stays had no ancillary charges because we assumed that the cost data from these facilities were inaccurate or incomplete. This is the trimming methodology that we applied to the analysis described in the technical report released along with the FY 2023 IPF PPS proposed rule. As previously discussed, the IPF PPS regression model uses the sum of routine and ancillary costs as the dependent variable, and we assumed that data from facilities without ancillary charge data would be inadequate to capture variation in costs. When we examined the claims from 2018, which we used for prior analysis, this trimming step resulted in removing almost one-quarter of total stays from the unrestricted 2018 MedPAR dataset (82,491 out of 364,080 total stays). This trimming step also resulted in disproportionate exclusion of certain types of facilities, particularly freestanding psychiatric hospitals that were for-profit or government-operated, as well as all-inclusive rate providers. Approximately 55 percent of stays from freestanding facilities would be removed, compared to just 0.3 percent of stays in psychiatric units. In the analysis described in the FY 2023 IPF PPS proposed rule (87 FR 19429), we attempted to address this disproportionate removal of stays by facility type by applying weights by facility type and ownership in the regression model to account for excluded providers and to avoid biasing the sample towards stays from providers in psychiatric units.

In response to the analysis described in the FY 2023 IPF PPS proposed rule (87 FR 19429), commenters raised concerns about the large number of stays excluded from the regression analysis, and questioned whether the ancillary charge data were truly missing, as all-inclusive rate providers are not required to report separate ancillary charges. We agree that this trimming step reduces the representativeness of the IPF population used in the regression model and may increase the potential for bias of the regression coefficients used for payment adjustments. Furthermore, as discussed in section III.E.4. of this proposed rule, we are clarifying cost reporting requirements and implementing operational changes that we believe will increase the accuracy of the cost information reported in the future. Specifically, CMS will issue instructions to the MACs and put in place edits for cost reporting periods beginning on or after October 1, 2024, ensuring that only government-owned or tribally owned IPF hospitals will be permitted to file an all-inclusive cost report. All other IPF hospitals would be required to have a charge structure and to report ancillary costs and charges on their cost reports. We expect that this proposed change would support increased accuracy of future payment refinements to the IPF PPS.

When we examined the claims from CY 2019 to CY 2021, this trimming step would have resulted in a loss of a significant number of providers (324 providers in CY 2019, 330 providers in CY 2020, and 336 providers in CY 2021). Due to the concerns that commenters previously raised (which we summarized in the FY 2024 IPF PPS final rule (88 FR 51097 through 51098)), and to include as many claims as possible in the regression analysis, we have not trimmed stays from facilities with zero or minimal ancillary charges. As a result, we observed a significant reduction in data loss when comparing our latest regression model with the model described in the FY 2023 IPF PPS proposed rule. By including, rather than trimming, facilities with low or no ancillary charge data, we prevented the loss of 288 providers across the three years, allowing for a more inclusive analysis. These providers accounted for approximately 194,673 stays included in our data set.

We present our regression results in section III.C.3.e. of this proposed rule without the application of any trimming or subsequent weighting to account for the removal of stays from facilities with zero or minimal ancillary charges.

c. Calculation of the Dependent Variable

The IPF PPS regression model uses the natural logarithm of per diem total cost as the dependent variable. We computed a per diem cost for each Medicare inpatient psychiatric stay, including routine operating, ancillary, and capital components, using information from the combined CY 2019 through 2021 MedPAR file and data from the 2018 through 2021 Medicare cost reports. For each MedPAR CY, we examined the corresponding Medicare cost report, and if a provider's cost-to-charge ratio was missing from the matching year's cost report, we looked at the provider's cost report from the prior year to obtain the most recent cost-to-charge value for the provider. We applied a prior-year cost-to-charge ratio to 8 providers from the CY 2019 MedPAR claims, 5 providers from the CY 2020 MedPAR claims, and 35 providers from the CY 2021 MedPAR claims.

To calculate the total cost per day for each inpatient psychiatric stay, routine costs were estimated by multiplying the routine cost per day from the IPF's Medicare cost report (Worksheet D–1, Part II, column 1, line 38) by the number of Medicare covered days in the MedPAR stay record. Ancillary costs were estimated by multiplying each departmental cost-to-charge ratio (calculated by dividing the amount obtained from Worksheet C, columns 5, by the sum of Worksheet C, columns 6 and 7) by the corresponding ancillary charges in the MedPAR stay record. The total cost per day was calculated by summing routine and ancillary costs for the stay and dividing it by the number of Medicare covered days for each day of the stay.

To address extreme cost-to-charge ratios, we winsorized the distributions of the 17 ancillary cost centers from Worksheet C of the cost report at the 2nd and 98th percentiles. That is, if the cost-to-charge ratio was missing and there was a charge on the claim, the cost-to-charge ratio was imputed to the calculated median value for each respective cost center.

The total cost per day (also referred to as per diem cost) was adjusted for differences in cost across geographic areas using the FY 2019 through 2021 IPF wage index and COLA corresponding to each MedPAR data year. We adjusted the labor-related portion of the per diem cost using the IPF wage index to account for geographic differences in labor cost and adjusted the non-labor portion of the per diem cost by the COLA adjustment factors for IPFs in Alaska and Hawaii. We used IPF PPS labor-related share and non-labor-related share finalized for each year, FY 2019 through FY 2021, to determine the amount of the per diem cost that is adjusted by the wage index and the COLA, respectively. We calculated the adjusted cost using the following formula:

Wage adjusted per diem cost = per diem cost/(wage index * labor-related share + COLA * (1-labor-related share)).

d. Independent Variables

Independent variables in the regression model are patient-level and facility-level characteristics that affect

the dependent variable in the model, which is per diem cost. As discussed in the following sections, the updated regression model for this proposed rule includes adjustment-related variables and control variables. Adjustment related variables are used for adjusting payment, and as we discuss in section III.C.4 of this proposed rule, we are proposing to revise the IPF PPS patient-level adjustment factors based on the regression results for many of the adjustment-related variables in the model. Control variables are used to account for variation in the dependent variable that is associated with factors outside the adjustment factors of the payment model.

(1) Adjustment-Related Variables

Patient-level adjustment-related variables included in the regression model are variables for DRG assignment, comorbidity categories, age, and length of stay. We note that facility-level adjustment-related variables for rural status and teaching status are also included in the model; however, we are not proposing revisions to the rural or teaching adjustments for FY 2025. We discuss the latest results of the regression analysis for facility-level adjustments in greater detail in section IV.A. of this proposed rule.

(2) Control Variables

The regression model used to determine IPF PPS payment adjustments in the RY 2005 IPF PPS final rule (69 FR 66922) included control variables to account for facilities' occupancy rate, a control variable to indicate if the patient received ECT, and a control variable for IPFs that do not bill for ancillary charges. In the updated regression model for this FY 2025 IPF PPS proposed rule, we have removed the occupancy control variables and the control variable for IPFs that do not bill for ancillary charges. In addition, we have retained the control variable for patients receiving ECT and added control variables for the data year. We also added a control variable for the presence of ED charges on the claim. We discuss considerations related to these control variables and others in the following paragraphs.

The 2004 regression model included two control variables for occupancy rate. One was a continuous variable for the facility's logarithmic-transformed occupancy rate. The other was a categorical variable indicating a facility had an occupancy rate below 30 percent. Both of these variables were found to be associated with statistically significant increases in cost. In the RY 2005 IPF PPS final rule, we adopted the structural approach and included these control variables in the regression. We explained that it was appropriate to control for variations in the occupancy rate in estimating the effects of the payment variables on per diem cost to avoid compensating facilities for inefficiency associated with underutilized fixed costs (69 FR 66934). As we discussed in the FY 2023 IPF PPS proposed rule, our analysis found that the occupancy control variables were associated with rural status. We solicited comments on the potential removal of the occupancy control variables from the model (87 FR 19429). In response, we received several comments in support of removing the occupancy control variables, due to the relationship between these control variables and the rural adjustment (87 FR 46865). Commenters cited the importance of rural IPFs as the primary points of care and access for many Medicare beneficiaries who cannot travel to urban areas for mental health services. We considered the potential negative impact to rural facilities of retaining the occupancy control variables in the regression model. We agree with the commenters who noted the importance of maintaining stability in payments for rural IPFs; therefore, we did not include any occupancy control variables in our regression model.

In addition, we considered including a control variable for IPFs that do not bill for ancillary services. As we discussed in the RY 2005 IPF PPS final rule (69 FR 66936), we included variables in the regression to control for psychiatric hospitals that do not bill ancillary costs. However, at that time, the number of IPFs who did not bill for ancillary costs was relatively small and consisted mostly of government-operated facilities. As we discuss later in section III.E.4 of this proposed rule, an increasing number of IPFs have stopped reporting ancillary charges on their claims, which means that ancillary cost information is not available for stays at these IPFs.

We considered whether to include a control variable for facilities that do not report ancillary charges. We considered that the inclusion of a control variable would only account for differences in the level of cost between IPFs with and without reported ancillary costs and would not facilitate comparison of costs between all IPFs in our sample. In addition, we found that facilities that did not report ancillary charges also tended to have lower routine costs; that is, our analysis showed that these facilities would have overall lower costs per day, regardless of whether ancillary costs were considered in the cost variable. We considered that the inclusion of a control variable in the regression model would account for these differences in overall cost, which would impact the size of payment-related adjustment factors that are correlated with the prevalence of missing ancillary charge data. For this reason, in developing a regression model for proposing revisions to the IPF PPS, we did not include a control variable to account for facilities that report zero or minimal ancillary charges.

As noted earlier, the original model also included a control variable for the presence of ECT. This is because ECT is paid on a per-treatment basis under the IPF PPS. As discussed in more detail in section III.B.2. of this FY 2025 IPF PPS proposed rule, we continue to observe that IPF stays with ECT have significantly higher costs per day. We are proposing to continue paying for ECT on a per-treatment basis; therefore, we included a control variable to account for the additional costs associated with ECT, which would continue to be paid for outside the regression model.

Similarly, we included a control variable for stays with emergency department (ED)-related charges. The original model did not include an ED control variable, because ED costs were excluded from the dependent variable of IPF per diem costs. Our regression model for this FY 2025 IPF PPS proposed rule includes all costs associated with each IPF stay, including ED costs. As discussed in section III.D.4. of this proposed rule, we are proposing to calculate the ED adjustment in accordance with our longstanding methodology, separate from the regression model. However, we included a control variable for stays with ED charges to control for the additional costs associated with ED admissions, which are paid under the ED adjustment outside the regression model.

Lastly, we included control variables for the data year. Because the model used a combined set of data from 3 years, these control variables are included in the model to account for differences in cost levels between 2019, 2020, and 2021, which would be driven by economic inflation and other external factors unrelated to the independent variables in the regression model.

e. Regression Results

Table 2 presents the results of our regression model. We discuss these results and our related proposals to

revise the IPF PPS patient-level adjustment factors in section III.C.4 of this proposed rule.

This regression model includes a total of 806,611 stays, and the r-squared value of the model is 0.32340, meaning that the independent variables included in the regression model can explain approximately 32.3 percent of the variation in per diem cost among IPF stays.

Except for the teaching variable, each of the adjustment factors in Table 2 is the exponentiated regression coefficient of our regression model, which as we previously noted uses the natural logarithm of per diem total cost as the dependent variable. We present the exponentiated regression results, as these most directly translate to the way that IPF PPS adjustment factors are calculated for payment purposes. That is, the exponentiated adjustment factors presented below represent a percentage increase or decrease in per diem cost for IPF stays with each characteristic. In the case of the teaching variable, the result in Table 2 is the un-exponentiated regression coefficient. As discussed in section III.D of this proposed rule, the current IPF PPS teaching adjustment is calculated as 1 + a facility's ratio of interns and residents to beds, raised to the power of 0.5150. The coefficient for teaching status presented in Table 2 can be interpreted in the same way.

For certain categorical variables, including DRG, age, length of stay, and the year control variables, results for the reference groups are not shown in Table 2. The DRG reference group is DRG 885, because this DRG represents the majority of IPF PPS stays. The age reference group is the Under 45 category, because this group is associated with the lowest costs after accounting for all other patient characteristics in the model. The reference group for length of stay is 10 days, which corresponds to the reference group used in the original regression model from the RY 2005 IPF PPS final rule. Lastly, the year control reference group is CY 2021. Each of these reference groups not shown in Table 2 effectively has an adjustment factor of 1.00 in the regression model.

As shown in Column 5 of Table 2, we considered the regression factors to be statistically significant when the p-value was less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***). Columns 6 and 7 of Table 2 show the lower and upper bounds of the 95-percent confidence interval (CI).

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Table 2: IPF PPS Per Diem Cost Regression Results with Data from CY 2019 through CY 2021

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
Degenerative nervous system disorders w MCC	4,287	0.5%	1.12818	***	1.09253	1.16500
Degenerative nervous system disorders w/out MCC	40,584	5.0%	1.11030	***	1.07727	1.14434
OR procedures with principal diagnosis of mental health	751	0.1%	1.28830	***	1.24616	1.33185
Acute adjustment reaction and psychosocial dysfunction	7,529	0.9%	1.07632	**	1.02387	1.13146
Depressive neuroses	23,566	2.9%	1.06153	***	1.03586	1.08784
Neuroses except depressive	10,143	1.3%	1.02156		0.96798	1.07811
Disorders of personality and impulse control	5,804	0.7%	1.17059	***	1.13015	1.21249

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
Organic disturbances and intellectual disability	55,842	6.9%	1.08234	***	1.05502	1.11038
Behavioral and developmental disorders	1,582	0.2%	1.06940	***	1.03421	1.10578
Other mental disorder diagnoses	321	0.0%	1.12075		0.92590	1.35661
Alcohol, Drug Abuse or Dependence, Left AMA	3,060	0.4%	0.86061	***	0.81619	0.90745
Alcohol, Drug Abuse or Dependence w rehab therapy	12,361	1.5%	0.89569	***	0.84258	0.95215
Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC	891	0.1%	1.02242		0.98132	1.06523
Alcohol, Drug Abuse or Dependence w/out rehab therapy w/out MCC	34,767	4.3%	0.94524	***	0.91415	0.97738
Poisoning and toxic effects of drugs w MCC	137	0.0%	1.19428	***	1.12732	1.26521
Poisoning and toxic effects of drugs w/out MCC	843	0.1%	1.11591	***	1.08122	1.15172
Signs and Symptoms w MCC	58	0.0%	1.12739	**	1.03077	1.23307
Signs and Symptoms w/out MCC	805	0.1%	1.09033	**	1.02230	1.16289
Age 45 to 54 years	121,498	15.1%	1.01993	***	1.01372	1.02617
Age 55 to 59 years	74,512	9.2%	1.04746	***	1.03741	1.05762
Age 60 to 64 years	68,136	8.4%	1.06561	***	1.05234	1.07904
Age 65 to 69 years	94,473	11.7%	1.08783	***	1.07098	1.10495
Age 70 to 79 years	126,280	15.7%	1.11724	***	1.09341	1.14158
Age over 79 years	87,442	10.8%	1.12790	***	1.09902	1.15754
Acute Renal Failure	19,064	2.4%	1.06093	***	1.03735	1.08503
Artificial Openings - Digestive & Urinary	3,713	0.5%	1.07435	***	1.05526	1.09379
Cardiac conditions	22,152	2.7%	1.04946	***	1.03362	1.06554
Conduct Disorder	5,113	0.6%	0.98245		0.93588	1.03134
Chronic Renal Failure	46,274	5.7%	1.07955	***	1.06588	1.09340
Coagulation Factor Deficit	492	0.1%	1.01663		0.98084	1.05373
Chronic Obstructive Pulmonary Disease	11,994	1.5%	1.06933	***	1.04771	1.09140
Developmental Disabilities	27,020	3.3%	1.02102		0.99556	1.04712
Uncontrolled Diabetes	21,939	2.7%	1.05366	***	1.03528	1.07238
Drug/Alcohol Induced Mental Disorders	59,437	7.4%	0.96084	**	0.93690	0.98538

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
Eating Disorder	2,812	0.3%	1.09353	***	1.05295	1.13567
Gangrene	223	0.0%	1.11781	***	1.05627	1.18294
Infectious diseases	38,562	4.8%	1.01549	.	0.99930	1.03193
Severe Protein Malnutrition	5,119	0.6%	1.16750	***	1.12231	1.21452
Oncology Treatment	12	0.0%	1.45578	***	1.20449	1.75949
Poisoning	5,966	0.7%	1.16190	***	1.13990	1.18432
Severe Musculoskeletal & Connective Tissue Disease	4,272	0.5%	1.04856	***	1.03163	1.06577
Tracheostomy	304	0.0%	1.09464	***	1.04885	1.14244
Intensive Management for High-Risk Behavior	19,884	2.5%	1.06997	***	1.03021	1.11128
ECT Indicator	12,654	1.6%	1.33080	***	1.27553	1.38846
ER Indicator	261,643	32.4%	1.38913	***	1.34596	1.43369
Rural	101,483	12.6%	1.19139	***	1.12333	1.26357
Teaching Status	155,458	19.3%	0.72862	***	0.57860	0.87864
Length of stay - 1 day	16,891	2.1%	1.27494	***	1.24324	1.30744
Length of stay - 2 days	28,370	3.5%	1.20173	***	1.17710	1.22688
Length of stay - 3 days	42,298	5.2%	1.14873	***	1.12808	1.16976
Length of stay - 4 days	48,187	6.0%	1.11669	***	1.09984	1.13381
Length of stay - 5 days	54,187	6.7%	1.08356	***	1.06837	1.09897
Length of stay - 6 days	59,215	7.3%	1.06079	***	1.04833	1.07340
Length of stay - 7 days	63,095	7.8%	1.02646	***	1.01538	1.03767
Length of stay - 8 days	51,491	6.4%	1.01682	***	1.00766	1.02605
Length of stay - 9 days	42,855	5.3%	1.00908	**	1.00225	1.01596
Length of stay - 11 days	35,092	4.4%	0.99518		0.98910	1.00130
Length of stay - 12 days	32,030	4.0%	0.99592		0.98943	1.00245
Length of stay - 13 days	32,356	4.0%	0.99819		0.98886	1.00761
Length of stay - 14 days	34,727	4.3%	0.99885		0.98382	1.01412
Length of stay - 15 days	24,919	3.1%	0.98872		0.97489	1.00275
Length of stay - 16 days	18,907	2.3%	0.98779		0.97362	1.00216

Description	Number of Stays	% of Stays	Adjustment Factors	Significance[1]	CI Lower Bound	CI Upper Bound
Length of stay - 17 days	16,128	2.0%	0.98944		0.97588	1.00318
Length of stay - 18 days	14,191	1.8%	0.98559		0.97134	1.00005
Length of stay - 19 days	13,085	1.6%	0.98792		0.97199	1.00411
Length of stay - 20 days	13,302	1.6%	0.98446		0.96789	1.00130
Length of stay - 21 days	12,628	1.6%	0.98476		0.96361	1.00637
Length of stay - greater or equal to 22 days	113,912	14.1%	0.98771		0.96017	1.01604
CY2019 Stay	330,574	41.0%	0.89833	***	0.88733	0.90947
CY2020 Stay	259,052	32.1%	0.94927	***	0.94041	0.95822

[1] Statistical significance based on p-value less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***)

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4. Proposed Updates and Revisions to the IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS–DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments. As discussed in section III.C.3. of this proposed rule, we are proposing to derive updated IPF PPS adjustment factors for FY 2025 using a regression analysis of data from the CY 2019 through 2021 MedPAR data files and Medicare cost report data from the 2018 through FY 2021 Hospital Cost Report Information System (HCRIS). However, we have used more recent claims (specifically, the December, 2023 update of the FY 2023 IPF PPS MedPAR claims) and cost data from the January, 2024 update of the provider-specific file (PSF) to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates. More information about the data used for the impact simulations is found in section VIII.C of this FY 2025 IPF PPS proposed rule. As discussed in section III.C.3. of this proposed rule, by adjusting for DRGs, comorbidities, age, and length of the stay, along with the facility-level variables and control variables in the model, we were able to explain approximately 32.3 percent of the variation in per diem cost among IPF stays.

In addition, we are proposing routine coding updates for FY 2025 for our longstanding code first and IPF PPS comorbidities. Furthermore, as discussed in section III.C.4.a.(2) of this proposed rule, we are proposing to adopt a sub-regulatory process for future routine coding updates.

a. Proposed Updated and Revisions to MS–DRG Assignment

(1) Background

We believe it is important to maintain for IPFs the same diagnostic coding and DRG classification used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD–9–CM) and DRG patient classification system (MS–DRGs) that were utilized at the time under the IPPS. In the RY 2009 IPF PPS notice (73 FR 25709), we discussed CMS's effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS–DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the RY 2009 IPF PPS notice (73 FR 25716), we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS–DRGs. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS–DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis discussed in detail in the RY 2004 IPF proposed rule (68 FR 66923; 66928 through 66933) and the RY 2005 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment.

In the FY 2015 IPF PPS final rule published August 6, 2014 in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)'' (79 FR 45945 through 45947), we finalized conversions of the ICD–9–CM–based MS–DRGs to ICD–10–CM/PCS–based MS–DRGs, which were implemented on October 1, 2015. Further information on the ICD–10–CM/PCS MS–DRG conversion project can be found on the CMS ICD–10–CM website at *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-ms-drg-conversion-project.*

(2) Proposal To Adopt Sub-Regulatory Process for Publication of Coding Changes

As discussed in the FY 2015 IPF PPS proposed rule (79 FR 26047) every year, changes to the ICD–10–CM and the ICD–10–PCS coding system have been addressed in the IPPS proposed and final rules. The changes to the codes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. In accordance with § 412.428(e), we have historically described in the IPF PPS proposed and final rules the ICD–10–CM coding changes and DRG classification changes that have been discussed in the annual proposed and final hospital IPPS regulations. This has typically involved a discussion in the proposed rule about coding updates to be effective October 1 of each year, with a summary of comments in the final rule along with a description of additional finalized codes for October.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates in addition to the annual October 1 update of ICD–10–CM diagnosis and ICD–10–PCS procedure codes, beginning with April 1, 2022. In that rule, we noted the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. Currently, as noted earlier in this proposed rule, the IPF PPS uses the IPPS DRG assignments, which are applied to IPF PPS claims; these DRG assignments reflect the change in process that the IPPS adopted for FY 2022. To maintain consistency with IPPS policy, we are proposing to follow the same process beginning in FY 2025. This means that for routine coding updates that incorporate new or revised codes, we are proposing to adopt these changes through a sub-regulatory process. Beginning in FY 2025, we would operationalize such coding changes in a Transmittal/Change Request, which would align with the way coding changes are announced under the IPPS.

For example, we are proposing that for April 2025, we would adopt routine coding updates for the IPF PPS comorbidity categories, code first policy, ECT code list, and DRG assignment via sub-regulatory guidance. These coding updates would take effect April 1, 2025. In accordance with § 412.428(e), we would describe these coding changes, along with any coding updates that would be effective for October 1, 2025, in the FY 2026 IPF PPS proposed rule. We would summarize and respond to any comments on these April and October coding changes in the FY 2026 IPF PPS final rule.

The proposed update aims to allow flexibility in the ICD–10 code update process for the IPF PPS and reduces the lead time for making routine coding updates to the IPF PPS code first list, comorbidities, and ECT coding categories. In addition, the IPPS sub-regulatory process continues to manage DRG assignment changes which apply to the DRG assignments used in the IPF PPS. Finally, we are clarifying that we would only apply this sub-regulatory process for routine coding updates. Any future substantive revisions to the IPF PPS DRG adjustments, comorbidities, code first policy, or ECT payment policy would be proposed through notice and comment rulemaking. We solicit public comments on this proposal.

(3) Routine Coding Updates for DRG Assignments

The diagnoses for each IPF MS–DRG will be updated as of October 1, 2024, using the final IPPS FY 2025 ICD–10–CM/PCS code sets. The FY 2025 IPPS/LTCH PPS final rule will include tables of the changes to the ICD–10–CM/PCS code sets that underlie the proposed FY 2025 IPF MS–DRGs. Both the FY 2025 IPPS final rule and the tables of final changes to the ICD–10–CM/PCS code sets, which underlie the FY 2025 MS–DRGs, will be available on the CMS IPPS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

(4) Code First

As discussed in the ICD–10–CM Official Guidelines for Coding and Reporting, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD–10–CM has a coding convention that requires the underlying condition be sequenced first, followed by the manifestation. Wherever such a combination exists, there is a ''use additional code'' note at the etiology code, and a ''code first'' note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes (etiology followed by manifestation). In accordance with the ICD–10–CM Official Guidelines for Coding and Reporting, when a primary (psychiatric) diagnosis code has a code first note, the provider will follow the instructions in the ICD–10–CM Tabular List. The submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign a DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment. For more information on the code first policy, we refer readers to the RY 2005 IPF PPS final rule (69 FR 66945). We also refer readers to sections I.A.13 and I.B.7 of the FY 2020 ICD–10–CM Coding Guidelines, which is available at *https://www.cdc.gov/nchs/data/icd/10cmguidelinesFY2020_final.pdf.* In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar manifestation codes where the code first instructions apply in ICD–10–CM that were present in ICD–10–CM (79 FR 46009). In FY 2018, FY 2019, and FY 2020, there were no changes to the final ICD–10–CM codes in the IPF Code First table. For FY 2021 and FY 2022, there were 18 ICD–10–CM codes deleted from the final IPF Code First table. For FY 2023, there were 2 ICD–10–CM codes deleted and 48 ICD–10–CM codes added to the IPF Code First table. For FY 2024, there were no proposed changes to the Code First Table.

We are proposing to continue our existing code first policy. As outlined in our proposal to incorporate a sub-regulatory process for the publication of coding changes, we are proposing to adopt a sub-regulatory approach to handle the coding updates, which removes the requirement to discuss coding updates in the **Federal Register** during regulatory updates prior to implementation, which would mirror the approach taken by the IPPS. The proposed FY 2025 Code First table is shown in Addendum B on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

(5) Proposed Revisions to MS–DRG Adjustment Factors

For FY 2025, we are proposing to revise the payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis, following our longstanding policy of using the ICD–10–CM/PCS–based MS–DRG system. As discussed in the following paragraphs, we are proposing to maintain DRG adjustments for 15 of the existing 17 IPF MS–DRGs for which we currently adjust payment in FY 2024. We are proposing to replace two existing DRGs with two new DRGs to reflect changes in coding practices over time and proposing to add two DRGs that are associated with poisoning. We are also proposing to

revise the adjustment factors for the DRG adjustments as described in Table 3, based on the results of our latest regression analysis described in Section III.C.3 of this proposed rule. Addendum A is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.* The website includes the proposed DRG adjustment factors for FY 2025. In accordance with our longstanding policy, we are proposing that psychiatric principal diagnoses that do not group to one of the 19 proposed designated MS–DRGs would still receive the Federal per diem base rate and all other applicable adjustments; however, the payment would not include an MS–DRG adjustment.

(a) Proposed Replacement of DRGs

We are proposing to remove DRGs 080 (Nontraumatic stupor & coma w MCC) and 081 (Nontraumatic stupor & coma w/o MCC), and to replace these with DRGs 947 (Signs and Symptoms w MCC) and 948 (Signs and Symptoms w/ out MCC). As previously discussed, we observed that the number of cases in DRGs 080 and 081 have decreased significantly since 2004. We selected DRGs 947 and 948 as the most clinically appropriate replacements, because most of the ICD–10–CM codes that previously grouped to DRGs 080 or 081 now group to DRGs 947 or 948. Table 3 compares the current adjustment factors for DRGs 080 and 081 to the regression-derived adjustment factors for DRGs 947 and 948. As shown in Table 3, the proposed adjustment factors for DRGs 947 and 948 would each be greater than the current DRG adjustment for DRGs 080 and 081. Therefore, we are proposing that claims with DRGs 080 or 081 would still receive the Federal per diem base rate and all other applicable adjustments; however, the payment would not include an MS–DRG adjustment.

As discussed in section III.F of this proposed rule, we are proposing to implement this revision to the DRG adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule. Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 DRG adjustment factors.

Table 3: Proposed Replacements for DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Proposed Adjustment Factors
DRG 080- Nontraumatic stupor & coma w MCC	1.07	1	0.00%	**N/A**
DRG 081-Nontraumatic stupor & coma w/o MCC	1.07	1	0.00%	**N/A**
DRG 947-Signs and Symptoms w MCC	N/A	58	0.01%	**1.13**
DRG 948-Signs and Symptoms w/out MCC	N/A	805	0.10%	**1.09**

(b) Proposed Additions of DRGs

We are proposing to recognize DRG adjustments for two DRGs associated with poisoning; specifically, DRG 917 (Poisoning and toxic effects of drugs w MCC) and 918 (Poisoning and toxic effects of drugs w/out MCC). As discussed earlier in this proposed rule, we have identified that a small but increasing number of IPF stays contain these poisoning-related DRG assignments, and that stays with these DRGs have increased costs per day that are statistically significant. Table 4 summarizes the frequency of these stays and the proposed adjustment factors for FY 2025. As discussed in section III.F of this proposed rule, we are proposing to implement this revision to the DRG adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule.

Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 DRG adjustment factors.

Table 4: Proposed Additions for DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Proposed Adjustment Factors
DRG 917-Poisoning and toxic effects of drugs w MCC	N/A	137	0.02%	**1.19**
DRG 918-Poisoning and toxic effects of drugs w/out MCC	N/A	843	0.10%	**1.12**

(c) Proposed Revisions to Adjustment Factors for Existing DRG Adjustments

We are proposing to revise the adjustment factors for the remaining 15 of the existing 17 DRGs that currently receive a DRG adjustment in FY 2024. These proposed revisions are based on the results of our latest regression analysis described in section III.C.3 of this proposed rule.

As previously discussed, our analysis found that some of the adjustment factors in the regression model for DRGs that currently receive an adjustment are no longer statistically significant. Specifically, we found that the adjustment factors for DRG 882 (Neuroses except depressive), DRG 887 (Other mental disorder diagnoses), and DRG 896 (Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC) were not statistically significant. For each of these DRGs, we examined whether the current adjustment factor falls within the confidence interval for our latest regression analysis. The current adjustment for DRG 882 is 1.02, and this falls within the confidence interval of 0.96798 to 1.07811 for the latest regression model discussed in section III.C.3 of this proposed rule. We believe it would be appropriate to maintain the current adjustment factor of 1.02 for DRG 882, because the latest regression results indicate that the current adjustment factor would be a reasonable approximation of the increased costs associated with DRG 882. For DRGs 887 and 896; however, the current adjustment factors (0.92 and 0.88, respectively) do not fall within the confidence interval for each of these DRGs. Therefore, we are proposing to apply an adjustment factor of 1.00 for IPF stays with these DRGs.

Table 5 summarizes the frequency of these stays and the proposed adjustment factors for FY 2025. As discussed in section III.F of this proposed rule, we are proposing to implement this revision to the DRG adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule.

Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 DRG adjustment factors.

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Table 5: Proposed Updates to Existing DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Proposed Adjustment Factors
DRG 056-Degenerative nervous system disorders w MCC	1.05	4,287	0.53%	1.13
DRG 057-Degenerative nervous system disorders w/out MCC	1.05	40,584	5.03%	1.11
DRG 876-OR procedure with principal diagnoses of mental illness	1.22	751	0.09%	**1.29**
DRG 880-Acute adjustment reaction and psychosocial dysfunction	1.05	7,529	0.93%	**1.08**
DRG 881-Depressive neuroses	0.99	23,566	2.92%	**1.06**
DRG 882-Neuroses except depressive	1.02	10,143	1.26%	**1.02**
DRG 883-Disorders of personality and impulse control	1.02	5,804	0.72%	**1.17**
DRG 884-Organic disturbances and intellectual disabilities	1.03	55,842	6.92%	**1.08**
DRG 885-Psychoses	1.00	603,280	74.79%	**1.00**
DRG 886-Behavioral and developmental disorders	0.99	1,582	0.20%	**1.07**
DRG 887-Other mental disorder diagnoses	0.92	321	0.04%	**1.00**
DRG 894-Alcohol, Drug Abuse or Dependence, Left AMA	0.97	3,060	0.38%	**0.86**
DRG 895-Alcohol, Drug Abuse or Dependence w rehab therapy	1.02	12,361	1.53%	**0.90**
DRG 896-Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC	0.88	891	0.11%	**1.00**
DRG 897-Alcohol, Drug Abuse or Dependence w/out rehab therapy w/out MCC	0.88	34,767	4.31%	**0.95**

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b. Proposed Payment for Comorbid Conditions

(1) Proposed Revisions to Comorbidity Adjustments

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat.

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, LOS, or both treatment and LOS.

The current comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD–9–CM code first instructions applied. In a code first situation, the submitted claim goes through the CMS processing system, which identifies the principal diagnosis code as non-psychiatric and searches the secondary codes for a psychiatric code to assign an MS–DRG code for adjustment. The system continues to search the secondary codes for those that are appropriate for a comorbidity adjustment.

In our RY 2012 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD–9–CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

As discussed in section C.4.a.(1) of this proposed rule, it is our policy to

maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD–9–CM codes were converted to ICD–10–CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD–10–CM implementation as it would be if the same record had been coded in ICD–9–CM and submitted prior to ICD–10–CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for discharge claims, on or after October 1, 2015, require IPFs to enter the complete ICD–10–CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

As previously discussed in section III.C.4.a.(2) of this proposed rule, we are proposing to adopt an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates, in addition to the annual October 1 update, beginning with April 1, 2025 for the IPF PPS. For FY 2025 and future years, coding updates related to the IPF PPS comorbidity categories would be adopted following a sub-regulatory process as discussed earlier in this proposed rule.

For FY 2025, we are proposing to revise the comorbidity adjustment factors based on the results of the 2019 through 2021 regression analysis described in section III.C.3.e. of this proposed rule. We are also proposing additions and changes to the comorbidity categories for which we adjust payment based on our analysis of ICD–10–CM codes currently included in each category as well as public comments received in response to the FY 2022 and FY 2023 IPF PPS proposed rules.

Based on analysis of the ICD–10–CM codes, we considered the statistical significance of the adjustment factor and whether the current (FY 2024) adjustment factor fell within the confidence interval in the 2019 through 2021 regression to determine the FY 2025 IPF PPS proposed comorbidity categories and adjustment factors. As previously discussed for the DRG adjustment factors, when the regression factor is not statistically significant, but the current adjustment factor is within the confidence interval, we are proposing to maintain the current adjustment factor. When a regression factor is not statistically significant and the current adjustment factor is not within the confidence interval, we are proposing to remove the comorbidity category.

Specifically, we are proposing to increase the adjustment factors for the Gangrene, Severe Protein Malnutrition, Oncology Treatment, Poisoning, and Tracheostomy comorbidity categories based on the adjustment factors derived from the regression analysis discussed in section III.C.3 of this proposed rule. For these comorbidity categories, the regression results produced a statistically significant increase in the adjustment factors.

We are proposing to remove the comorbidity categories for the Coagulation Factor Deficit, Drug/Alcohol Induced Mental Disorders, and Infectious Diseases adjustment factors because the regression factor for the ICD–10–CM codes associated with Coagulation Factor Deficit and Infectious Diseases were not statistically significant, and the current adjustment factors did not fall within the confidence intervals in the 2019 through 2021 regression.

The current adjustment factor for Drug/Alcohol Induced Mental Disorders is 1.03; however, the adjustment factor derived from our latest regression results was statistically significant at 0.96084, meaning payments would be reduced if we applied the regression-derived adjustment factor as a comorbidity adjustment for this category. In order to understand the drivers of changing costs for the Drug/Alcohol Induced Mental Disorders comorbidity category, we examined a subset of ICD–10–CM codes within the comorbidity category associated with opioid disorders which make up the majority of stays that qualify for the current Drug/Alcohol Induced Mental Disorders comorbidity adjustment. These opioid disorder codes are listed in Table 6. When we separately analyzed these codes associated with opioid disorder, the results suggested that patients with opioid disorder are significantly less expensive than patients without opioid disorder. Because stays with opioid disorders make up the majority of stays in the Drug/Alcohol Induced Mental Disorders comorbidity category, we observe a statistically-significant negative adjustment factor for the comorbidity category overall. The application of a comorbidity adjustment derived from our latest regression analysis would result in reduced payments for all stays in this comorbidity category. We do not believe it is appropriate to apply negative adjustment factors (that is, adjustment factors less than 1.00) for comorbidities because that would result in reduced rather than increased payments. Although we apply adjustment factors less than 1.00 for DRGs, this is because the DRG adjustment reflects the cost of stays relative to stays with the baseline DRG 885. In contrast, comorbidity adjustments reflect the cost relative to a stay with no comorbidities. A negative payment adjustment would not be consistent with the intent of a comorbidity adjustment, which is intended to provide additional payments to providers to account for the costs of treating patients with comorbid conditions. Therefore, we have not historically included any negative adjustment factors for comorbid conditions.

Therefore, we are proposing to remove the Drug/Alcohol Induced Mental Disorders comorbidity category beginning in FY 2025. IPF stays that include these codes as a non-principal diagnosis would no longer receive the current Drug/Alcohol Induced Mental Disorders comorbidity category adjustment factor of 1.03; nor would they receive a reduction in payment. However, many IPF stays that include these ICD–10–CM diagnosis codes as a principal diagnosis would continue to receive a DRG adjustment. We refer readers to section III.C.3.a of this proposed rule for a detailed discussion of proposed DRG adjustments under the IPF PPS.

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Table 6: ICD–10–CM Codes for Opioid Disorder

ICD–10–CM Code	Description
F1123	Opioid dependence with withdrawal
F1120	Opioid dependence, uncomplicated
F1124	Opioid dependence with opioid-induced mood disorder
F11259	Opioid dependence w opioid-induced psychotic disorder, unsp
F11229	Opioid dependence with intoxication, unspecified
F1193	Opioid use, unspecified with withdrawal
F11251	Opioid depend w opioid-induc psychotic disorder w hallucin
F11250	Opioid depend w opioid-induc psychotic disorder w delusions
F1129	Opioid dependence with unspecified opioid-induced disorder
F11288	Opioid dependence with other opioid-induced disorder
F11220	Opioid dependence with intoxication, uncomplicated
F11282	Opioid dependence with opioid-induced sleep disorder
F11921	Opioid use, unspecified with intoxication delirium
F11221	Opioid dependence with intoxication delirium
F11951	Opioid use, unsp w opioid-induc psych disorder w hallucin
F1114	Opioid abuse with opioid-induced mood disorder
F1194	Opioid use, unspecified with opioid-induced mood disorder
F11151	Opioid abuse w opioid-induced psychotic disorder w hallucin
F1113	Opioid abuse with withdrawal
F1110	Opioid abuse, uncomplicated
F1199	Opioid use, unsp with unspecified opioid-induced disorder
F11929	Opioid use, unspecified with intoxication, unspecified
F11922	Opioid use, unsp w intoxication with perceptual disturbance

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We believe removal of the Drug/Alcohol Induced Mental Disorders comorbidity category under the IPF PPS would more appropriately align payment with resource use, as reflected in the latest regression results. As previously discussed in section III.F of this proposed rule, all of these proposed revisions would be applied budget-neutrally. Therefore, we believe the removal of the Drug/Alcohol Induced Mental Disorders comorbidity adjustment would appropriately increase the IPF PPS Federal per diem base rate and thereby increase payment for IPF stays that are costlier. However, we are soliciting comments on whether a lack of ancillary charge data may be contributing to the results of our regression analysis as it relates to opioid disorders. We note that our analysis of the ICD–10–CM codes associated with opioid disorder also indicates that there is significant overlap between facility characteristics and stays including opioid disorder diagnoses. In particular, for-profit freestanding IPFs were found to serve the majority of patients with opioid disorders. As discussed in section III.E.4 of this proposed rule, our ongoing analysis has found an increase in the number of for-profit freestanding IPFs that are consistently reporting no ancillary charges or very minimal ancillary charges on their cost report. As a result, we have previously noted that data that is necessary for accurate Medicare ratesetting is excluded from the information these facilities are reporting.

As stated previously, the regression factor for Drug/Alcohol Induced Mental Disorders was statistically significant, but is less than 1, meaning payments would be reduced if we applied it as a comorbidity adjustment. We are interested in understanding whether there is data and information that could better inform our understanding of the costs of treating these conditions. In addition, we are interested in understanding whether commenters believe it may be more appropriate to maintain the existing Drug/Alcohol Induced Mental Disorders comorbidity category adjustment factor of 1.03, given that many providers that treat these patients also report minimal or no ancillary charges on their claims and cost reports. We note that if we were to maintain the adjustment factor of 1.03 for these IPF stays, we expect it would have a negative impact on the refinement standardization factor, thereby slightly reducing the IPF PPS Federal per diem base rate and ECT per treatment amount.

We are also proposing to modify the Eating and Conduct Disorders comorbidity category and redesignate it as the Eating Disorders comorbidity category. That is, we are proposing to remove conduct disorders from the codes eligible for a comorbidity adjustment. When we separately analyzed the ICD–10–CM codes for eating disorders (specifically, *F5000 Anorexia nervosa, unspecified, F5001*

Anorexia nervosa, restricting type, F5002 Anorexia nervosa, binge eating/purging type, and F509 Eating disorder, unspecified) and conduct disorders (F631 Pyromania, F6381 Intermittent explosive disorder, and F911 Conduct disorder, childhood-onset type), our regression results identified a positive, statistically significant adjustment factor associated with eating disorders. In contrast, conduct disorders had a negative and non-significant factor. These results suggest that eating disorders are associated with an increased level of resource use compared to conduct disorders, and that only eating disorders have an increase resource use at a level that is statistically significant. Based on these findings, we are proposing to remove conduct disorders from the proposed newly designated Eating Disorders comorbidity category.

In addition, we are proposing to modify the Chronic Obstructive Pulmonary Disease comorbidity category to include ICD–10–CM codes associated with sleep apnea (specifically, G*4733 Obstructive sleep apnea (adult) (pediatric), 5A09357 Assistance with Respiratory Ventilation, <24 Hrs, CPAP, Z9981 Dependence on supplemental oxygen,* and *Z9989 Dependence on other enabling machines and devices*). In response to the FY 2023 and FY 2024 IPF PPS proposed rules, commenters requested that CMS analyze the additional cost associated with patients with sleep apnea. Patients with sleep apnea often need to use a continuous positive airway pressure (CPAP) machine with a cord to manage their condition. Based on the clinical expertise of CMS Medical Officers, we determined that patients with sleep apnea in the IPF setting would have increased ligature risk (that is, anything that could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation), similar to the risk associated with patients in the IPF setting that have chronic obstructive pulmonary disease. We expect the additional staffing resources involved in treating IPF patients with sleep apnea would be similar to the resources involved in treating IPF patients with chronic obstructive pulmonary disease, as patients with chronic obstructive pulmonary disease may also require the presence of an additional device with a cord in the patient's room, such as a bilevel positive airway pressure (BiPAP) machine. We evaluated adding codes associated with sleep apnea to our regression model, on the basis of our expectation that we would observe higher costs associated with these codes that would be comparable to the costs associated with chronic obstructive pulmonary disease. The results of our 2019 through 2021 regression model suggest that sleep apnea is in fact associated with an increased level of resource use. Therefore, we are proposing to redesignate the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category.

Further, we analyzed costs associated with the ICD–10–CM codes in Table 7 that indicate high-risk behavior. In response to the FY 2023 and FY 2024 IPF PPS proposed rules, commenters requested that CMS analyze the additional cost associated with patients exhibiting violent behavior during their stay in an IPF. We considered these comments in coordination with CMS Medical Officers, and determined that patients exhibiting violent behavior would require more intensive management during an IPF stay. We determined that certain ICD–10–CM codes could describe the types of high-risk behaviors that require intensive management during an IPF stay. These could include patients exhibiting violent behavior as well as other high-risk, non-violent behaviors. We examined ICD–10–CM codes in the R45 code family (Symptoms and Signs Related to Emotional State) that could indicate high-risk behavior during an IPF stay, which would lead to increased resource use. The regression analysis found that several codes, *R451 Restlessness and agitation, R454 Irritability and anger,* and *R4584 Anhedonia* codes are associated with a statistically significant adjustment factor. In other words, patients presenting with restlessness and agitation, irritability and anger, or anhedonia are more costly than patients who do not present these conditions. Therefore, we are proposing to add a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior.

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Table 7:ICD-10-CM Codes for High-Risk Behavior Analyzed

ICD–10–CM Code	Description	Proposed Action for FY 2025 Intensive Management for High-Risk Behavior Comorbidity Category
R45	Symptoms and signs involving emotional state	
R450	Nervousness	
R451	Restlessness and agitation	Add
R452	Unhappiness	
R453	Demoralization and apathy	
R454	Irritability and anger	Add
R455	Hostility	
R456	Violent behavior	
R457	State of emotional shock and stress, unspecified	
R458	Other symptoms and signs involving emotional state	
R4581	Low self-esteem	
R4582	Worries	
R4583	Excessive crying of child, adolescent or adult	
R4584	Anhedonia	Add
R4585	Homicidal and suicidal ideations	
R45850	Homicidal ideations	
R45851	Suicidal ideations	
R4586	Emotional lability	
R4587	Impulsiveness	
R4589	Other symptoms and signs involving emotional state	

Lastly, we are proposing to maintain the adjustment factors for the Developmental Disabilities and Uncontrolled Diabetes comorbidity categories. Based on the regression analysis, the Developmental Disabilities comorbidity category adjustment factor was not statistically significant; however, the current adjustment factor is within the confidence interval. As discussed in section III.C.3.a of this proposed rule, a non-statistically significant adjustment factor within the confidence interval indicates that the current adjustment factor would be a reasonable approximation of the increased costs. The Uncontrolled Diabetes comorbidity category adjustment factor did not change from the current adjustment factor based on the 2019 through 2021 regression.

We are also proposing to decrease the adjustment factors for the following comorbidity categories: Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, Infectious Diseases, and Severe Musculoskeletal & Connective Tissue Diseases.

The regression analysis found the Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, Infectious Diseases, and Severe Musculoskeletal & Connective Tissue Diseases comorbidity categories resulted in a statistically significant adjustment factor. While payment would still be increased when the claim includes one of these comorbidity categories, the proposed adjustment factors for FY 2025 would be less than the current adjustment factors for these categories. The proposed FY 2025 comorbidity adjustment factors are displayed in Table 8, and can be found in Addendum A, available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.*

Table 8 : Comparison of FY 2024 and Proposed FY 2025 IPF PPS Comorbidity Category Adjustments

Description	Current Adjustment Factor	Proposed FY 2025 Adjustment Factor
Renal Failure, Acute	1.11	1.06
Artificial Openings – Digestive & Urinary	1.08	1.07
Cardiac Conditions	1.11	1.05
Renal Failure, Chronic	1.11	1.08
Coagulation Factor Deficit	1.13	N/A
Chronic Obstructive Pulmonary Disease	1.12	N/A
Chronic Obstructive Pulmonary Disease and Sleep Apnea	N/A	1.07
Developmental Disabilities	1.04	1.04
Uncontrolled Diabetes	1.05	1.05
Drug/Alcohol Induced Mental Disorders	1.03	N/A
Eating and Conduct Disorders	1.12	N/A
Eating Disorders	N/A	1.09
Gangrene	1.10	1.12
Infectious Diseases	1.07	N/A
Severe Protein Malnutrition	1.13	1.17
Oncology Treatment	1.07	1.46
Poisoning	1.11	1.16
Severe Musculoskeletal & Connective Tissue Diseases	1.09	1.05
Tracheostomy	1.06	1.09
Intensive Management for High-Risk Behavior	N/A	1.07

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As discussed in section III.F of this proposed rule, we are proposing to implement revisions to the comorbidity category adjustments budget-neutrally. A detailed discussion of the distributional impacts of these proposed changes is found in section VIII.C of this proposed rule.

We solicit comments on these proposed revisions to the comorbidity category adjustment factors. Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the final FY 2025 comorbidity category adjustment factors.

(2) Proposed Coding Updates for FY 2025

For FY 2025, we are proposing to add 2 ICD–10–CM/PCS codes to the Oncology Treatment comorbidity category. The proposed FY 2025 comorbidity codes are shown in Addenda B, available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.*

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2025 ICD–10–CM codes to remove codes that were site ''unspecified'' in terms of laterality from the FY 2023 ICD–10–CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or a condition exists should be used when coding patients' diagnoses whenever these codes are available. We finalized in the FY 2015 IPF PPS rule, that we would remove site ''unspecified'' codes from the IPF PPS ICD–10–CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. There were no proposed changes to the FY 2025 ICD–10–CM/PCS codes, therefore, we are not proposing to remove any of the new codes.

c. Proposed Patient Age Adjustments

As explained in the RY 2005 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are costlier than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant. While our regression analysis of CY 2019 through CY 2021 data supports maintaining a payment adjustment factor based on age as was established in the RY 2005 IPF PPS final rule, the results suggest that revisions to the adjustment factor for age are warranted.

For FY 2025, we are proposing to revise the patient age adjustments as shown in Addendum A of this proposed rule, which is available on the CMS website at (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets*). We are proposing to adopt the patient age adjustments derived from the regression

model using a blended set of 2019 through 2021 data, as discussed in section III.C.3 of this proposed rule. Table 9 summarizes the current and proposed patient age adjustment factors for FY 2025. As discussed in section III.F of this proposed rule, we are proposing to implement this revision to the patient age adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule.

We solicit comment on these proposed revisions to the patient age adjustment factors. Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the final FY 2025 patient age adjustment factors.

Table 9 : Proposed Updates to Patient Age Adjustments

Age (in years)	Current Adjustment Factors	# of Stays CY 2019-CY 2021	% of Stays CY 2019-CY 2021	Proposed Adjustment Factors
Under 45	1.00	234,270	29.04%	1.00
45 and under 50	1.01			
50 and under 55	1.02			
45 and under 55	*N/A*	121,498	15.06%	1.02
55 and under 60	1.04	74,512	9.24%	1.05
60 and under 65	1.07	68,136	8.45%	1.07
65 and under 70	1.10	94,473	11.71%	**1.09**
70 and under 75	1.13			
75 and under 80	1.15			
70 and under 80	*N/A*	126,280	15.66%	**1.12**
80 and over	1.17	87,442	10.84%	**1.13**

d. Proposed Variable Per Diem Adjustments

We explained in the RY 2005 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. As discussed in the RY 2005 IPF PPS final rule, where a complete discussion of the variable per diem adjustments can be found, we used a regression analysis to estimate the average differences in per diem cost among stays of different lengths (69 FR 66947 through 66950). As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section III.D.4 of this proposed rule.

For FY 2025, we are proposing to revise the variable per diem adjustment factors as indicated in the table below, and shown in Addendum A to this rule, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets.* We are proposing to increase the adjustment factors for days 1 through 9. As shown in Table 10, the results of the latest regression analysis indicate that there is not a statistically significant decrease in cost per day after day 10; therefore, we are proposing that days 10 and above would receive a 1.00 adjustment. Table 10 summarizes the current and proposed variable per diem adjustment factors for FY 2025. As discussed in section III.F of this proposed rule, we are proposing to implement this revision to the variable per diem adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule.

We solicit comments on these proposed revisions to the variable per diem adjustment factors. Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the

final FY 2025 variable per diem adjustment factors.

Table 10 : Proposed Updates to Variable Per Diem Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Proposed Adjustment Factors
Length of stay - 1 day without ED	1.19	17,141	2.09%	1.27
Length of stay - 1 day *with a qualified ED*	1.31	N/A	N/A	1.53
Length of stay - 2 days	1.12	28,370	3.52%	1.20
Length of stay - 3 days	1.08	42,298	5.24%	1.15
Length of stay - 4 days	1.05	48,187	5.97%	1.12
Length of stay - 5 days	1.04	54,187	6.72%	1.08
Length of stay - 6 days	1.02	59,215	7.34%	1.06
Length of stay - 7 days	1.01	63,095	7.82%	1.03
Length of stay - 8 days	1.01	51,491	6.38%	1.02
Length of stay - 9 days	1.00	42,855	5.31%	1.01
Length of stay – greater than or equal to 10 days	1.00 – 0.92	400,022	49.59%	1.00

D. Proposed Updates to the IPF PPS Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED. We are proposing to use the existing regression-derived facility-level adjustment factors established in the RY 2005 IPF final rule for FY 2025.

As previously discussed, in section I.A of this proposed rule, we are proposing to revise the methodology for determining payments under the IPF PPS as required by the CAA, 2023. We are not proposing changes to the facility-level adjustment factors for rural location and teaching status for FY 2025; however, section IV.A of this proposed rule includes a request for information regarding potential future updates to these facility-level adjustments. We are particularly interested in comments on the results of our updated regression analysis as they apply to facility-level adjustors.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), and the RY 2009 IPF PPS (73 FR 25719) and RY 2010 IPF PPS notices (74 FR 20373), to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area, as defined in § 412.64(b)(1)(ii)(A) and (C).

Due to the variation in costs and because of the differences in geographic wage levels, in the RY 2005 IPF PPS final rule, we required that payment rates under the IPF PPS be adjusted by a geographic wage index. We proposed and finalized a policy to use the unadjusted, pre-floor, pre-reclassified IPPS hospital wage index to account for geographic differences in IPF labor costs. We implemented use of the pre-floor, pre-reclassified IPPS hospital wage data to compute the IPF wage index since there was not an IPF-specific wage index available. We believe that IPFs generally compete in the same labor market as IPPS hospitals therefore, the pre-floor, pre-reclassified IPPS hospital wage data should be reflective of labor costs of IPFs. We believe this pre-floor, pre-reclassified IPPS hospital wage index to be the best available data to use as proxy for an IPF-specific wage index. As discussed in the RY 2007 IPF PPS final rule (71FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without considering geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390). Our wage index policy at § 412.424(a)(2) provides that we use the best Medicare data available to estimate costs per day, including an appropriate wage index to adjust for wage differences.

When the IPF PPS was implemented in the RY 2005 IPF PPS final rule, with

an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows a RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore, the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

In FY 2020, we finalized the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we finalized the use of the pre-floor, pre-reclassified IPPS hospital wage index from the FY concurrent with the IPF FY as the basis for the IPF wage index. For example, the FY 2020 IPF wage index was based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

We explained in the FY 2020 proposed rule (84 FR 16973), that using the concurrent pre-floor, pre-reclassified IPPS hospital wage index will result in the most up-to-date wage data being the basis for the IPF wage index. We noted that it would also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. We indicated that the Medicare skilled nursing facility (SNF) PPS already used the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. We proposed and finalized similar policies to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index data in other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. Thus, the wage adjusted Medicare payments of various provider types are based upon wage index data from the same timeframe. For FY 2025, we are proposing to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

In the FY 2023 IPF PPS final rule (87 FR 46856 through 46859), we finalized a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and we stated that we would apply this cap in a budget neutral manner. In addition, we finalized a policy that a new IPF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new IPF would not have a wage index in the prior FY. We amended the IPF PPS regulations at § 412.424(d)(1)(i) to reflect this permanent cap on wage index decreases. We refer readers to the FY 2023 IPF PPS final rule for a more detailed discussion about this policy.

We are proposing to apply the IPF wage index adjustment to the labor-related share of the national IPF PPS base rate and ECT payment per treatment. The proposed labor-related share of the IPF PPS national base rate and ECT payment per treatment is 78.8 percent in FY 2025. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2025 and is 0.1 percentage point higher than the FY 2024 labor-related share (see section III.A.3 of this proposed rule).

b. Office of Management and Budget (OMB) Bulletins

(1) Background

The wage index used for the IPF PPS is calculated using the unadjusted, pre-reclassified and pre-floor IPPS wage index data and is assigned to the IPF based on the labor market area in which the IPF is geographically located. IPF labor market areas are delineated based on the Core-Based Statistical Area (CBSAs) established by the OMB.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. These bulletins contain information regarding CBSA changes, including changes to CBSA numbers and titles. OMB bulletins may be accessed online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*. In accordance with our established methodology, the IPF PPS has historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the IPPS hospital wage index used to determine the IPF wage index and, when necessary and appropriate, has proposed and finalized transition policies for these changes.

In the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the RY 2009 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applied to the IPPS hospital wage index used to determine the current IPF wage index and stated that we expected to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721).

Subsequently, CMS adopted the changes that were published in past OMB bulletins in the FY 2016 IPF PPS final rule (80 FR 46682 through 46689), the FY 2018 IPF PPS rate update (82 FR 36778 through 36779), the FY 2020 IPF PPS final rule (84 FR 38453 through 38454), and the FY 2021 IPF PPS final rule (85 FR 47051 through 47059). We direct readers to each of these rules for more information about the changes that were adopted and any associated transition policies.

As discussed in the FY 2023 IPF PPS final rule, we did not adopt OMB Bulletin 20–01, which was issued March 6, 2020, because we determined this bulletin had no material impact on

the IPF PPS wage index. This bulletin creates only one Micropolitan statistical area, and Micropolitan areas are considered rural for the IPF PPS wage index. That is, the constituent county of the new Micropolitan area was considered rural effective as of FY 2021 and would continue to be considered rural if we adopted OMB Bulletin 20–01.

Finally, on July 21, 2023, OMB issued Bulletin 23–01, which revises the CBSA delineations based on the latest available data from the 2020 census. This bulletin contains information regarding updates of statistical area changes to CBSA titles, numbers, and county or county equivalents.

(2) Proposed Implementation of New Labor Market Area Delineations

We believe it is important for the IPF PPS to use, as soon as is reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We believe that using the most current delineations would increase the integrity of the IPF PPS wage index system by creating a more accurate representation of geographic variations in wage levels. We have carefully analyzed the impacts of adopting the new OMB delineations and find no compelling reason to delay implementation. Therefore, we are proposing to implement the new OMB delineations as described in the July 21, 2023, OMB Bulletin No. 23–01, effective beginning with the FY 2025 IPF PPS wage index. We are proposing to adopt the updates to the OMB delineations announced in OMB Bulletin No. 23–01 effective for FY 2025 under the IPF PPS.

As previously discussed, we finalized a 5-percent permanent cap on any decrease to a provider's wage index from its wage index in the prior year. For more information on the permanent 5-percent cap policy, we refer readers to the FY 2023 IPF PPS final rule (87 FR 46856 through 46859). In addition, we are proposing to phase out the rural adjustment for IPFs that are transitioning from rural to urban based on these CBSA revisions, as discussed in section III.D.1.c. of this proposed rule.

(a) Micropolitan Statistical Areas

OMB defines a ''Micropolitan Statistical Area'' as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's IPF PPS rural wage index. We refer readers to the FY 2007 IPF PPS final rule (71 FR 27064 through 27065) for a complete discussion regarding treating Micropolitan Areas as rural. We are not proposing any changes to this policy for FY 2025.

(b) Change to County-Equivalents in the State of Connecticut

The June 6, 2022 Census Bureau Notice (87 FR 34235 through 34240), OMB Bulletin No. 23–01 replaced the 8 counties in Connecticut with 9 new ''Planning Regions.'' Planning regions now serve as county-equivalents within the CBSA system. We have evaluated the changes and are proposing to adopt the planning regions as county equivalents for wage index purposes. We believe it is necessary to adopt this migration from counties to planning region county-equivalents to maintain consistency with OMB updates. We are providing the following crosswalk for each county in Connecticut with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

Table 11: Change to County-Equivalents in the State of Connecticut

FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Region Area (County Equivalent)	Proposed CBSA
09003	HARTFORD	25540	09110	CAPITOL	25540
09015	WINDHAM	49340	09150	NORTHEASTERN CONNECTICUT	7
09005	LITCHFIELD	7	09160	NORTHWEST HILLS	7
09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
09001	FAIRFIELD	14860	09120	GREATER BRIDGEPORT	14860
09011	NEW LONDON	35980	09180	SOUTHEASTERN CONNECTICUT	35980
09013	TOLLAND	25540	09110	CAPITOL	25540
09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
09007	MIDDLESEX	25540	09130	LOWER CONNECTICUT RIVER VALLEY	25540

(c) Urban Counties That Would Become Rural Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the new OMB labor market area delineations (based upon OMB Bulletin No. 23–01) beginning in FY 2025. Our analysis shows that a total of 53 counties (and county equivalents) and 15 providers are located in areas that were previously considered part of an urban CBSA but would be considered rural beginning in FY 2025 under these revised OMB delineations. Table 12 lists the 53 urban counties that would be rural if we finalize our proposal to implement the revised OMB delineations.

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Table 12: Counties Previously Considered Part of an Urban CBSA that Would Become Rural Areas Under Revised OMB Delineations

County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
01129	WASHINGTON	AL	33660	Mobile, AL
05025	CLEVELAND	AR	38220	Pine Bluff, AR
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
05069	JEFFERSON	AR	38220	Pine Bluff, AR
05079	LINCOLN	AR	38220	Pine Bluff, AR
10005	SUSSEX	DE	41540	Salisbury, MD-DE
13171	LAMAR	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17077	JACKSON	IL	16060	Carbondale-Marion, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
17183	VERMILION	IL	19180	Danville, IL
17199	WILLIAMSON	IL	16060	Carbondale-Marion, IL
18121	PARKE	IN	45460	Terre Haute, IN
18133	PUTNAM	IN	26900	Indianapolis-Carmel-Anderson, IN
18161	UNION	IN	17140	Cincinnati, OH-KY-IN
21091	HANCOCK	KY	36980	Owensboro, KY
21101	HENDERSON	KY	21780	Evansville, IN-KY
22045	IBERIA	LA	29180	Lafayette, LA
24001	ALLEGANY	MD	19060	Cumberland, MD-WV
24047	WORCESTER	MD	41540	Salisbury, MD-DE
25011	FRANKLIN	MA	44140	Springfield, MA
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
31051	DIXON	NE	43580	Sioux City, IA-NE-SD
36123	YATES	NY	40380	Rochester, NY
37049	CRAVEN	NC	35100	New Bern, NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
37087	HAYWOOD	NC	11700	Asheville, NC
37103	JONES	NC	35100	New Bern, NC
37137	PAMLICO	NC	35100	New Bern, NC
42037	COLUMBIA	PA	14100	Bloomsburg-Berwick, PA
42085	MERCER	PA	49660	Youngstown-Warren-Boardman, OH-PA
42089	MONROE	PA	20700	East Stroudsburg, PA
42093	MONTOUR	PA	14100	Bloomsburg-Berwick, PA

County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
42103	PIKE	PA	35084	Newark, NJ-PA
45027	CLARENDON	SC	44940	Sumter, SC
48431	STERLING	TX	41660	San Angelo, TX
49003	BOX ELDER	UT	36260	Ogden-Clearfield, UT
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54043	LINCOLN	WV	16620	Charleston, WV
54057	MINERAL	WV	19060	Cumberland, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72055	GUANICA	PR	49500	Yauco, PR
72081	LARES	PR	10380	Aguadilla-Isabela, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR
72141	UTUADO	PR	10380	Aguadilla-Isabela, PR

We are proposing that the wage data for all providers located in the counties listed above would now be considered rural, beginning in FY 2025, when calculating their respective state's rural wage index. This rural wage index value would also be used under the IPF PPS. We recognize that rural areas typically have lower area wage index values than urban areas, and providers located in these counties may experience a negative impact in their IPF payment due to the proposed adoption of the revised OMB delineations. However, as discussed in section III.D.1.c of this proposed rule, providers located in these counties would receive a rural adjustment beginning in FY 2025, which would mitigate the impact of decreases to the wage index for these providers. In addition, the permanent 5-percent cap on wage index decreases under the IPF PPS would further mitigate large wage index decreases for providers in these areas.

(d) Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the new OMB labor market area delineations (based upon OMB Bulletin No. 23–01) beginning in FY 2025. Analysis of these OMB labor market area delineations shows that a total of 54 counties (and county equivalents) and 10 providers are located in areas that were previously considered rural but would now be considered urban under the revised OMB delineations. Table 13 lists the 54 rural counties that would be urban if we finalize our proposal to implement the revised OMB delineations.

Table 13: Counties that Would Gain Urban Status Under Revised OMB Delineations

County Code	County/County Equivalent	State	New CBSA	Labor Market Area
01087	Macon	AL	12220	Auburn-Opelika, AL
01127	Walker	AL	13820	Birmingham, AL
12133	Washington	FL	37460	Panama City-Panama City Beach, FL
13187	Lumpkin	GA	12054	Atlanta-Sandy Springs-Roswell, GA
15005	Kalawao	HI	27980	Kahului-Wailuku, HI
17053	Ford	IL	16580	Champaign-Urbana, IL
17127	Massac	IL	37140	Paducah, KY-IL
18159	Tipton	IN	26900	Indianapolis-Carmel-Greenwood, IN
18179	Wells	IN	23060	Fort Wayne, IN
20021	Cherokee	KS	27900	Joplin, MO-KS
21007	Ballard	KY	37140	Paducah, KY-IL
21039	Carlisle	KY	37140	Paducah, KY-IL
21127	Lawrence	KY	26580	Huntington-Ashland, WV-KY-OH
21139	Livingston	KY	37140	Paducah, KY-IL
21145	Mc Craken	KY	37140	Paducah, KY-IL
21179	Nelson	KY	31140	Louisville/Jefferson County, KY-IN
22053	Jefferson Davis	LA	29340	Lake Charles, LA
22083	Richland	LA	33740	Monroe, LA
26015	Barry	MI	24340	Grand Rapids-Wyoming-Kentwood, MI
26019	Benzie	MI	45900	Traverse City, MI
26055	Grand Traverse	MI	45900	Traverse City, MI
26079	Kalkaska	MI	45900	Traverse City, MI
26089	Leelanau	MI	45900	Traverse City, MI
27133	Rock	MN	43620	Sioux Falls, SD-MN
28009	Benton	MS	32820	Memphis, TN-MS-AR
28123	Scott	MS	27140	Jackson, MS
30007	Broadwater	MT	25740	Helena, MT
30031	Gallatin	MT	14580	Bozeman, MT

County Code	County/County Equivalent	State	New CBSA	Labor Market Area
30043	Jefferson	MT	25740	Helena, MT
30049	Lewis and Clark	MT	25740	Helena, MT
30061	Mineral	MT	33540	Missoula, MT
32019	Lyon	NV	39900	Reno, NV
37125	Moore	NC	38240	Pinehurst-Southern Pines, NC
38049	McHenry	ND	33500	Minot, ND
38075	Renville	ND	33500	Minot, ND
38101	Ward	ND	33500	Minot, ND
39007	Ashtabula	OH	17410	Cleveland, OH
39043	Erie	OH	41780	Sandusky, OH
41013	Crook	OR	13460	Bend, OR
41031	Jefferson	OR	13460	Bend, OR
42073	Lawrence	PA	38300	Pittsburgh, PA
45087	Union	SC	43900	Spartanburg, SC
46033	Custer	SD	39660	Rapid City, SD
47081	Hickman	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	Aransas	TX	18580	Corpus Christi, TX
48035	Bosque	TX	47380	Waco, TX
48079	Cochran	TX	31180	Lubbock, TX
48169	Garza	TX	31180	Lubbock, TX
48219	Hockley	TX	31180	Lubbock, TX
48323	Maverick	TX	20580	Eagle Pass, TX
48407	San Jacinto	TX	26420	Houston-Pasadena-The Woodlands, TX
51063	Floyd	VA	13980	Blacksburg-Christiansburg-Radford, VA
51181	Surry	VA	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
55123	Vernon	WI	29100	La Crosse-Onalaska, WI-MN

We are proposing that when calculating the area wage index, beginning with FY 2025, the wage data for providers located in these counties would be included in their new respective urban CBSAs. Typically, providers located in an urban area receive a wage index value higher than or equal to providers located in their state's rural area. We also note that providers located in these areas would no longer be considered rural beginning in FY 2025. We refer readers to section III.D.1.c of this proposed rule for a discussion of the proposed policy to phase out the payment of the rural adjustment for providers in these areas.

(e) Urban Counties That Would Move to a Different Urban CBSA Under the New OMB Delineations

In certain cases, adopting the new OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 10540 (Albany-Lebanon, OR) would experience a change to its name, and become CBSA 10540 (Albany, OR), while its one constituent county would remain the same. Table 14 shows the current CBSA code and our proposed CBSA code where we are proposing to change either the name or CBSA number only. We are not discussing further in this section these proposed changes because they are inconsequential changes with respect to the IPF PPS wage index.

Table 14: Current CBSAs and their New CBSA Codes and Titles

Current CBSA Code	Current CBSA Title	Proposed CBSA Code	Proposed CBSA Title
10540	Albany-Lebanon, OR	10540	Albany, OR
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock-San Marcos, TX
12540	Bakersfield, CA	12540	Bakersfield-Delano, CA
15260	Brunswick, GA	15260	Brunswick-St. Simons, GA
16540	Chambersburg-Waynesboro, PA	16540	Chambersburg, PA
16984	Chicago-Naperville-Evanston, IL	16984	Chicago-Naperville-Schaumburg, IL
19430	Dayton-Kettering, OH	19430	Dayton-Kettering-Beavercreek, OH
19740	Denver-Aurora-Lakewood, CO	19740	Denver-Aurora-Centennial, CO
21820	Fairbanks, AK	21820	Fairbanks-College, AK
22660	Fort Collins, CO	22660	Fort Collins-Loveland, CO
23224	Frederick-Gaithersburg-Rockville, MD	23224	Frederick-Gaithersburg-Bethesda, MD
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Greer, SC
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Port Royal, SC
26380	Houma-Thibodaux, LA	26380	Houma-Bayou Cane-Thibodaux, LA
29820	Las Vegas-Henderson-Paradise, NV	29820	Las Vegas-Henderson-North Las Vegas, NV
31020	Longview, WA	31020	Longview-Kelso, WA
34740	Muskegon, MI	34740	Muskegon-Norton Shores, MI
35840	North Port-Sarasota-Bradenton, FL	35840	North Port-Bradenton-Sarasota, FL
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Fremont-Berkeley, CA
36540	Omaha-Council Bluffs, NE-IA	36540	Omaha, NE-IA
39340	Provo-Orem, UT	39340	Provo-Orem-Lehi, UT
39540	Racine, WI	39540	Racine-Mount Pleasant, WI
41620	Salt Lake City, UT	41620	Salt Lake City-Murray, UT
42680	Sebastian-Vero Beach, FL	42680	Sebastian-Vero Beach-West Vero Corridor, FL
42700	Sebring-Avon Park, FL	42700	Sebring, FL
44420	Staunton, VA	44420	Staunton-Stuarts Draft, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
47220	Vineland-Bridgeton, NJ	47220	Vineland, NJ
48300	Wenatchee, WA	48300	Wenatchee-East Wenatchee, WA
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL

In some cases, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. We consider this type of change, where CBSAs are split into multiple new CBSAs, or a CBSA loses one or more counties to another urban CBSA to be significant modifications.

Table 15 lists the urban counties that would move from one urban CBSA to another newly proposed or modified CBSA if we adopted the new OMB delineations.

Table 15: Urban Counties That Would Move to a Newly Proposed or Modified CBSA Under Revised OMB Delineations

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
06039	MADERA	CA	31460	Madera, CA	23420	Fresno, CA
11001	THE DISTRICT	DC	47894	Washington -Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
12053	HERNANDO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12057	HILLSBOROUGH	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12101	PASCO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12103	PINELLAS	FL	45300	Tampa-St. Petersburg-Clearwater, FL	41304	St. Petersburg-Clearwater-Largo, FL
12119	SUMTER	FL	45540	The Villages, FL	48680	Wildwood-The Villages, FL
13013	BARROW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13015	BARTOW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13035	BUTTS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
13045	CARROLL	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13057	CHEROKEE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13063	CLAYTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13067	COBB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13077	COWETA	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13085	DAWSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13089	DE KALB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13097	DOUGLAS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13113	FAYETTE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13117	FORSYTH	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13121	FULTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
13135	GWINNETT	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13143	HARALSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13149	HEARD	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13151	HENRY	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13159	JASPER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13199	MERIWETHER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13211	MORGAN	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13217	NEWTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13223	PAULDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13227	PICKENS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13231	PIKE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
13247	ROCKDALE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13255	SPALDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13297	WALTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
18073	JASPER	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18089	LAKE	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18111	NEWTON	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18127	PORTER	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
21163	MEADE	KY	21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN
22103	ST. TAMMANY	LA	35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville-Covington, LA
25015	HAMPSHIRE	MA	44140	Springfield, MA	11200	Amherst Town-Northampton, MA
24009	CALVERT	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD
24017	CHARLES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24033	PRINCE GEORGES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24037	ST. MARYS	MD	15680	California-Lexington Park, MD	30500	Lexington Park, MD
37019	BRUNSWICK	NC	34820	Myrtle Beach-	48900	Wilmington, NC

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
				Conway-North Myrtle Beach, SC-NC		
34009	CAPE MAY	NJ	36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
34023	MIDDLESEX	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34025	MONMOUTH	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34029	OCEAN	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34035	SOMERSET	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
36027	DUTCHESS	NY	39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
36071	ORANGE	NY	39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
39035	CUYAHOGA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39055	GEAUGA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39085	LAKE	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39093	LORAIN	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39103	MEDINA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39123	OTTAWA	OH	45780	Toledo, OH	41780	Sandusky, OH
72023	CABO ROJO	PR	41900	San Germán, PR	32420	Mayagücz, PR
72059	GUAYANILLA	PR	49500	Yauco, PR	38660	Ponce, PR
72079	LAJAS	PR	41900	San Germán, PR	32420	Mayagüez, PR
72111	PENUELAS	PR	49500	Yauco, PR	38660	Ponce, PR
72121	SABANA GRANDE	PR	41900	San Germán, PR	32420	Mayagüez, PR
72125	SAN GERMAN	PR	41900	San Germán, PR	32420	Mayagüez, PR

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
72153	YAUCO	PR	49500	Yauco, PR	38660	Ponce, PR
47057	GRAINGER	TN	34100	Morristown, TN	28940	Knoxville, TN
51510	ALEXANDRIA CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51013	ARLINGTON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51043	CLARKE	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51047	CULPEPER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51059	FAIRFAX	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51600	FAIRFAX CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51610	FALLS CHURCH CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51061	FAUQUIER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51630	FREDERICKSBURG CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51107	LOUDOUN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51683	MANASSAS CITY	VA	47894	Washington-Arlington-Alexandria,	11694	Arlington-Alexandria-Reston, VA-WV

County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
				DC-VA-MD-WV		
51685	MANASSAS PARK CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51153	PRINCE WILLIAM	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51157	RAPPAHANNOCK	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51177	SPOTSYLVANIA	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51179	STAFFORD	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51187	WARREN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
53061	SNOHOMISH	WA	42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA
55059	KENOSHA	WI	29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI
54037	JEFFERSON	WV	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV

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We have identified 68 IPF providers located in the affected counties listed in Table 15. If providers located in these counties move from one CBSA to another under the revised OMB delineations, there may be impacts, either negative or positive, upon their specific wage index values.

c. Proposed Adjustment for Rural Location

In the RY 2005 IPF PPS final rule, (69 FR 66954), we provided a 17-percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17-percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 17-percent adjustment has been part of the IPF PPS each year since the inception of the IPF PPS. As discussed earlier in this rule, we are proposing a number of revisions to the patient-level adjustment factors as well as changes to the CBSA

delineations. In order to minimize the scope of changes that would impact providers in any single year, we are proposing to use the existing regression-derived adjustment factor, which was established in RY 2005, for FY 2025 for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). See 69 FR 66954 for a complete discussion of the adjustment for rural locations. However, as discussed in the section IV.A of this FY 2025 IPF PPS proposed rule, we have completed analysis of more recent cost and claims information and are soliciting comments on those results.

As proposed earlier in this proposed rule, the adoption of OMB Bulletin No. 23–01 in accordance with our established methodology would determine whether a facility is classified as urban or rural for purposes of the rural payment adjustment in the IPF PPS. Overall, we believe implementing updated OMB delineations would result in the rural payment adjustment being applied where it is appropriate to adjust for higher costs incurred by IPFs in rural locations. However, we recognize that implementing these changes would have distributional effects among IPF providers, and that some providers would experience a loss of the rural payment adjustment because of our proposals. Therefore, we believe it would be appropriate to consider, as we have in the past, whether a transition period should be used to implement these proposed changes.

Prior changes to the CBSA delineations have included a phase-out policy for the rural adjustment for IPFs transitioning from rural to urban status. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census. We adopted these new OMB CBSA delineations in the FY 2016 IPF final rule (*80 FR 46682 through 46689*), and identified 105 counties and 37 IPFs that would move from rural to urban status due to the new CBSA delineations. To reduce the impact of the loss of the 17-percent rural adjustment, we adopted a budget-neutral 3-year phase-out of the rural adjustment for existing FY 2015 rural IPFs that became urban in FY 2016 and that experienced a loss in payments due to changes from the new CBSA delineations. These IPFs received two-thirds of the rural adjustment for FY 2016 and one-third of the rural adjustment in FY 2017. For FY 2018, these IPFs did not receive a rural adjustment.

For subsequent adoptions of OMB Bulletin No. 15–01 for FY 2018 (82 FR 36779 through 36780), OMB Bulletin 17–01 for FY 2020 (84 FR 38453 through 38454), and OMB Bulletin 18–04 for FY 2021 (85 FR 47053 through 47059), we identified that fewer providers were affected by these changes than by the changes relating to the adoption of OMB Bulletin 13–01. We did not phase out the rural adjustment when adopting these delineation changes.

For facilities located in a county that transitioned from rural to urban in Bulletin 23–01, we considered whether it would be appropriate to phase out the rural adjustment for affected providers consistent with our past practice of using transition policies to help mitigate negative impacts on hospitals of OMB Bulletin proposals that have a material effect on a number of IPFs. Adoption of the updated CBSAs in Bulletin 23–01 will change the status of 10 IPF providers currently designated as ''rural'' to ''urban'' for FY 2025 and subsequent fiscal years. As such, these 10 newly urban providers will no longer receive the 17-percent rural adjustment. Consistent with the transition policy adopted for IPFs in FY 2016 (80 FR 46682 through 4668980 FR 46682 through 46689), we are proposing a 3-year budget neutral phase-out of the rural adjustment for IPFs located in the 54 rural counties that will become urban under the new OMB delineations, given the potentially significant payment impacts for these IPFs. We believe that a phase-out of the rural adjustment transition period for these 10 IPFs specifically is appropriate because we expect these IPFs will experience a steeper and more abrupt reduction in their payments compared to other IPFs. Therefore, we are proposing to phase out the rural adjustment for these providers to reduce the impact of the loss of the FY 2024 rural adjustment of 17-percent over FYs 2025, 2026, and 2027. This policy would allow IPFs that are classified as rural in FY 2024 and would be classified as urban in FY 2025 to receive two-thirds of the rural adjustment for FY 2025. For FY 2026, these IPFs would receive one-third of the rural adjustment. For FY 2027, these IPFs would not receive a rural adjustment. We believe a 3-year budget-neutral phase-out of the rural adjustment for IPFs that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural adjustment for existing FY 2024 rural IPFs. The purpose of the gradual phase-out of the rural adjustment for these providers is to mitigate potential payment reductions and promote stability and predictability in payments for existing rural IPFs that may need time to adjust to the loss of their FY 2024 rural payment adjustment or that experience a reduction in payments solely because of this re-designation. This policy would be specifically for rural IPFs that become urban in FY 2025. We are not proposing a transition policy for urban IPFs that become rural in FY 2025 because these IPFs will receive the full rural adjustment of 17-percent beginning October 1, 2024. We solicit comments on this proposed policy.

d. Proposed Wage Index Budget Neutrality Adjustment

Changes to the wage index are made in a budget neutral manner so that updates do not increase expenditures. Therefore, for FY 2025, we are proposing to continue to apply a budget neutrality adjustment in accordance with our existing budget neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2025 are the same with or without the changes (that is, in a budget neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We are proposing to use the following steps to ensure that the rates reflect the FY 2025 update to the wage indexes (based on the FY 2021 hospital cost report data) and the labor-related share in a budget neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2024 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2024 IPF PPS final rule (88 FR 51054).

Step 2: Simulate estimated IPF PPS payments using the proposed FY 2025 IPF wage index values (available on the CMS website), and the proposed FY 2025 labor-related share (based on the latest available data as discussed previously).

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the proposed FY 2025 budget neutral wage adjustment factor of 0.9995.

Step 4: Apply the FY 2025 budget neutral wage adjustment factor from step 3 to the FY 2024 IPF PPS Federal per diem base rate after the application of the IPF market basket increase reduced by the productivity adjustment described in section III.A of this proposed rule to determine the FY 2025 IPF PPS Federal per diem base rate. As discussed in section III.F of this proposed rule, we are also proposing to apply a refinement standardization

factor to determine the FY 2025 IPF PPS Federal per diem base rate.

2. Proposed Teaching Adjustment

Background

In the RY 2005 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of fulltime equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census.

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the RY 2005 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's ''teaching variable,'' which is (1 + [the number of FTE residents training in the IPF's average daily census]). The teaching variable is then raised to the 0.5150 power to result in the teaching adjustment. This formula is subject to the limitations on the number of FTE residents, which are described in this section of this proposed rule.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a ''base year'' and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (69 FR 66955). A complete discussion of the temporary adjustment to the FTE cap to reflect residents due to hospital closure or residency program closure appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456).

In the regression analysis that informed the FY 2004 IPF PPS final rule, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the RY 2005 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721).

We are proposing to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate as we are not proposing refinements to the facility-level payment adjustments for rural location or teaching status for FY 2025. As noted earlier, given the scope of changes to the wage index and patient-level adjustment factors, we believe this will minimize the total impacts to providers in any given year.

3. Proposed Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the RY 2005 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. As a result of this analysis, we provided a COLA in the RY 2005 IPF PPS final rule. We refer readers to the FY 2024 IPF PPS final rule for a complete discussion of the currently applicable COLA factors (88 FR 51088 through 51089).

We adopted a new methodology to update the COLA factors for Alaska and Hawaii for the IPF PPS in the FY 2015 IPF PPS final rule (79 FR 45958 through 45960). For a complete discussion, we refer readers to the FY 2015 IPF PPS final rule.

We also specified that the COLA updates would be determined every 4 years, in alignment with the IPPS market basket labor-related share update (79 FR 45958 through 45960). Because the labor-related share of the IPPS market basket was updated for FY 2022, the COLA factors were updated in FY 2022 IPPS/LTCH rulemaking (86 FR 45547). As such, we also finalized an update to the IPF PPS COLA factors to reflect the updated COLA factors finalized in the FY 2022 IPPS/LTCH rulemaking effective for FY 2022 through FY 2025 (86 FR 42621 through 42622). This is reflected in Table 16 below. We are proposing to maintain the COLA factors in Table 16 for FY 2025 in alignment with the policy described in this paragraph.

Table 16: IPF PPS Cost-of-Living Adjustment Factors: IPFs Located in Alaska and Hawaii

Area	FY 2022 through FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

The proposed IPF PPS COLA factors for FY 2025 are also shown in Addendum A to this proposed rule, which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

4. Proposed Adjustment for IPFs With a Qualifying ED

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. As defined in § 412.402, qualifying emergency department means an emergency department that is staffed and equipped to furnish a comprehensive array of emergency services and meets the requirements of 42 CFR 489.24(b) and § 413.65.

We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a psychiatric hospital with a qualifying ED, or an excluded psychiatric unit of an IPPS hospital or a critical access hospital (CAH), and the overhead cost of maintaining the ED. This payment applies to all IPF admissions (with one exception which we describe in this section), regardless of whether the patient was admitted through the ED. The ED adjustment is made on every qualifying claim except as described in this section of this proposed rule. As specified at § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an IPPS hospital or CAH, and admitted to the same IPPS hospital's or CAH's excluded psychiatric unit. We clarified in the RY 2005 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the IPPS hospital or through the reasonable cost payment made to the CAH.

a. Proposed Update for FY 2025

For FY 2025, we are proposing to update the adjustment factor from 1.31 to 1.53 for IPFs with qualifying EDs using the same methodology used to determine ED adjustments in prior years. Thus, we are proposing to use the following steps, as used in prior years, to calculate the updated ED adjustment factor. (A complete discussion of the steps involved in the calculation of the ED adjustment factors can be found in the RY 2005 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).)

Step 1: Estimate the proportion by which the ED costs of a stay would increase the cost of the first day of the stay. Using the IPFs with ED admissions in years 2019 through 2021, we divided the average ED cost per stay when admitted through the ED ($519.97) by the average cost per day ($1,338.93), which equals 0.39.

Step 2: Adjust the factor estimated in step 1 to account for the fact that we would pay the higher first day adjustment for all cases in the qualifying IPFs, not just the cases admitted through the ED. Since on average, 66 percent of the cases in IPFs with ED admissions are admitted through the ED, we multiplied 0.39 by 0.66, which equals 0.26.

Step 3: Add the adjusted factor calculated in the previous 2 steps to the variable per diem adjustment derived from the regression equation that we used to derive our other payment adjustment factors. As discussed in section III.C.4.d. of this proposed rule, the proposed first day payment factor for FY 2025 is 1.27. Adding 0.26, we obtained a first day variable per adjustment for IPFs with a qualifying ED equal to 1.53.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. We are proposing that those IPFs with a qualifying ED would receive an adjustment factor of 1.53 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying ED, we are proposing that it would receive an adjustment factor of 1.27 as the variable per diem adjustment for day 1 of each patient stay, as discussed in section III.C.4.d. of this proposed rule. As discussed in section III.F of this proposed rule, we are proposing to implement this revision to the ED adjustment budget—neutrally by applying a refinement standardization factor. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this proposed rule.

We solicit comment on this proposal. Lastly, we are proposing that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 ED adjustment factor.

b. Alternatives Considered

In response to the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429) comment solicitation on our technical report describing the analysis of IPF PPS adjustments, two

commenters requested that we conduct further analysis related to the exception for the ED adjustment. These commenters indicated that patients transferred to an IPF from an acute care unit or hospital often have higher costs per stay than patients with similar comorbidities admitted from the community. Commenters requested that CMS analyze data related to source of admission and consider a payment adjustment to account for the resources used by these patients. In response to these comments, we conducted a regression analysis to investigate whether the source of admission is a statistically significant variable in the cost of a patient's care in an IPF. We analyzed the following sources of admission: clinic referral, transfer from hospital (different facility), transfer from a SNF or Intermediate Care Facility (ICF), transfer from another health care facility, court/law enforcement, information not available, transfer from hospital inpatient in the same facility, transfer from ambulatory surgical center, and transfer from hospice. In this context, it is important to note that the source of admission indicator ''court/law enforcement'' is not the equivalent of an involuntary admission; we do not currently collect data on involuntary admissions.

The regression analysis found that the source of admission was not a statistically significant factor in the cost of care. The results for the two source of admission variables that indicate higher costs (transfer from hospital inpatient in the same facility and transfer from ambulatory surgical center) are accounted for by the known difference in cost structures between hospital psychiatric units and freestanding psychiatric hospitals. We considered the results of our analysis, as well as the potential that adjusting payment based on source of admission could inadvertently create incentives for IPFs to prioritize certain admissions over others. Based on these considerations, we are not proposing to add additional payment adjustments based on source of admission (other than the existing adjustment for a qualifying ED) to the IPF PPS in FY 2025.

E. Other Proposed Payment Adjustments and Policies

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the RY 2005 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require costlier care; therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. The adjusted threshold amount is equal to the outlier threshold amount adjusted for wage area, teaching status, rural area, and the COLA adjustment (if applicable), plus the amount of the Medicare IPF payment for the case. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments.

2. Proposed Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we are proposing to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy, which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the federal per diem base rate for all other cases that are not outlier cases. We are proposing to maintain the established 2 percent outlier policy for FY 2025.

Our longstanding methodology for updating the outlier fixed dollar loss threshold involves using the best available data, which is typically the most recent available data. We note that for FY 2022 and FY 2023 only, we made certain methodological changes to our modeling of outlier payments, and we discussed the specific circumstances that led to those changes for those years (86 FR 42623 through 42624; 87 FR 46862 through 46864). We direct readers to the FY 2022 and FY 2023 IPF PPS proposed and final rules for a more complete discussion.

We are proposing to update the IPF outlier threshold amount for FY 2025 using FY 2023 claims data and the same methodology that we have used to set the initial outlier threshold amount each year beginning with the RY 2007 IPF PPS final rule (71 FR 27072 and 27073). For this FY 2025 IPF PPS rulemaking, consistent with our longstanding practice, based on an analysis of the latest available data (the December 2023 update of FY 2023 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.1 percent in FY 2024. Therefore, we are proposing to update the outlier threshold amount to $35,590 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2025. This proposed rule update is an increase from the FY 2024 threshold of $33,470.

Lastly, we are proposing that if more recent data become available for the FY 2025 IPF PPS final rule, we would use such data as appropriate to determine the final outlier fixed dollar loss threshold amount for FY 2025.

3. Proposed Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. To establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach

used under the IPPS and other PPSs. In the FY 2004 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for IPPS hospitals, because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As indicated in the RY 2005 IPF PPS final rule (69 FR 66961), we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS; therefore, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the RY 2005 IPF PPS final rule:

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the most recent Provider Specific File (PSF) available.

For FY 2025, we are proposing to continue following this methodology. To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The proposed upper threshold CCR for IPFs in FY 2025 is 2.3362 for rural IPFs, and 1.8600 for urban IPFs, based on current CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national median CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national median CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for which the Medicare Administrative Contractor (MAC) obtains inaccurate or incomplete data with which to calculate a CCR.

We are proposing to update the FY 2025 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS PSF.

Specifically, for FY 2025, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2023 PSF, we provide an estimated national median CCR of 0.5720 for rural IPFs and a national median CCR of 0.4200 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the current CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the RY 2005 IPF PPS final rule (69 FR 66961 through 66964).

Lastly, we are proposing that if more recent data become available, we would use such data to calculate the rural and urban national median and ceiling CCRs for FY 2025.

4. Requirements for Reporting Ancillary Charges and All-Inclusive Status Eligibility Under the IPF PPS

a. Background

As discussed in section III.E.4.b of this proposed rule, to analyze variation in cost between patients with different characteristics, it is crucial for us to have complete cost information about each patient, including data on ancillary services provided. Currently, IPFs and psychiatric units are required to report ancillary charges on cost reports. As specified at 42 CFR 413.20, hospitals are required to file cost reports on an annual basis and maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare program.

However, our ongoing analysis has found a notable increase in the number of IPFs, specifically for-profit freestanding IPFs, that appear to be erroneously identifying on form CMS–2552–10, Worksheet S–2, Part I, line 115, as eligible for filing all-inclusive cost reports. These hospitals identifying as eligible for filing all-inclusive cost reports (indicating that they have one charge covering all services) are consistently reporting no ancillary charges or very minimal ancillary charges and are not using charge information to apportion costs in their cost report. Generally, based on the nature of IPF services and the conditions of participation applicable to IPFs, we expect to see ancillary services and correlating charges, such as labs and drugs, on most IPF claims.[3]

[3] IPFs are subject to all hospital conditions of participation, including 42 CFR 482.25, which specifies that ''The hospital must have pharmaceutical services that meet the needs of the patients,'' and 482.27, which specifies that ''The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients.''

In the FY 2016 IPF PPS final rule (80 FR 46693 through 46694), we discussed analysis conducted to better understand IPF industry practices for future IPF PPS refinements. This analysis revealed that in 2012 to 2013, over 20 percent of IPF stays show no reported ancillary charges, such as laboratory and drug charges, on claims. In the FY 2016 IPF PPS final rule (80 FR 46694), FY 2017 IPF PPS final rule (81 FR 50513), FY 2018 IPF PPS final rule (82 FR 36784), FY 2019 IPF PPS final rule (83 FR 38588), and FY 2020 IPF PPS final rule (84 FR 38458), we reminded providers that we only pay the IPF for services furnished to a Medicare beneficiary who is an inpatient of that IPF, except for certain professional services, and payments are considered to be payments in full for all inpatient hospital services provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

On November 17, 2017, we issued Transmittal 12, which made changes to the hospital cost report form CMS–2552–10 (OMB No. 0938–0050) and included cost report level 1 edit 10710S, effective for cost reporting periods ending on or after August 31, 2017. Edit 10710S required that cost reports from psychiatric hospitals include certain ancillary costs or the cost report will be rejected. On January 30, 2018, we issued Transmittal 13, which changed the implementation date for Transmittal 12 to be for cost reporting periods ending on or after September 30, 2017. CMS suspended edit 10710S effective April 27, 2018, pending evaluation of the application of the edit to all-inclusive rate providers. We issued Transmittal 15 on October 19, 2018, reinstating the requirement that cost reports from psychiatric hospitals, except all-inclusive rate providers, include certain ancillary costs. This requirement is still currently in place. For details, we refer readers to see these Transmittals, which are available on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/transmittals.*

Under IPF PPS regulations at 42 CFR 412.404(e), all inpatient psychiatric facilities paid under the IPF PPS must meet the recordkeeping and cost reporting requirements as specified at § 413.24. Historically, in accordance with § 413.24(a)(1), most hospitals that were approved to file all-inclusive cost reports were Indian Health Services (IHS) hospitals, government-owned psychiatric and acute care hospitals, and nominal charge hospitals. Although IPFs are no longer reimbursed on the basis of reasonable costs, we continue to expect that most IPFs, other than government-owned or tribally owned

IPFs, should report cost data that is based on an approved method of cost finding and on the accrual basis of accounting. The option to elect to file an all-inclusive rate cost report is limited to providers that do not have a charge structure and that, therefore, must use an alternative statistic to apportion costs associated with services rendered to Medicare beneficiaries.

Current cost reporting rules allow hospitals that do not have a charge structure to file an all-inclusive cost report using an alternative cost allocation method. We refer readers to the Provider Reimbursement Manual (PRM) 15–1; chapter 22, § 2208 for detailed information on the requirements to file an alternative method.

b. Challenges Related to Missing IPF Ancillary Cost Data

In general, most providers allocate their Medicare costs using costs and charges as described at § 413.53(a)(1)(i) and referred to as the Departmental Method, which is the ratio of beneficiary charges to total patient charges for the services of each ancillary department. For cost reporting periods beginning on or after October 1, 1982, the cost report uses the Departmental Method to apportion the cost of the department to the Medicare program. Added to this amount is the cost of routine services for Medicare beneficiaries, determined based on a separate average cost per diem for all patients for general routine patient care areas as required at § 413.53(a)(1)(i) and (e); and 15–1, chapter 22, § 2200.1.[4]

We use cost-to-charge ratios (CCRs) from Medicare cost reports as the method of establishing reasonable costs for hospital services and as the basis for ratesetting for several hospital prospective payment systems. In general, detailed ancillary cost and charge information is necessary for accurate Medicare ratesetting. When hospitals identify as all-inclusive, they are excluded from ratesetting because they do not have CCRs but use an alternative basis for apportioning costs. When hospitals erroneously identify as all-inclusive but have a charge structure, data that is necessary for accurate Medicare ratesetting is improperly excluded.

Since the issuance of Transmittal 15, we have continued to identify an increase in the number of IPFs, specifically for-profit freestanding IPFs, that appear to be erroneously identifying on form CMS- 2552–10, Worksheet S–2, Part I, line 115, as filing all-inclusive cost reports. In conjunction with the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we posted a report on the CMS website that summarizes the results of the latest analysis of more recent IPF cost and claim information for potential IPF PPS adjustments and requested comments about the results summarized in the report. The report showed that approximately 23 percent of IPF stays were trimmed from the data set used in that analysis because they were stays at facilities where fewer than 5 percent of their stays had ancillary charges. The report is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/ipf-reports-and-educational-resources.*

Section 4125 of the CAA, 2023 authorizes the Secretary to collect data and information, specifically including charges related to ancillary services, as appropriate to inform revisions to the IPF PPS.

In the FY 2024 IPF PPS proposed rule (88 FR 21270 through 21272), we included a request for information (RFI) related to the reporting of charges for ancillary services, such as labs and drugs, on IPF claims. We were interested in better understanding IPF industry practices pertaining to the billing and provision of ancillary services to inform statutorily mandated IPF PPS refinements. We stated that we were considering whether to require charges for ancillary services to be reported on claims and potentially reject claims if no ancillary services are reported, and whether to consider payment for such claims to be inappropriate or erroneous and subject to recoupment.

In response to the comment solicitation, we received a comment from MedPAC regarding facilities that do not report ancillary charges on most or any of their claims. MedPAC stated that it is not known: whether IPFs fail to report ancillary charges separately because they were appropriately bundled with all other charges into an all-inclusive per diem rate; if no ancillary charges were incurred because the IPF cares for a patient mix with lower care needs or inappropriately fails to furnish the kinds of care reflected in ancillary charges when medically necessary; or if ancillary charges for services furnished during the IPF stay are inappropriately billed outside of the IPF base rate (unbundling). MedPAC recommended CMS conduct further investigation into the lack of certain ancillary charges and whether IPFs are providing necessary care and appropriately billing for inpatient psychiatric services under the IPF PPS.

MedPAC also encouraged CMS to require the reporting of ancillary charges and clarify the requirements related to IPFs' ''all-inclusive-rate'' hospital status. MedPAC noted that it observed in cost report data that IPFs that previously were not all-inclusive-rate hospitals have recently changed to an all-inclusive-rate status. MedPAC noted that the timing of many of these changes appears to correspond to CMS's transmittals requiring ancillary services to be reported on cost reports for IPFs that do not have an all-inclusive rate.

Other commenters, including IPFs and hospital associations, responded to the RFI stating that the lack of ancillary charges on claims does not indicate a lack of services being provided. The commenters strongly opposed any claim-level editing and stated that reporting ancillary charges at the claim level would be inefficient and burdensome, particularly for government and IHS all-inclusive hospitals.

c. Clarification of Eligibility Criteria for the Option To Elect To File an All-Inclusive Cost Report

After taking into consideration the feedback we received from both MedPAC and IPF providers, for FY 2025 we are clarifying the eligibility criteria to be approved to file all-inclusive cost reports. Only government-owned or tribally owned facilities are able to satisfy these criteria, and thus only these facilities will be permitted to file an all-inclusive cost report for cost reporting periods beginning on or after October 1, 2024.

We remind readers that in order to be approved to file an all-inclusive cost report, hospitals must either have an all-inclusive rate (one charge covering all services) or a no-charge structure.[5] We are clarifying that this does not mean any hospital can elect to have an all-inclusive rate or no-charge structure. Our longstanding policy as discussed in the PRM 15–1, chapter 22, § 2208.1, only allows a hospital to use an all-inclusive rate or no charge structure if it has never had a charge structure in place. In addition, we are clarifying that our expectation is that any new IPF would have the ability to have a charge structure under which it could allocate

[4] IPFs are subject to all hospital conditions of participation, including 42 CFR 482.25, which specifies that ''The hospital must have pharmaceutical services that meet the needs of the patients,'' and 482.27, which specifies that ''The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients.''

[5] PRM 15–1, chapter 22, § 2208.1.

costs and charges. As previously stated, only a government-owned or tribally owned facility will be able to satisfy these criteria and will be eligible to file its cost report using an all-inclusive rate or no charge structure.

For cost reporting periods beginning on or after October 1, 2024, we will issue instructions to the MACs and put in place edits to operationalize our longstanding policy that only government-owned or tribally owned IPF hospitals are permitted to file an all-inclusive cost report. All other IPF hospitals must have a charge structure and must report ancillary costs and charges on their cost reports. IPFs that have previously filed an all-inclusive cost report erroneously will no longer be able to do so. We further note that to the extent government-owned or tribally owned hospitals can report ancillary charges on their cost reports, we strongly encourage them to do so to allow CMS to review and analyze complete and accurate data.

We believe clarifying the current eligibility criteria to be approved to file all-inclusive cost reports and implementing these operational changes will appropriately require freestanding IPFs with the ability to have a charge structure, that is, all IPFs other than those which are government-owned or tribally owned, to track and report ancillary charge information. In addition, we expect that more IPFs reporting ancillary charge information will result in an increase of IPFs having a CCR, which will in turn result in an increased number of IPFs being included in ratesetting. Therefore, we believe these operational changes will improve the quality of data reported, which will result in increased accuracy of future payment refinements to the IPF PPS.

Furthermore, we believe collecting charges of ancillary services from freestanding IPFs supports the directive for competition under the Executive Order on Promoting Competition in the American Economy as it facilitates accurate payment, cost efficiency, and transparency.[6]

F. Refinement Standardization Factor

Section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, states that revisions in payment implemented pursuant to section 1886(s)(5)(D)(i) for a rate year shall result in the same estimated amount of aggregate expenditures under this title for psychiatric hospitals and psychiatric units furnished in the rate year as would have been made under this title for such care in such rate year if such revisions had not been implemented. We interpret this to mean that revisions in payment adjustments implemented for FY 2025 (and for any subsequent fiscal year) must be budget neutral.

Historically, we have maintained budget neutrality in the IPF PPS using the application of a standardization factor, which is codified in our regulations at § 412.424(c)(5) to account for the overall positive effects resulting from the facility-level and patient-level adjustments. As discussed in section III.B.1 of this proposed rule, section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the standardization factor by setting the total estimated IPF PPS payments, taking into account all of the adjustment factors under the IPF PPS, to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the RY 2005 IPF PPS final rule (69 FR 66926).

We believe the budget neutrality requirement of section 4125(a) of the CAA, 2023 is consistent with our longstanding methodology for maintaining budget neutrality under the IPF PPS. Therefore, for FY 2025, we are proposing to apply a refinement standardization factor in accordance with our existing policy at § 412.424(c)(5). This policy requires us to update IPF PPS patient-level adjustment factors, ED adjustment, and ECT per treatment amount as proposed in this FY 2025 IPF PPS proposed rule, in such a way that total estimated payments to IPFs for FY 2025 are the same with or without the changes (that is, in a budget neutral manner) by applying a refinement standardization factor to the IPF PPS rates. We are proposing to use the following steps to ensure that the rates reflect the FY 2025 update to the patient-level adjustment factors (as previously discussed in section III.C and III.D of this proposed rule, and summarized in Addendum A) in a budget neutral manner:

Step 1: Simulate estimated IPF PPS payments using the FY 2024 IPF patient-level and facility-level adjustment factor values and FY 2024 ECT payment per treatment (available on the CMS website).

Step 2: Simulate estimated IPF PPS payments using the proposed FY 2025 IPF patient-level and facility-level adjustment factor values (see Addendum A of this proposed rule, which is available on the CMS website) and ECT per treatment amount based on the CY 2022 geometric mean cost for ECT under the OPPS.

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the proposed FY 2025 refinement standardization factor of 0.9514.

Step 4: Apply the FY 2025 refinement standardization factor from step 3 to the FY 2024 IPF PPS Federal per diem base rate and ECT per treatment amount (based on the CY 2022 geometric mean cost for ECT under the OPPS), after the application of the wage index budget neutrality factor and the IPF market basket increase reduced by the productivity adjustment described in section III.A of this proposed rule to determine the FY 2025 IPF PPS Federal per diem base rate and FY 2025 ECT payment amount per treatment.

IV. Requests for Information (RFI) To Inform Future Revisions to the IPF PPS in Accordance With the CAA, 2023

As discussed in the following sections, we are requesting information on two main topics to inform future revisions to the IPF PPS, in accordance with the CAA, 2023. First, we are requesting information regarding potential revisions to the IPF PPS facility-level adjustments. Second, we are requesting information regarding the development of a patient assessment instrument under the IPFQR program.

Please note, each of these sections is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

[6] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.*

Respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

A. Request for Information Regarding Revisions to IPF PPS Facility-Level Adjustments

The CAA, 2023 added section 1886(s)(5)(D) to require CMS to revise the IPF PPS methodology for determining payment rates for FY 2025, and for any subsequent FY as determined appropriate by the Secretary. As detailed in sections III.C and III.D of this proposed rule, we are proposing to revise the patient-level payment adjustments in FY 2025 and retain the current facility-level payment adjustments for rural location and teaching status. We have also conducted analysis of the IPF PPS facility-level adjustments using an updated regression analysis of cost and claims data for CY 2019 through 2021, as discussed in section III.C.3. of this proposed rule. The updated analysis identified potential changes in the regression factors for rural location and teaching status and suggests there may be value in including a new facility-level variable for safety net patient population, based on the Medicare Safety Net Index (MSNI) methodology developed by MedPAC for the IPPS. We note that the analysis of MSNI builds on prior analysis that CMS conducted regarding the applicability of an adjustment for disproportionate share intensity. Our review is ongoing and may be used to inform future rulemaking.

In the following sections, we describe the results of our latest analysis and request public comment on them. We are interested in comments regarding whether it would be appropriate to consider proposing revisions to the IPF PPS facility-level adjustments in the future based on the results of our latest regression analysis in future years.

1. Adjustment for Rural Location

In our MedPAR data set, which included data from CY 2019 through CY 2021, 101,483 stays, or 12.6 percent of all stays, were at rural IPFs. Our analysis shows that the regression coefficient for rural stays is 1.19. This means that holding all other variables constant and controlling for area wage differences, stays at rural IPFs have approximately 19-percent higher cost per day than stays at urban IPFs. As previously discussed, we did not include control variables in our regression model to account for occupancy rate. However, we note that if we included these control variables, we estimate the rural adjustment in the regression would decrease to approximately 1.13.

In addition, as discussed later in section IV.A.3 of this proposed rule, we evaluated the potential inclusion of a new variable for facilities' safety net patient population, as measured by the MSNI ratio. We observe that the inclusion of the MSNI ratio in the regression model would have an impact on the rural adjustment factor. In the regression model that includes the MSNI ratio, the rural adjustment factor is 1.16. In other words, if we were to adopt an MSNI payment adjustment, our FY 2025 regression model indicates that the rural adjustment factor would decrease relative to the rural adjustment factor calculated without the MSNI variable. However, for rural facilities with a high level of safety net patients, the combined effect of the rural adjustment and a safety net adjustment would increase payments. These results are presented in Table 17, and we are seeking public comments on these results.

Table 17: Rural Adjustment Factor Regression Results CY 2019–CY 2021

Current Adjustment Factor	Updated Adjustment Factor without MSNI payment	Updated Adjustment Factor with MSNI payment
1.17	1.19	1.16

We have modeled informational impacts reflecting the potential change in payments, as discussed in section IV.A.4 of this proposed rule, though we note future additional data and analysis may produce results that differ from those presented in this proposed rule.

2. Teaching Adjustment

In the IPF PPS payment methodology, the teaching status for each facility is calculated as one plus the facility's ratio of intern and resident FTEs to the average daily census (69 FR 66954 through 66955). The teaching variable used in the regression is the natural log of each facility's teaching status, resulting in a continuous variable with a distribution ranging from 0.0000 to 1.6079. The payment adjustment for teaching status, as explained in section III.D.2 of this proposed rule, is calculated by raising a facility's teaching ratio to the power of the teaching status coefficient derived from the regression analysis.

In our updated regression analysis of data for CY 2019 through CY 2021, there

were 155,458 stays in teaching facilities, comprising 19.3 percent of IPF stays for the time period. As previously discussed in this proposed rule, we found that the occupancy variables used in the original IPF PPS regression model were correlated with rural status, and have been removed in this updated model. We note that if we were to include occupancy control variables in the regression model, the adjustment for teaching status would increase to 1.0087.

The teaching status variable continues to be statistically significant at the 0.001 level in all of our updated models; in other words, we found that a facility's teaching status explains differences in costs between IPF stays. As shown in Table 18, the teaching status coefficient would increase in either updated regression model compared to its current value.

Table 18: Teaching Status Adjustment Factor Regression Results CY 2019–CY 2021

Current Adjustment Factor	Updated Adjustment Factor without MSNI payment	Updated Adjustment Factor with MSNI payment
0.5150	0.7286	0.6955

As discussed in section IV.A.4. of this proposed rule, we have modeled informational impacts reflecting the potential change in payments from these adjustment factors. We are seeking public comment on these results. We note that future additional data and analysis may produce results that differ from those presented in this proposed rule.

3. Adjustment for Safety Net Patient Population

a. Prior Analysis of Disproportionate Share Hospital Status

In contrast to other Medicare hospital payment systems, the IPF PPS does not have an adjustment that recognizes disproportionate share intensity. Section 1886(s) of the Act does not require any specific adjustment of this type, nor does it require the use of any particular methodology. In the past, we have explored the application of the disproportionate share hospital (DSH) variable used in other Medicare prospective payment systems (that is, the sum of the proportion of Medicare days of care provided to recipients of Supplemental Security Income and the proportion of the total days of care provided to Medicaid beneficiaries) for the IPF PPS. We refer readers to the RY 2005 IPF PPS final rule (69 FR 66958 through 66959) and the FY 2023 IPF PPS final rule (87 FR 46865). For psychiatric units, both proportions are specific to the unit and not the entire hospital.

In the RY 2005 IPF PPS final rule, we explained that the DSH variable was highly significant in our cost regressions; however, we found that facilities with higher DSH had lower per diem costs. We note that the previously cited study for the American Psychiatric Association also found the same results. The relationship of high DSH with lower costs cannot be attributed to downward bias in the Medicaid proportion due to the IMD exclusion. This is because public psychiatric hospitals already have lower costs on average than other types of IPFs. Therefore, if we had proposed a DSH adjustment based on the regression analysis, IPFs with high DSH shares would have been paid lower per diem rates (69 FR 66958).

In the FY 2023 IPF PPS proposed rule, we summarized and discussed the results of more recent analysis using data from 2018 (87 FR 19428 through 19429). In response to that proposed rule, commenters encouraged CMS to continue evaluating ways to increase IPF PPS payments for disproportionate share intensity. MedPAC recommended that we consider the applicability of the MSNI, which has previously been discussed in the context of the IPPS, to the IPF PPS. As discussed in the following paragraphs, we have conducted analysis of the MSNI and are soliciting comments on our findings.

b. Analysis of the Medicare Safety Net Index in the IPF PPS

(1) Background

MSNI is an index that MedPAC developed as its recommended alternative to the current statutorily required methodology for disproportionate share payments to IPPS hospitals. In their March 2023 Report to Congress, MedPAC recommend that MSNI would better target scarce Medicare resources to support hospitals that are key sources of care for low-income Medicare beneficiaries and may be at risk of closure.[7] For further discussion of this safety net index in the context of the Medicare program, we refer readers to the FY 2024 IPPS final rule (88 FR 58640), which includes a discussion of how MSNI could be calculated for acute care hospitals and an RFI on the potential use of MSNI or other safety net indicators in the IPPS, such as the area deprivation index (ADI) or Social Deprivation Index (SDI).

For our analysis, we constructed an MSNI for each IPF in our data set, which we calculated as the sum of three ratios:

- The low-income subsidy (LIS) volume ratio, which is the ratio of total stays for low-income beneficiaries to a facility's total stays for Medicare beneficiaries. For our analysis, low-income beneficiaries are identified based on dual-enrollment or enrollment in Part D low-income subsidies, and stays are identified from MedPAR claims. This ratio was defined the same way in the FY 2024 IPPS final rule's discussion of MSNI (88 FR 59306).
- The proportion of revenue spent on uncompensated care (UCC), defined the same way as it was in the FY 2024 IPPS final rule's discussion of MSNI (88 FR 59306). UCC and total revenue are available data elements from the hospital cost report, but only for the acute care hospital. These elements are not currently detailed at the level of the IPF unit.
- The Medicare dependency ratio, which is a hospital's total covered days for Medicare patients divided by its total patient days. This information comes from the hospital cost report. We have also defined this ratio in the same way as it was defined in the FY 2024 IPPS final rule's discussion of MSNI (88 FR 59306).

The final MSNI score is calculated as: LIS Volume Ratio + Proportion of Revenue Spent on UCC ratio + 0.5 * Medicare Dependency Ratio. This formula follows MedPAC's methodology based on its analysis of data for the IPPS hospital setting. As discussed in its

[7] Medicare Payment Advisory Commission. (2023). Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC_v2.pdf.* Accessed on January 22, 2024.

March 2023 Report to Congress, the Medicare Dependency Ratio is multiplied by 0.5 because MedPAC's prior analysis of costs in the IPPS setting found that the Medicare Dependency Ratio had approximately half the effect on cost as the other two components of MSNI.

(2) Regression Analysis Results

The adjusted r-square, a measure of how much of the variation in costs between stays our model can explain, increases by approximately 2.8 percent when we add the variable for MSNI to the updated model analyzing cost and claims data for CY 2019 through CY 2021. The adjusted r-square for the model without the MSNI variable is 0.32340, while the adjusted r-square for the model with the MSNI variable is 0.33250. Our regression analysis indicates an MSNI coefficient of 0.5184, which is statistically significant at the .001 level.

Table 19: Example MSNI Payment Adjustments by Facility Type

	Urban		Rural	
	Hospitals	Units	Hospitals	Units
MSNI	0.8051	0.9841	0.8780	0.9940
(1 + MSNI factor)^0.5184	1.36	1.43	1.39	1.43

Section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, states that revisions in payment implemented pursuant to section 1886(s)(5)(D)(i) for a rate year shall result in the same estimated amount of aggregate expenditures under this title for psychiatric hospitals and psychiatric units furnished in the rate year as would have been made under this title for such care in such rate year if such revisions had not been implemented. Therefore, our estimates of payments associated with a potential MSNI payment adjustment include the application of a standardization factor, which we note would reduce the IPF PPS Federal per diem base rate by approximately $245. Total payments to IPFs would remain the same, but there would be significant distributional impacts, which would reduce payments to IPFs with a lower MSNI and increase payments to IPFs with a higher MSNI. We refer readers to section IV.A.4 of this proposed rule for informational analysis and discussion of the potential distributional impacts estimated for the MSNI payment adjustment.

We note that for certain elements of the MSNI calculation, some data was not available for IPFs at the same level of detail available for IPPS hospitals. We also identified that for some elements, data reported by IPFs may be incomplete. First, as mentioned above, both UCC amounts and total revenue amounts are reported at the hospital level only. As a result, we were able to calculate a UCC ratio for IPF units based on the overall ratio of the hospital's UCC to its revenues. This assumes that a hospital's overall UCC ratio would be comparable to that of its IPF unit. However, because we lack unit-level data, we are not able to validate this assumption. Table 20 shows that most freestanding IPF hospitals are not reporting any UCC, which leads to lower MSNI values for these IPFs. We recognize that the absence of UCC for nonprofit IPFs, which we believe in fact provide a significant amount of UCC, may reflect differences in reporting, rather than provision of UCC.

Table 20: Mean Values of MSNI and its Components by Facility Type

	Urban		Rural	
	Hospitals	Units	Hospitals	Units
LIS Volume	0.7296	0.6723	0.7763	0.6562
Uncompensated Care Ratio	0.0006	0.0362	0.0000	0.0381
Medicare Dependency	0.1496	0.5510	0.2033	0.5994
MSNI	0.8051	0.9841	0.8780	0.9940

There are also a number of key differences between our analysis and the way that MedPAC has recommended that MSNI be applied to payments in the IPPS setting. For the IPPS, MedPAC recommends to the Congress in their March 2023 report that they create an MSNI pool of funds for MSNI add-on payments of about $2 billion, which could be increased each year by the market basket update. MedPAC contemplates hospitals choosing between an MSNI payment and other special payment rates designed to protect access, for example, in rural areas, or the adoption of a percentage-based cap on all special payment rates.[8] In contrast, our modeling of an MSNI payment adjustment in the IPF PPS, assumes that IPFs could be eligible for both an MSNI payment and the payment adjustment for rural location, for example, without a cap imposed. Our modeling also assumes that an MSNI payment adjustment would be budget neutral; in other words, the payment would not be an add-on. In contrast to the recommended approach for the IPPS, which would come from a new funding pool, we estimate that the application of an MSNI adjustment would affect the Federal IPF PPS per diem base rate. As a result, the MSNI payment in our model would represent a redistribution of funds within the IPF PPS, as is

[8] Medicare Payment Advisory Commission. (2023). Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC_v2.pdf.* Accessed on January 22, 2024.

statutorily required under section 4125(a) of the CAA, 2023.

We constructed the MSNI variable in our regression model similarly to the construction of the teaching adjustment (that is, as the natural log of a facility's MSNI ratio plus 1). Consequently, a payment adjustment derived from our regression results would work like the teaching status adjustment: the MSNI adjustment factor is expressed in an un-exponentiated form. A provider's MSNI factor plus one would be raised to the power of the MSNI adjustment factor to calculate the facility's MSNI payment adjustment.

We are considering the potential operational changes that would be necessary to implement an adjustment for MSNI in the future. For example, we anticipate the need to periodically recalculate facilities' MSNI ratios, which could potentially correspond to a facility's cost report settlement process. We also anticipate the need to develop a reconciliation process, should such an adjustment for MSNI be implemented in the future. Further, we expect that because a facility's LIS ratio would not be an available data element on the hospital cost report, we may need to develop and publish a facility-level file with this information or consider collecting additional data on the hospital cost report. As discussed in the following section, we are seeking public comment on our regression results, as well as our methodology used to construct the MSNI variable for IPFs, and on the operational considerations we have noted. We note that future additional data and analysis produce results that differ from those presented in this proposed rule.

(3) Request for Information

We are particularly seeking comment on the following questions:

- Should we consider adjusting payment using MedPAC's MSNI formula with adaptations, as described above? What, if any, changes to the methodology should we consider for the IPF setting? For example, should we develop a separate payment adjustment for each component (that is, the low-income ratio, uncompensated care ratio, and Medicare dependency ratio)?
- We note that our construction of the MSNI did not scale or index facility-level variables to a national standard or median value. We anticipate that doing so would result in less of a change to the IPF Federal per diem base rate but would still result in comparable distributional impacts (that is, IPFs with lower MSNIs would receive lower payments, and IPFs with higher MSNIs would receive higher payments). Should we consider scaling or indexing the MSNI to a national average MSNI for all IPFs?
- Is MedPAC's MSNI formula, as adapted, an accurate and appropriate measure of the extent to which an IPF acts as a safety-net hospital for Medicare beneficiaries?
- Should additional data be collected through the cost report to improve the calculation of MSNI, such as collecting UCC and revenue at the IPF unit level?
- Is the current cost report data submitted by IPFs sufficiently valid and complete to support the implementation of an MSNI payment? We note our concerns about the low or non-existent amounts reported for uncompensated care for freestanding IPFs and the use of hospital-level UCC and revenue amounts to calculate the UCC ratio for IPF units.
- What administrative burden or challenges might providers face in reporting their UCC and low-income patient stays?
- Would IPFs have the information necessary to report their low-income patient stays to CMS for the purpose of the MSNI calculation? What challenges might IPFs face in gathering and reporting this information?
- In the FY 2023 IPPS proposed rule, CMS noted that, when calculating the MSNI, the following circumstances may be encountered: new hospitals (for example, hospitals that begin participation in the Medicare program after the available audited cost report data), hospital mergers, hospitals with multiple cost reports and/or cost reporting periods that are shorter or longer than 365 days, cost reporting periods that span fiscal years, and potentially aberrant data. How should CMS consider addressing these circumstances when calculating the MSNI for IPFs?

4. Informational Impacts of Potential Facility-Level Revisions on IPF PPS Payments

We estimate that an MSNI payment adjustment in concert with the potential rural payment adjustment and teaching adjustments detailed in this section would have a refinement standardization factor of 0.7202. In other words, adoption of these facility-level payment adjustments as described in this section of this proposed rule would decrease the Federal per diem base rate by $244.81. In contrast, we estimate that updating only the rural and teaching adjustments without MSNI would have a refinement standardization factor of 0.9926, which would decrease the Federal per diem base rate by $6.48.

Estimates of distributional impacts by facility type, location, ownership, teaching status, and region are detailed in Table 21. We are seeking public comment on these informational impacts to potentially inform future rulemaking.

To illustrate the impacts of these potential changes to the IPF PPS facility-level adjustments, our analysis begins with the same FY 2023 IPF PPS claims (based on the 2023 MedPAR claims, December 2023 update) as discussed in section VIII.C of this proposed rule. We begin with estimated FY 2025 IPF PPS payments using these 2023 claims, the proposed FY 2025 IPF PPS Federal per diem base rate and ECT per treatment amount, the proposed refinements to the FY 2025 IPF PPS patient and facility level adjustment factors, and the proposed FY 2025 IPF PPS wage index. At each stage, total outlier payments are maintained at 2 percent of total estimated FY 2025 IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The potential updates to the IPF teaching adjustment and rural adjustment, without the addition of an adjustment for MSNI.
- Adding an adjustment for MSNI and reducing the IPF rural adjustment and teaching adjustment as shown in the third column of Tables 17 and 18 of this proposed rule.

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Table 21 – Informational Impacts of Potential Facility-Level Revisions

Facility by Type	Number of Facilities	Update Rural and Teaching, without MSNI	Update Rural, Teaching, and MSNI	Overall Impact
(1)	(2)	(3)	(4)	(6)
All Facilities	1,430	0.0	0.0	0.0
Total Urban	1,171	-0.1	0.0	-0.1
Urban unit	655	0.1	1.9	2.0
Urban hospital	516	-0.4	-2.3	-2.7
Total Rural	259	0.9	-0.2	0.7
Rural unit	199	1.0	-0.4	0.5
Rural hospital	60	0.9	0.3	1.2
By Type of Ownership:				
Freestanding IPFs				
Urban Psychiatric Hospitals				
Government	117	1.4	-2.1	-0.7
Non-Profit	98	-0.4	-2.5	-2.8
For-Profit	301	-0.7	-2.3	-3.0
Rural Psychiatric Hospitals				
Government	30	0.9	-1.8	-0.9
Non-Profit	12	0.8	-2.6	-1.7
For-Profit	18	0.9	2.0	2.9
IPF Units				
Urban				
Government	95	1.0	3.0	4.0
Non-Profit	436	0.0	1.5	1.5
For-Profit	124	-0.5	2.0	1.5
Rural				
Government	45	0.9	-0.5	0.5
Non-Profit	114	1.0	-0.3	0.6
For-Profit	40	0.9	-0.5	0.4
By Teaching Status:				
Non-teaching	1,230	-0.4	-0.4	-0.8

Facility by Type	Number of Facilities	Update Rural and Teaching, without MSNI	Update Rural, Teaching, and MSNI	Overall Impact
Less than 10% interns and residents to beds	104	0.3	1.2	1.5
10% to 30% interns and residents to beds	71	2.2	3.0	5.3
More than 30% interns and residents to beds	25	9.8	-3.1	6.4
By Region:				
New England	102	0.0	0.5	0.5
Mid-Atlantic	193	0.1	0.8	0.9
South Atlantic	226	0.1	0.1	0.2
East North Central	228	-0.2	-0.3	-0.5
East South Central	140	0.0	-1.9	-1.9
West North Central	99	0.1	-0.5	-0.4
West South Central	214	0.0	-1.9	-1.9
Mountain	102	-0.4	-0.6	-1.0
Pacific	126	0.0	1.9	2.0
By Bed Size:				
Psychiatric Hospitals				
Beds: 0-24	87	0.9	-2.4	-1.6
Beds: 25-49	87	-0.4	-2.3	-2.7
Beds: 50-75	92	-0.5	-1.6	-2.1
Beds: 76 +	310	-0.4	-2.1	-2.5
Psychiatric Units				
Beds: 0-24	450	0.1	-0.8	-0.7
Beds: 25-49	234	0.3	3.0	3.3
Beds: 50-75	98	0.4	3.1	3.5
Beds: 76 +	72	0.3	2.8	3.1

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B. Request for Information (RFI)—Patient Assessment Instrument Under IPFQR Program (IPF PAI) To Improve the Accuracy of the PPS

Section 4125(b)(1) of CAA, 2023 amended section 1886(s)(4) of the Act, by inserting a new paragraph (E), to require IPFs participating in the IPFQR Program to collect and submit to the Secretary certain standardized patient assessment data, using a standardized patient assessment instrument (PAI) developed by the Secretary, for RY 2028 (FY 2028) and each subsequent rate year. IPFs must submit such data with respect to at least the admission to and discharge of an individual from the IPF, or more frequently as the Secretary determines appropriate. For IPFs to meet this new data collection and reporting requirement for RY 2028 and each subsequent rate year, the Secretary must implement a standardized PAI that collects data with respect to the following categories: functional status; cognitive function and mental status; special services, treatments, and interventions for psychiatric conditions; medical conditions and comorbidities; impairments; and other categories as determined appropriate by the Secretary. This IPF–PAI must enable comparison of the patient assessment data across all IPFs which submit these data. In other words, the data must be standardized such that data from IPFs participating in the IPFQR Program can be compared; the IPF–PAI each IPF administers must be made up of identical questions and identical sets of response options to which identical standards and definitions apply.

As we develop the IPF–PAI, in accordance with these new statutory requirements, we seek to collect information that will help us achieve the following goals: (1) improve the quality of care in IPFs, (2) improve the accuracy of the IPF PPS in accordance with section 4125(b)(2) of CAA, 2023, and (3) improve health equity.[9] In this Request for Information (RFI), we are soliciting comments for development of this IPF–PAI, in accordance with these new statutory requirements, and to achieve these goals.

This RFI consists of four sections. The first section discusses a general framework or set of principles for development of the IPF–PAI. The second section outlines potential approaches that could be used to develop the items or data elements that

[9] For more information on our strategic goals to improve health equity by expanding the collection, reporting, and analysis of standardized data, we refer readers to Priority 1 of our Framework for Health Equity at *https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework*.

make up the PAI. This section also discusses patient assessment data elements in use in PAIs for skilled nursing facilities and other healthcare settings that could potentially be adapted for use in the IPF–PAI. The third section outlines potential approaches that could be used to collect patient assessment data. Finally, the fourth section solicits public comment on the principles and approaches listed in the first three sections and seeks other input regarding the IPF–PAI.

1. Framework for Development of the IPF–PAI

We considered similar legislatively derived PAIs previously implemented for certain post-acute care (PAC) providers to inform the goals and guiding principles for the IPF–PAI because of similarities of section 4125(b) of CAA, 2023 to the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014), codified at section 1899B of the Act. Similar to section 4125(b) of CAA, 2023, section 1899B of the Act requires certain PAC providers, specifically home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), to submit certain standardized patient assessment data (as set forth at section 1899B(b)(1)(B)) using a standardized PAI under the PAC providers' respective quality reporting programs. While IPFs are acute care providers and not PAC providers, given the similarities between the CAA, 2023 and section 1899B of the Act, we considered the goals and guiding principles that we followed to implement section 1899B of the Act for certain PAC providers and examined their applicability and appropriateness for IPFs.

We previously identified four key considerations when assessing Standardized Patient Assessment Data Elements for the PAC PAIs to collect: (1) Overall clinical relevance; (2) Interoperable exchange to facilitate care coordination during transitions in care; (3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and (4) Scientific reliability and validity, general consensus agreement for its usability.[10] For the reasons discussed in the following subsections, we believe that these considerations are also appropriate for the development of the IPF–PAI. In addition, we seek to balance the need to collect meaningful patient data to improve care with the need to minimize administrative burden. The remainder of this section describes each of these considerations in the context of the IPF–PAI. As we discuss in section IV.B.4.a of this proposed rule, we are soliciting comment on these considerations.

a. Overall Clinical Relevance

In each category of assessment required by section 1886(s)(4)(E)(ii), as added by section 4125(b) of CAA, 2023, (functional status; cognitive function and mental status; special services, treatments, and interventions for psychiatric conditions; medical conditions and comorbidities; impairments, and other categories as determined appropriate by the Secretary), we seek to establish Standardized Patient Assessment Data Elements that providers can use to support high quality care and outcomes in the IPF setting. As we evaluate Standardized Patient Assessment Data Elements in PAIs designed for other care settings, we intend to work with CMS Medical Officers, including psychiatrists, to consider the clinical relevance for IPF patients as a determining factor in whether an item merits inclusion in the IPF–PAI. For an example of a PAI in use in another setting, we refer readers to the IRF–PAI instrument available at *https://www.cms.gov/files/document/irf-pai-version-40-eff-10012022-final.pdf*. We are particularly interested in learning about specific instruments and tools in each area of assessment that have high clinical relevance in the IPF setting and welcome comments regarding Standardized Patient Assessment Data Elements that may not be clinically relevant to the IPF setting.

To ensure the clinical relevance of the instrument across a diverse group of IPF patients, we are considering structuring the assessment with conditional questions, so that certain sets of questions are only indicated if the questions are relevant to the patient. Furthermore, we note that some data elements may only be appropriate for collection at certain times during the patient's stay (for example, only at admission or only at discharge). We solicit comments regarding the most effective structure to employ in the development of the IPF–PAI.

b. Interoperability

Interoperability is a key priority and initiative at CMS. Across the organization, we aim to promote the secure exchange, access, and use of electronic health information to support better informed decision making and a more efficient healthcare system. As a part of this effort, we make interoperability a priority for standardized data collection. We intend to ensure that the IPF–PAI meets Health Level 7® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) standards.

As part of our interoperability considerations, we are interested in whether Standardized Patient Assessment Data Elements already in use in the CMS Data Element Library (DEL) are appropriate and clinically relevant for the IPF setting. In CY 2021, approximately 8,000 admissions to IPFs were individuals transferred from SNFs or IRFs. We are interested in whether Standardized Patient Assessment Data Elements already used in the DEL can be used to better support interoperability between providers, given the high number of transfers.

c. Ability To Capture Medical Complexity and Risk Factors

We intend to expand our efforts to refine the IPF PPS to increase the accuracy of the payment system by better identifying patient characteristics that best predict resource use during an IPF stay. To identify Standardized Patient Assessment Data Elements that would help predict resource use, we intend to evaluate Standardized Patient Assessment Data Elements for their ability to explain medical complexity, the need for special services and treatments, and to measure case-mix differences that impact costs. It is our expectation that an IPF–PAI that effectively differentiates treatment needs between patients will also help IPFs plan and distribute their resources. Our hope is that the IPF–PAI can therefore integrate with IPFs' business practices. In addition, Standardized Patient Assessment Data Elements that capture patient risk factors can

[10] We refer readers to the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal fiscal year 2020 final rule (84 FR 38767); the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal fiscal year 2020 and Updates to the IRF Quality Reporting Program final rule (84 FR 39110), the Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements CY 2020 final rule (84 FR 60567), and the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and fiscal year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals final rule (84 FR 42537).

contribute to quality of care and patient safety.

d. Scientific Reliability and Validity

Standardized Patient Assessment Data Elements considered for inclusion in the IPF–PAI must be scientifically reliable and valid in IPF settings. We intend to draw on our significant experience in development of quality measures in the IPFQR Program and development of Standardized Patient Assessment Data Elements for other PAIs, such as the IRF–PAI and the Minimum Data Set (MDS) (the PAI for SNFs), in our development of Standardized Patient Assessment Data Elements for the IPF–PAI.[11] It is important to note that the statutorily required timeframe for implementation of the IPF–PAI for RY 2028 limits our ability to develop and test a full battery of new Standardized Patient Assessment Data Elements for the launch of the IPF–PAI. We anticipate the need and opportunity for incremental revisions to the IPF–PAI in the future.

We anticipate that our development process for new Standardized Patient Assessment Data Elements will include working with teams of researchers for each category including a group of advisors made up of clinicians and academic researchers for each team with expertise in IPFs. We expect to convene a Technical Expert Panel (TEP) to provide expert input on new and existing Standardized Patient Assessment Data Elements that merit consideration for inclusion and testing, including environmental scans and reviews of scientific literature. In an ideal scenario, Standardized Patient Assessment Data Elements would be tested in a representative sample of IPFs for appropriateness in different IPF settings and across a range of patients. Standardized Patient Assessment Data Elements would be tested for inter-rater (that is, consistency in results regardless of who is administering the assessment) and inter-organizational reliability, for validity in all IPF settings, for internal consistency, and for breadth of application among a range of IPF patients. We anticipate that Standardized Patient Assessment Data Elements would also need to be tested for their ability to detect differences among patients and costs of treatment. Due to the constraints of the statutorily required implementation timeframe, it may not be possible to complete all testing before launching the IPF–PAI.

The process for scientifically testing each question and set of responses is lengthy and resource-intensive. This process is based on the steps for quality measure development described in the Blueprint Measure Lifecycle,[12] developed by the CMS Measures Management System. These steps include literature review and environmental scanning; various levels of field testing to understand the ''real world'' performance of the data elements; and iterative expert and interested parties engagement to include broader perspectives on topics, candidate data elements, and interpretation of testing results. If appropriate, using data currently collected by IPFs or Standardized Patient Assessment Data Elements that have been tested and validated for use in other clinical settings can reduce these timeframes because test data are already available.

e. Administrative Burden

In evaluating Standardized Patient Assessment Data Elements for inclusion in the IPF–PAI, we are considering the burden of data collection through the PAI and aiming to minimize additional burden by considering whether any data that is currently collected through IPFQR Program measures or on IPF claims could be collected as Standardized Patient Assessment Data Elements to avoid duplication of data that IPFs are already reporting. We are also considering how collecting some data for some IPFQR Program measures through the IPF–PAI and collecting other data through the Hospital Quality Reporting (HQR) system would affect the reporting burden for participating IPFs. Licensing, permissions costs, or copyright restrictions that would add to administrative costs and burdens are also a consideration as we evaluate existing PAIs and mechanisms or tools for submitting IPF–PAI data.

As we develop the IPF–PAI, we are interested in receiving information about how to find a balance between collecting the most relevant and useful information and the administrative burden of administering the assessment and submitting the assessment data.

2. Elements of the IPF–PAI

Section 1886(s)(4)(E)(ii) of the Act, added by section 4125(b)(1)(C) of the CAA, 2023, requires that the standardized patient assessment data to be collected in the IPF–PAI must be with respect to six enumerated categories.

a. Functional Status

The first enumerated category of data for the IPF–PAI is functional status. Section 1886(s)(4)(E)(ii)(I) of the Act provides that functional status may include mobility and self-care at admission to a psychiatric hospital or unit and before discharge from a psychiatric hospital or unit. We note that information in this category is generally found in a patient's discharge summary and are interested in learning about standardized elements that correspond to functional status as relevant to IPFs. We are interested in what assessments may be currently in use in the IPF setting and meet criteria for inclusion in the IPF–PAI.

b. Cognitive Function and Mental Status

The second enumerated category of data for the IPF–PAI is cognitive function and mental status. Section 1886(s)(4)(E)(ii)(II) of the Act provides that cognitive function may include the ability to express ideas and to understand, and mental status may include depression and dementia. We note that in the IPF setting, a patient's diagnoses, which can be abstracted from their medical chart, provide some information related to this category. We are aware that IPFs may be currently assessing cognitive function using existing instruments. We are interested in hearing from IPFs about which instruments are currently in use to measure cognitive function in IPFs and which have high clinical relevance for the IPF setting.

c. Special Services, Treatments, and Interventions

The third enumerated category of data for the IPF–PAI is special services, treatments, and interventions for psychiatric conditions. Section 1886(s)(4)(E)(ii)(III) of the Act neither addresses what these terms mean nor provides any illustrative examples. As discussed in section V.C. of this rule, the IPFQR Program already collects information about the use of restraint and seclusion through quality measures (Hospital Based Inpatient Psychiatric Services (HBIPS)–2, Hours of Physical Restraint, and HBIPS–3, Hours of Seclusion Use), while claims include information about ECT treatments provided. Other areas of interest in this

[11] For more information on other PAIs, we refer readers to *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/pai* (for the IRF–PAI), to *https://www.cms.gov/medicare/quality/home-health/oasis-data-sets* (for the OASIS data set for HHAs), to *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual* (for the CARE data set for LTCHs), and to *https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual* (for the Minimum Data Set (MDS) Resident Assessment Instrument (RAI)).

[12] *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview.*

category may include high-cost medications, use of chemical restraints, one-to-one observation, and high-cost technologies. We are interested in whether these or any other special services, treatments, or interventions should be considered for inclusion in the IPF–PAI.

d. Medical Conditions and Comorbidities

The fourth enumerated category of data for the IPF–PAI is medical conditions and comorbidities. Section 1886(s)(4)(E)(ii)(IV) of the Act provides that medical conditions and comorbidities may include diabetes, congestive heart failure, and pressure ulcers. We note that IPF claims record a significant number of medical conditions and comorbidities to receive the payment adjustment for comorbidities in the IPF PPS and conditions that are relevant to the IPF stay. In reviewing Standardized Patient Assessment Data Elements listed in this category in PAIs in use in PAC settings, we observed that these PAIs include Standardized Patient Assessment Data Elements regarding pain interference in this category, such as the effect of pain on sleep, pain interference with therapy activities, and pain interference with day-to-day activities. We are interested in learning from commenters whether these existing data elements from the PAC settings would be clinically relevant for inclusion in this category for the IPF–PAI.

e. Impairments

The fifth enumerated category of data for the IPF–PAI is impairments. Section 1886(s)(4)(E)(ii)(V) of the Act provides that impairments may include incontinence and an impaired ability to hear, see, or swallow. PAIs in use in other settings include Standardized Patient Assessment Data Elements regarding hearing and vision (for example, Section B, ''Hearing, Speech, and Vision'' of the IRF–PAI Version 4.2 (Effective October 1, 2024)).[13] We are interested both in whether Standardized Patient Assessment Data Elements regarding additional impairments merit consideration for the IPF–PAI, and whether the Standardized Patient Assessment Data Elements regarding hearing and vision included in the IRF–PAI are appropriate for the IPF setting. We note that the Standardized Patient Assessment Data Element categories are not intended to be duplicative, so we would seek to avoid any overlap in measuring cognitive deficits in the Cognitive Function category with the Impairments category.

f. Other Categories Deemed Appropriate

The sixth enumerated category of data for the IPF–PAI is other categories as determined appropriate by the Secretary. We believe this provision allows for flexibility to include additional areas in the IPF–PAI.

One of our strategic priorities, as laid out in the CMS Strategic Plan,[14] reflects our deep commitment to improvements in health equity by addressing the health disparities that underlie our health system. In line with that strategic priority, we are interested in Standardized Patient Assessment Data Elements that would provide insight about any demographic factors (for example, race, national origin, primary language, ethnicity, sexual orientation, and gender identity) as well as SDOH (for example, housing status and food security) associated with underlying inequities. We are also interested in whether there are Standardized Patient Assessment Data Elements that would provide insight into special interventions that IPFs are providing to support patients after discharge which could serve to potentially reduce the incidence of readmissions.

We note that, beginning with mandatory reporting of CY 2025 data for FY 2027 payment determination, the IPFQR Program includes the Screening for SDOH measure, which assesses the percentage of patients, aged 18 years and over at the time of admission, who are screened for five specific health-related social needs (HRSNs)—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety, but which does not require reporting of that information at the patient-level (88 FR 51117). Furthermore, we note that PAIs adopted for the PAC settings discussed previously include collection of SDOH data under section 1899B(b)(1)(B)(vi) of the Act, which contains a similar provision for other categories deemed appropriate by the Secretary.[15]

We note that, if we deem it appropriate to add a SDOH category for the IPF–PAI and these SDOH data are included as Standardized Patient Assessment Data Elements in the PAI, they could potentially be used to risk adjust or stratify measures collected for the IPFQR Program. We are interested in learning whether using some of these SDOH data adopted in other PAIs to risk adjust or stratify these measures would make the measures in the IPFQR Program more meaningful.

3. Implementation of the PAI—Data Submission

We plan to develop flexible methods for providers to submit IPF–PAI data to CMS, including batch uploads in specified formats and a portal for submission of files. We welcome public comment on tools and methods for submission of data that balance administrative burden and ease of use.

4. Request for Information on IPF–PAI

In this proposed rule, we are requesting information from the public to inform the selection of Standardized Patient Assessment Data Elements to be collected on the IPF–PAI and the implementation process. We are seeking information about PAIs IPFs currently use upon admission and discharge, as well as information about how IPFs estimate resource needs to determine capacity before a patient is admitted. We are also seeking information about methods for IPFs to submit patient assessment data and the potential administrative burden on IPFs, MACs, and CMS. Finally, we are seeking input on the relationship between the IPF–PAI and the measures within the IPFQR Program.

We solicit comment on the following topics:

a. Principles for Selecting Standardized Patient Assessment Data Elements

- To what extent do you agree with the principles for selecting and developing Standardized Patient Assessment Data Elements for the IPF–PAI?
- What, if any, principles should CMS eliminate from the Standardized

[13] *https://www.cms.gov/files/document/irf-pai-version-42-effective-10-01-24.pdf.*

[14] The CMS Strategic Plan. Available at *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.* Accessed February 20, 2024.

[15] For further information detailing the rationale for adopting SDOH Standardized Patient Assessment Data Elements in these settings, we refer readers to the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal fiscal year 2020 final rule (84 FR 38805 through 38817); the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal fiscal year 2020 and Updates to the IRF Quality Reporting Program final rule (84 FR 39149 through 38161), the Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements CY 2020 final rule (84 FR 60597 through 60608), and the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and fiscal year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals final rule (84 FR 42577 through 42588).

Patient Assessment Data Element selection criteria?

- What, if any, principles should CMS add to the Standardized Patient Assessment Data Element selection criteria?

b. Patient Assessments Recommended for Use in the IPF–PAI

- Are there PAIs currently available for use, or that could be adapted or developed for use in the IPF–PAI, to assess patients': (1) functional status; (2) cognitive function and mental status; (3) special services, treatments, and interventions for psychiatric conditions; (4) medical conditions and comorbidities; (5) impairments; (6) health disparities; or (7) other areas not mentioned in this RFI?

c. Functional Status Standardized Patient Assessment Data Elements

- What aspects of function are most predictive of medical complexity or increased resource needs to treat a patient in the IPF setting?
- Which of the Standardized Patient Assessment Data Elements related to mobility (that is, the ability to toilet transfer, walk 10 feet, car transfer, walk 10 feet on an uneven surface, 1 step up (that is, a curb), 4 steps up, 12 steps up, and pick up an object) currently collected by PAC settings in their respective PAIs are clinically relevant in the IPF setting? Do they otherwise meet the principles for inclusion in the IPF–PAI?

d. Cognitive Function and Mental Status Standardized Patient Assessment Data Elements

- What aspects of cognitive function and mental status are most predictive of medical complexity or increased resource needs to treat a patient in the IPF setting?
- What components or instruments are used to assess cognitive function, mental status, or a combination thereof upon admission? What, if any, differences are there between assessments administered at admission and at discharge? What are the components of the mental status assessments administered at admission and discharge?

e. Special Services, Treatments, and Interventions for Psychiatric Conditions Standardized Patient Assessment Data Elements

- What special services, treatments, and interventions are most predictive of increased resource intensity during an IPF stay?
- Do data currently collected as part of the IPFQR Program related to special services and treatments (such as HBIPS–2 Hours of Physical Restraint Use and HBIPS–3 Hours of Seclusion Use) meet the criteria for inclusion in the IPF–PAI?

f. Medical Conditions and Comorbidities Standardized Patient Assessment Data Elements

- Is the Standardized Patient Assessment Data Element regarding pain interference (effect on sleep, interference with therapy activities, interference with day-to-day activities) currently collected by PAC settings in their respective PAIs clinically relevant in the IPF setting? Does it otherwise meet the criteria for inclusion in the IPF–PAI?
- Do the medical conditions and comorbidities coded on IPF claims meet the criteria for inclusion in the IPF–PAI?

g. Impairments Standardized Patient Assessment Data Elements

- Are Standardized Patient Assessment Data Elements related to impairments (that is, the ability to hear and see in adequate light) currently collected PAC settings in their respective PAIs clinically relevant in the IPF setting? Do they otherwise meet the principles for inclusion in the IPF–PAI?
- What impairments are most predictive of increased resource intensity during an IPF stay?

h. Other Categories of Standardized Patient Assessment Data Elements

- What other assessment elements would contribute to the clinical utility of the IPF–PAI?
- What other assessment elements would best capture medical complexity in the interest of refining and improving the accuracy of the IPF PPS?
- What other assessment elements would inform CMS's understanding of health equity for IPF patients?
- Are there special interventions that IPFs provide which support patients after discharge, and which could serve to reduce the incidence of hospital readmissions for psychiatric conditions? What, if any, assessment elements would inform CMS's understanding of such interventions?

i. Implementation

- We anticipate that IPFs will need to make changes to systems and processes and train staff in order to administer the assessment and submit assessment data by the implementation date. What operational or practical limitations would IPFs face in making those necessary changes? Are there particular categories of Standardized Patient Assessment Data Elements that would be more or less feasible for IPFs to operationalize? We are particularly interested in impacts to facilities of varying sizes and ownership characteristics.
- What forms of training and guidance would be most useful for CMS to provide to support IPFs in the implementation of the IPF–PAI?

j. Relationship to the IPFQR Program

- Would having some measures which require data submission through the HQR system and having other measures, which require data collection and submission through the IPF–PAI increase operational complexity or administrative burden? If so, how would you recommend mitigating this complexity or burden?
- Would any of the current chart-abstracted measures be easier to report through the IPF–PAI? If so, which measures?
- Would any of the current measures in the program be more meaningful if they were stratified or risk-adjusted using data from the required patient assessment categories or other categories not specified by the CAA, 2023 that should be added to the IPF–PAI?
- What new measure concepts, which would use data collected through Standardized Patient Assessment Data Elements in the IPF–PAI, should we consider?

V. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

The Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program is authorized by section 1886(s)(4) of the Act, and it applies to psychiatric hospitals and psychiatric units paid by Medicare under the IPF PPS (see section II.A. of this proposed rule for a detailed discussion of entities covered under the IPF PPS). Section 1886(s)(4)(A)(i) requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges occurring during such rate year [16] for

[16] We note that the statute uses the term ''rate year'' (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the IPF PPS RY means the 12-month period from October 1 through September 30, which we refer to as a ''fiscal year'' (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms ''rate year,'' as used in the statute, and ''fiscal year'' as

any IPF that does not comply with quality data submission requirements under IPFQR program, set forth in section 1886(s)(4)(C) of the Act, with respect to an applicable rate year.

Section 1886(s)(4)(C) of the Act requires IPFs to submit to the Secretary data on quality measures specified by the Secretary under section 1886(s)(4)(D) of the Act. Except as provided in section 1886(s)(4)(D)(ii) of the Act, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the consensus-based entity (CBE) with a contract under section 1890(a) of the Act. Section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the CBE with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Section 4125(b)(1) of CAA, 2023 amended section 1886(s)(4) of the Act, by inserting a new paragraph (E), to require IPFs participating in the IPFQR Program to collect and submit to the Secretary certain standardized patient assessment data, using a standardized patient assessment instrument (PAI) developed by the Secretary, for RY 2028 (FY 2028) and each subsequent rate year. We refer readers to section IV.B of this proposed rule in which we solicit public comment on the development of this PAI.

We refer readers to the FY 2019 IPF PPS final rule (83 FR 38589) for a discussion of the background and statutory authority of the IPFQR Program. We have codified procedural requirements and reconsideration and appeals procedures for IPFQR Program decisions in our regulations at 42 CFR 412.433 and 412.434. Consistent with previous IPFQR Program regulations, we refer to both inpatient psychiatric hospitals and psychiatric units as ''facilities'' or ''IPFs.'' This usage follows the terminology in our IPF PPS regulations at § 412.402.

For additional information on procedural requirements related to statutory authority, participation and withdrawal, data submission, quality measure retention and removal, extraordinary circumstances exceptions, and public reporting we refer readers to 42 CFR 412.433 Procedural requirements under the IPFQR Program.

For the IPFQR Program, we refer to the year in which an IPF would receive the 2-percentage point reduction to the annual update to the standard Federal rate as the *payment determination* year. An IPF generally meets IPFQR Program requirements by submitting data on specified quality measures in a specified time and manner during a *data submission period* that occurs prior to the payment determination year. These data reflect a period prior to the data submission period during which the IPF furnished care to patients; this period is known as the *performance period.* For example, for a measure for which CY 2025 is the performance period which is required to be submitted in CY 2026 and affects FY 2027 payment determination, if an IPF did not submit the data for this measure as specified during CY 2026 (and meets all other IPFQR Program requirements for the FY 2027 payment determination) we would reduce by 2-percentage points that IPF's update for the FY 2027 payment determination year.

B. Measure Adoption

We strive to put patients and caregivers first, ensuring they are empowered to partner with their clinicians in their healthcare decision making using information from data driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with our programs. In combination with other efforts across HHS, we believe the IPFQR Program helps to incentivize IPFs to improve healthcare quality and value while giving patients and providers the tools and information needed to make the best individualized decisions. Consistent with these goals, our objective in selecting quality measures for the IPFQR Program is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have primarily focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. When possible, we also propose to incorporate measures that directly evaluate patient outcomes and experience. We refer readers to the CMS National Quality Strategy,[17] the Behavioral Health Strategy,[18] the Framework for Health Equity,[19] and the Meaningful Measures Framework [20] for information related to our priorities in selecting quality measures.

1. Measure Selection Process

Section 1890A(a) of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the CBE contracted under 1890(a) of the Act, to solicit input from multi-stakeholder groups on the selection of quality and efficiency measures for the IPFQR Program. Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of Measures Under Consideration (MUC list), which is published annually. Following publication on the MUC list, a multi-stakeholder group convened by the CBE reviews the measures under consideration for the IPFQR Program, among other federal programs, and provides input on those measures to the Secretary. Under the Partnership for Quality Measurement (PQM), which is convened by the entity which currently holds the contract under 1890(a) of the Act, this process is known as the Pre-Rulemaking Measure Review (PRMR). We consider the input and recommendations provided by this multi-stakeholder group in selecting all measures for the IPFQR Program, including the 30-Day Risk-Standardized All-Cause Emergency Department (ED) Visit Following an IPF Discharge measure discussed in this proposed rule.

used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

[17] Schreiber, M, Richards, A, et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

[18] CMS. (2022). CMS Behavioral Health Strategy. Available at *https://www.cms.gov/cms-behavioral-health-strategy.*

[19] CMS. (2022). CMS Framework for Health Equity 2022–2032. Available at *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[20] CMS. (2023). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20.* Accessed on March 20, 2024.

2. Proposal To Adopt the 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge Measure Beginning With the CY 2025 Performance Period/FY 2027 Payment Determination

a. Background

We have consistently stated our commitment to identifying measures that examine the care continuum for patients with mental health conditions and substance use disorders and to quantify outcomes following IPF-discharge (see for example, the adoption of the Medication Continuation Following Hospitalization in an IPF measure in the FY 2020 IPF PPS Final Rule, 84 FR 38460 through 38462). Post-discharge outcomes are an important part of our measurement strategy because patient-centered discharge planning and coordination of care for patients with any combination of mental health conditions and substance use disorders improves long-term outcomes, including reducing readmissions and other post-discharge acute care services.[21] [22]

Although not all post-discharge acute care visits are preventable, there are actions that the IPF can take to maximize the chance for patients' successful community reintegration.[23] For example, care transition models to reduce the need for additional acute care following an inpatient stay have been adapted to the inpatient psychiatric setting. To implement these models, IPFs may need to consider how to include the patient and their caregivers, including family, in discharge planning, how to communicate with post-discharge providers, and how to ensure whole-person care for patients during and following their discharge.[24] Specifically, IPFs may need to assist patients in connecting with outpatient providers, such as coordinating with the patient and their caregiver to schedule the patient's first post-discharge follow-up appointment, arranging for the patient's intensive outpatient (IOP) care, or connecting to peer support services. Additionally, IPFs may need to identify and address barriers patients may face in accessing medications and adhering to scheduled post-discharge follow-up appointments. Barriers may include financial factors, transportation, and childcare, which may necessitate support from social services, beginning during hospitalization and continuing after discharge.[25] [26] Barriers may also include the patient's concerns regarding the stigmatization associated with seeking care post-discharge. This can be addressed through treatment provided during the IPF stay.[27] [28] Improvements in patient experience of care and patient-centeredness of care have been associated with improved follow-up post-discharge and a reduction in patients requiring post-discharge acute care.[29] [30] In summary, by proactively addressing potential barriers to post-charge care, improving patient experience of care and patient-centeredness of care, and implementing care transition models, IPFs can reduce the need for post-discharge acute care.

The IPFQR Program currently has three measures that assess post-discharge outcomes: (1) Follow-up After Psychiatric Hospitalization (FAPH); (2) Medication Continuation Following Inpatient Psychiatric Discharge; and (3) Thirty Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization (CBE #2860, the IPF Unplanned Readmission measure). Each of these measures serves a unique role in assessing care coordination and post-discharge outcomes.

The FAPH measure, which we adopted in the FY 2022 IPF PPS Final Rule (86 FR 42640 through 42645), uses Medicare FFS claims to determine the percentage of inpatient discharges from an IPF stay for which the patient received a follow-up visit for treatment of mental illness. The FAPH measure represents an important component of post-discharge care coordination, specifically the transition of care to an outpatient provider. However, this measure does not quantify patient outcomes.

The Medication Continuation Following Inpatient Psychiatric Discharge measure, which we adopted in FY 2020 IPF PPS Final Rule (84 FR 38460 through 38465), assesses whether patients admitted to IPFs with diagnoses of Major Depressive Disorder (MDD), schizophrenia, or bipolar disorder filled at least one evidence-based medication prior to discharge or during the post-discharge period. Medication continuation is important for patients discharged from the IPF setting with these disorders because of significant negative outcomes associated with non-adherence to medication regimes. However, this measure does not quantify patient outcomes with respect to the use of acute care services post-discharge.

The IPF Unplanned Readmission measure, which we adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57241 through 57246), assesses outcomes associated with worsening condition, potentially due to insufficient discharge planning and post-discharge care coordination, by assessing post-discharge use of acute care. The IPF Unplanned Readmission measure estimates the incidence of unplanned, all-cause readmissions to IPFs or short-stay acute care hospitals following discharge from an eligible IPF index admission. A readmission is defined as any admission that occurs within 3 to 30 days after the discharge date from an eligible index admission to an IPF, except those considered planned.[31] However, this measure does not quantify the proportion of patients 18 and older with an ED visit, without

[21] Nelson, E.A. Maruish, M.E., Axler, J.L. Effects of Discharge Planning with Outpatient Appointments on Readmission Rates. *https://ps.psychiatryonline.org/doi/10.1176/appi.ps.51.7.885*.

[22] Steffen S, Kösters M, Becker T, Puschner B. Discharge planning in mental health care: a systematic review of the recent literature. Acta Psychiatr Scand. 2009 Jul;120(1):1–9. doi: 10.1111/j.1600–0447.2009.01373.x. Epub 2009 Apr 8. PMID: 19486329.

[23] Haselden, M., Corbeil, T., Tang, F., Olfson, M., Dixon, L.B., Essock, S.M., Wall, M.M., Radigan, M., Frimpong, E., Wang, R., Lamberti, S., Schneider, M., & Smith, T.E. (2019). Family Involvement in Psychiatric Hospitalizations: Associations With Discharge Planning and Prompt Follow-Up Care. Psychiatric Services, 70(10), 860–866. *https://doi.org/10.1176/appi.ps.201900028*.

[24] Pincus, Harold, Care Transition Interventions to Reduce Psychiatric Re-Hospitalizations. National Association of State Mental Health Program Directors. 2015. Available at *https://nasmhpd.org/sites/default/files/Assessment%20%233_Care%20Transitions%20Interventions%20toReduce%20Psychiatric%20Rehospitalization.pdf*. Accessed on January 23, 2024.

[25] Allen, E.M., Call, K.T., Beebe, T.J., McAlpine, D.D., & Johnson, P.J. (2017). Barriers to Care and Healthcare Utilization among the Publicly Insured. Medical Care, 55(3), 207–214. doi:10.1097/MLR.0000000000000644.

[26] Mutschler, C., Lichtenstein, S., Kidd, S.A., & Davidson, L. (2019). Transition experiences following psychiatric hospitalization: A systematic review of the literature. Community Mental Health Journal, 55(8), 1255–1274. doi:10.1007/s10597–019–00413–9.

[27] Allen, E.M., Call, K.T., Beebe, T.J., McAlpine, D.D., & Johnson, P.J. (2017). Barriers to Care and Healthcare Utilization among the Publicly Insured. Medical Care, 55(3), 207–214. doi:10.1097/MLR.0000000000000644.

[28] Mutschler, C., Lichtenstein, S., Kidd, S.A., & Davidson, L. (2019). Transition experiences following psychiatric hospitalization: A systematic review of the literature. Community Mental Health Journal, 55(8), 1255–1274. doi:10.1007/s10597–019–00413–9.

[29] Donisi V, Tedeschi F, Wahlbeck K, Haaramo P, Amaddeo F. Pre-discharge factors predicting readmissions of psychiatric patients: a systematic review of the literature. BMC Psychiatry. 2016 Dec 16;16(1):449. doi: 10.1186/s12888–016–1114–0. PMID: 27986079; PMCID: PMC5162092.

[30] Morgan C Shields, Mara A G Hollander, Alisa B Busch, Zohra Kantawala, Meredith B Rosenthal, Patient-centered inpatient psychiatry is associated with outcomes, ownership, and national quality measures, Health Affairs Scholar, Volume 1, Issue 1, July 2023, qxad017, *https://doi.org/10.1093/haschl/qxad017*.

[31] *https://p4qm.org/measures/2860*.

subsequent admission, within 30 days of discharge from an IPF. Without collecting this information in a measure, we believe there is a gap in our understanding regarding patients' successful reintegration into their communities following their IPF discharge.

To further understand this gap, we analyzed post-discharge outcomes using claims data. In this analysis, we determined that, for patients discharged from IPFs, the risk-adjusted rate of ED visits after an IPF discharge between June 1, 2019 and July 31, 2021 (excluding the first two quarters of 2020 due to the COVID–19 public health emergency) was 20.7 percent. The rate of readmissions captured under the IPF Unplanned Readmission measure for this same period was 20.1 percent.[32] This means that approximately 40 percent of patients discharged from an IPF had either an ED visit or an unplanned readmission within 30-days of IPF discharge, but only about half of those visits are being captured in the publicly reported IPF Unplanned Readmission measure. Visits to an ED within 30 days of discharge from an IPF (regardless of whether that visit results in a hospital readmission, observation stay, discharge, or patient leaving without being seen) often indicate deteriorating or heightened mental or physical health needs. That is, these visits often represent a patient seeking care for symptoms that were present during the patient's stay in the IPF, regardless of whether the symptom was the reason for the admission, that have become worse for the patient in the time since discharge. Therefore, we believe that IPFs and the public would benefit from having these data made publicly available to inform care decisions and quality improvement efforts. Specifically, members of the public could use these data to inform care decisions and IPFs could use these data to compare their performance to that of similar IPFs. For example, by having these data publicly reported IPFs could compare their performance with that of other IPFs with similar patient populations, a comparison which is not possible without this measure. If IPFs identified that other IPFs with similar patient populations had better rates of post-discharge ED visits (that is, other IPFs had fewer patients seek care in an ED within 30 days of discharge from the IPF), the IPF could identify a need to evaluate discharge planning and post-discharge care coordination to identify process changes which could improve outcomes.

To address this gap, we developed and are proposing the inclusion of the new, claims-based 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge measure (the IPF ED Visit measure) in the IPFQR program beginning with the CY 2025 performance period/FY 2027 payment determination. This proposed IPF ED Visit measure aims to provide information to patients, caregivers, other members of the public, and IPFs about the proportion of patients who seek care in ED in the 30 days following discharge from an IPF, but are not admitted as an inpatient to an acute care hospital or IPF. This proposed measure would assess the proportion of patients 18 and older with an ED visit, including observation stays, for any cause, within 30 days of discharge from an IPF, without subsequent admission.

We recognize that not all post-discharge ED visits are preventable, nor are all post-discharge ED visits associated with the initial IPF admission. However, we developed an all-cause ED visit rate, as opposed to a more narrowly focused measure of ED admissions for mental health or substance use concerns, for three primary reasons. First, such a measure aligns most closely with the IPF Unplanned Readmission measure as this measure is also an all-cause measure. Second, an all-cause measure emphasizes the importance of whole-person care for patients. Whole-person care, during the inpatient stay and through referral at discharge, includes addressing the conditions that may jeopardize a patient's health, but are not the reason for admission to the IPF, if the IPF has reason to identify these conditions during the course of treatment. For example, if an IPF were to identify through metabolic screening that a patient has diabetes, it would be appropriate for that IPF to recommend appropriate follow-up for that patient, such as with a primary care provider, endocrinologist, or dietician. Such post-discharge coordination of care could prevent the patient from seeking acute care after discharge from the IPF for complications of diabetes, such as diabetic ketoacidosis. Third, this measure includes ED visits for all conditions because patients visiting the ED may do so for physical symptoms associated with a mental health condition or substance use disorder. An example is a patient with anxiety that presents to the ED with chest pain and shortness of breath. If the clinician documents the primary diagnosis as chest pain (R07.9) or shortness of breath (R06.02), the patient would not be included in a mental health and substance use-specific IPF ED Visit measure, despite their history of anxiety (F41.9), a potential contributor to their presenting symptoms at the ED. We recognize that it is possible that such a visit may not be related to the patient's anxiety. However, while not all acute care visits after discharge from an IPF are preventable or necessarily related to the quality of care provided by the IPF, there is evidence that improvements in the quality of care for patients in the IPF setting can reduce rates of patients seeking acute care after discharge from an IPF, representing an improved outcome for patients.[33]

Additionally, we considered whether 30 days was an appropriate timeframe for this measure. That is, we sought to identify whether a measure that assessed post-discharge ED visits over a period shorter or longer than 30 days would be more appropriate. Because IPFs are already familiar with interpreting data for the 30-day period in the IPF Unplanned Readmission measure, we determined that it would be appropriate to maintain the 30-day period for the IPF ED Visit measure. Additionally, by maintaining the same timeframe as the IPF Unplanned Readmission measure, we can provide IPFs and patients with a more complete picture of acute care among IPF patients after discharge from the IPF.

Pursuant to the Meaningful Measures 2.0 Framework (a CMS initiative that identifies priority domains for measures within CMS Programs[34]), this measure addresses the ''Seamless Care Coordination'' and the ''Person-Centered Care'' quality domains by encouraging facilities to provide patient-centric discharge planning and support post-discharge care transitions. The IPF ED Visit measure also aligns with the CMS National Quality Strategy Goals[35] of ''Engagement'' and ''Outcomes and Alignment.'' It supports outcomes and

[32] As depicted in the April 2023 file available at *https://data.cms.gov/provider-data/archived-data/hospitals.*

[33] See for instance Chung, D.T., Ryan, C.J., Hadzi-Pavlovic, D., Singh, S.P., Stanton, C., & Large, M.M. (2017). Suicide rates after discharge from psychiatric facilities: A systematic review and meta-analysis. JAMA Psychiatry, 74(7), 694–702. *https://doi.org/10.1001/jamapsychiatry.2017.1044* or Durbin, J., Lin, E., Layne, C., et al. (2007). Is readmission a valid indicator of the quality of inpatient psychiatric care? Journal of Behavioral Health Services Research, 34, 137–150. doi:10.1007/s11414- 007–9055–5.

[34] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20.*

[35] Schreiber, M, Richards, A, et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

alignment because this measure provides a quantified estimate of one post-discharge outcome that patients may experience, that is a post-discharge acute care visit that does not result in an admission. It also supports the Behavioral Health Strategy [36] domains of ''Quality of Care'' and ''Equity and Engagement'' because engaging patients to improve post-discharge outcomes is an element of providing quality care. Furthermore, similar to the Meaningful Measures domain of ''Person-Centered Care,'' this measure supports the Universal Foundation domain of ''Person-Centered Care.''

b. Overview of Measure

The IPF ED Visit measure was developed with input from clinicians, patients, and policy experts; the measure was subject to the pre-rulemaking process required by section 1890A of the Act, as discussed further in section V.B.1 of this rule. Consistent with the CMS key elements of the CMS Measure Development Lifecycle,[37] we began with measure conceptualization during which we performed a targeted literature review and solicited input from a behavioral health technical expert panel (TEP). This allowed us to ensure that this topic addresses a gap that is important to interested parties. After confirming this, we developed the measure specifications for the IPF ED Visit measure. With these specifications, we issued a 30-day call for public comment in the **Federal Register** and performed empirical testing using claims data, including modeling for risk-adjustment. After refining the measure specifications based on testing and public comment, we performed an equity analysis in which we tested the risk-adjustment methodology to ensure that the measure does not reflect access issues related to patient demographics instead of quality of care. By following steps in accordance with the Measure Development Lifecycle, we sought to ensure that this is a vetted, valid, reliable, and ready-to-implement claims-based measure which would assess the proportion of patients 18 and older with an ED visit, including observation stays, for any cause, within 30 days of discharge from an IPF, without subsequent admission. By using the same definitions of index admission and patient populations as those used in the IPF Unplanned Readmission measure, we have designed the IPF ED Visit measure to complement the IPF Unplanned Readmission measure to the extent possible. We have also sought to minimize administrative burden by developing this as a claims-based measure so that it adds no information collection burden to clinicians and staff working in the IPF setting.

(1) Measure Calculation

The focus population for this measure is adult Medicare FFS patients with a discharge from an IPF. The measure is based on all eligible index admissions from the focus population. An eligible index admission is defined as any IPF admission for which the patient meets the following criteria: (1) age 18 or older at admission; (2) discharged alive from an IPF; (3) enrolled in Medicare FFS Parts A and B during the 12 months before the admission date, the month of admission, and at least one month after the month of discharge from the index admission (that is, the original stay in an IPF); and (4) discharged with a principal diagnosis that indicates a psychiatric disorder. Excluded from the measure are patients discharged against medical advice (AMA) from the IPF index admission (because the IPF may not have had the opportunity to conduct full discharge planning for these patients); patients with unreliable data regarding death demographics or a combination thereof in their claims record (because these data are unreliable, they may lead to inaccuracies in the measure calculation); patients who expired during the IPF stay (because post-discharge care is not applicable to these patients); patients with a discharge resulting in a transfer to another care facility (because the receiving care facility would be responsible for discharge planning for these patients); and patients discharged but readmitted within 3 days of discharge, also known as an interrupted stay (because interrupted stays are often reflective of patient needs outside of the IPF, such as treatment for another condition).

To calculate the measure, we would use the following data sources which are all available from Medicare administrative records and data submitted by providers through the claims process: (1) Medicare beneficiary and coverage files, which provide information on patient demographic, enrollment, and vital status information to identify the measure population and certain risk factors; (2) Medicare FFS Part A records, which contain final action claims submitted by acute care and critical access hospitals, IPFs, home health agencies, and skilled nursing facilities to identify the measure population, readmissions, and certain risk factors; and (3) Medicare FFS Part B records, which contain final action claims submitted by physicians, physician assistants, clinical social workers, nurse practitioners, and other outpatient providers to identify certain risk factors. To ensure that diagnoses result from encounters with providers trained to establish diagnoses, this measure would not use claims for services such as laboratory tests, medical supplies, or other ambulatory services. Index admissions and ED visits would be identified in the Medicare FFS Part A records. Comorbid conditions for risk-adjustment would be identified in the Medicare Part A and Part B records in the 12 months prior to admission, including the index admission. Demographic and FFS enrollment data would be identified in the Medicare beneficiary and coverage files.

To calculate the IPF ED Visit measure, CMS would: (1) identify all IPF admissions in the one-year performance period; (2) apply inclusion and exclusion criteria to identify index admissions; (3) identify ED visits and observation stays within 30 days of discharge from each index admission; (4) identify risk factors in the 12 months prior to index admission and during the index admission; and (5) run hierarchical logistic regression to compute the risk-standardized ED visit rate for each IPF.[38] This hierarchical logistic regression would allow us to apply the risk-adjustment factors developed in measure testing to ensure that measure results are comparable across IPFs regardless of the clinical complexity of each IPF's patient population.

(2) Pre-Rulemaking Measure Review and Measure Endorsement

As required under section 1890A of the Act, the CBE established the Partnership for Quality Measurement (PQM) to convene clinicians, patients, measure experts, and health information technology specialists to participate in the pre-rulemaking process and the measure endorsement process. The pre-rulemaking process, also called the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the PQM for the purpose

[36] CMS. (2022). CMS Behavioral Health Strategy. Available at *https://www.cms.gov/cms-behavioral-health-strategy*.

[37] *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview*.

[38] For an example of the hierarchal logistic risk-adjustment algorithm, we refer readers to the algorithm for the IPF Unplanned Readmission measure at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/downloads/inpatient-psychiatric-facility-readmission-measure.zip*.

of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the IPFQR Program. The PRMR process includes opportunities for public comment through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within five days of the close of the public comment period.[39] More details regarding the PRMR process may be found in the CBE's Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review, including details of the measure review process in Chapter 3.[40]

The CBE-established PQM also conducts the measure endorsement and maintenance (E&M) process to ensure measures submitted for endorsement are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver-level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level, and are consistent across types of health care providers, including hospitals and physicians (see section 1890(b)(2) of the Act). The PQM convenes several E&M project groups twice yearly, formally called E&M Committees, each comprised of an E&M Advisory Group and an E&M Recommendations Group, to vote on whether a measure meets certain quality measure criteria. More details regarding the E&M process may be found in the E&M Guidebook, including details of the measure endorsement process in the section titled, ''Endorsement and Review Process.'' [41]

As part of the PRMR process, the IPF ED Visit measure was reviewed during the PRMR Hospital Recommendation Group meeting on January 18, 2024. For the voting procedures of the PRMR and E&M process, the PQM utilized the Novel Hybrid Delphi and Nominal Group (NHDNG) multi-step process, which is an iterative consensus-building approach aimed at a minimum of 75 percent agreement among voting members, rather than a simple majority vote, and supports maximizing the time spent to build consensus by focusing discussion on measures where there is disagreement. For example, the PRMR Hospital Recommendation Group can reach consensus and have the following voting results: (A) Recommend, (B) Recommend with conditions (with 75 percent of the votes cast as recommend with conditions or 75 percent between recommend and recommend with conditions), and (C) Do not recommend. If no voting category reaches 75 percent or greater (including the combined [A] Recommend and [B] Recommend with conditions) the PRMR Hospital Recommendation Group did not come to consensus and the voting result is ''Consensus not reached.'' Consensus not reached signals continued disagreement amongst the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. More details regarding the PRMR voting procedures may be found in Chapter 4 of the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.[42] More details regarding the E&M voting procedures may be found in the PQM Endorsement and Maintenance (E&M) Guidebook.[43] The PRMR Hospital Recommendation Group [44] reached consensus and recommended including this measure in the IPFQR Program with conditions.

Seven members of the group recommended adopting the measure into the IPFQR program without conditions; eleven members recommended adoption with conditions; and one committee member voted not to recommend the measure for adoption. Taken together, 94.73 percent of the votes were between recommend & recommend with conditions.

The conditions specified by the PRMR Hospital Recommendation Group were: (1) that the measure be considered for endorsement by a consensus-based entity; and (2) further consideration of how the measure addresses 72-hour transfers to the ED. We have taken those considerations into account and are proposing this measure for adoption because we believe we have adequately addressed the concerns raised by those considerations.

To address the first condition, we have submitted the measure to the CBE for consideration. For more information on submission to and consideration by the CBE we refer readers to section V.B.2.b.(3) of this rule.

The second voting condition requested that we further consider how the measure addresses 72-hour transfers to the ED because of concerns that IPFs may appear to have worse performance if ''interrupted stays'' are not excluded from the measure. An ''interrupted stay'' occurs when a patient is discharged from an IPF and readmitted to the same IPF within 72 hours. This frequently occurs when a patient needs medical treatment that is beyond the scope of the IPF, such as care in an ED for an emergent health issue. We believe that this concern is sufficiently addressed in the ED Visit measure's specifications because these ''interrupted stays'' are excluded from the measure, as described in section V.B.2.b.(1) of this rule. This exclusion is defined as an index admission with a readmission on Days 0, 1, or 2 post-discharge. In other words, patients transferred to the ED and subsequently readmitted to the IPF within 72 hours are excluded from the measure. Therefore ''interrupted stays'' are excluded from the measure as per the group's recommendation.

(3) CBE Endorsement

Section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (that is, the CBE). After a measure has been submitted to the CBE, the committee responsible for reviewing the measure evaluates the measure on five domains: (1) Importance; (2) Feasibility; (3) Scientific Acceptability (that is, reliability and validity); (4) Equity; and (5) Use and Usability. Committee members evaluate whether the measure the domain is ''Met'', ''Not Met but Addressable'' or ''Not Met'' for each domain using a set of criteria provided by the CBE.[45] When a measure is submitted it is assigned to one of the CBE's projects based on where in the patient's healthcare experience the measure has the most relevance. The five projects are (1) Primary Prevention; (2) Initial Recognition and Management; (3) Management of Acute Events, Chronic Disease, Surgery, Behavioral Health; (4) Advanced Illness and Post-Acute Care; and (5) Cost and Efficiency.

The measure developer submitted the measure for CBE endorsement consideration in the Fall 2023 review

[39] These materials are available at the PRMR section of the PQM website: *https://p4qm.org/PRMR.*

[40] *https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf.*

[41] The Partnership for Quality Measurement. (October 2023). Endorsement and Maintenance (E&M) Guidebook. Available at: *https://p4qm.org/sites/default/files/2023-12/Del-3-6-Endorsement-and-Maintenance-Guidebook-Final__0.pdf.*

[44] We note that the PRMR Hospital Recommendation Group was previously the Measure Applications Partnership (MAP) Hospital Workgroup under the pre-rulemaking process followed by the previous CBE.

[45] *https://p4qm.org/EM.*

cycle. The measure was assigned to the Cost and Efficiency Project. The CBE Cost and Efficiency Endorsement committee met on January 31, 2024 and did not reach consensus regarding the IPF ED Visit measure, with 60.6 percent voting in favor of endorsement or endorsement with conditions and the remaining members voting to not endorse, which is below the 75 percent threshold necessary for the endorsement of the measure, as described in V.B.2.b. During the Cost and Efficiency Endorsement committee's meeting, members of the committee discussed whether an all-cause measure was appropriate and whether IPFs are able to implement interventions to reduce post-discharge acute care.[46]

As discussed in section V.B.2.a of this proposed rule, an all-cause measure would complement the IPF Unplanned Readmission measure, would emphasize whole-person care, and would capture visits to the ED for patients with physical symptoms associated with mental health conditions. Additionally, evidence shows that there are interventions that reduce post-discharge acute care. These include adopted care transition models, proactively connecting patients with post-discharge providers, identifying and addressing patients' barriers to post-discharge care, and focusing on providing patient-centered care and improving patient experience of care.

Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) of the Act states that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We have determined that this is an appropriate topic for the adoption of a measure absent CBE endorsement because where possible we focus on measures that assess patient outcomes. Unplanned use of acute care after discharge from an IPF is often associated with worsening condition, potentially due to insufficient discharge planning and post-discharge care coordination. While the IPFQR Program currently has a measure that assesses unplanned readmissions after discharge from an IPF, there is a gap in the measure set with respect to unplanned ED visits without a subsequent admission to an acute care hospital or IPF. The IPF ED Visit measure fills that gap. We also reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures that assess outcomes that solely result in a patient's ED visit after the patient's discharge from an IPF. The only endorsed measure that we identified that addresses an IPF patient seeking acute care after discharge is the IPF Unplanned Readmission measure. As we discussed previously, the IPF Unplanned Readmission measure does not assess ED visits that do not result in an admission. Therefore, we believe that the IPF ED Visit measure is an important complement to the IPF Unplanned Readmission measure. We did not find any other measures that assess post-discharge ED visits without a subsequent admission, and therefore the exception in section 1886(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission, and Reporting

Because all files used to calculate the IPF ED Visit measure are available on Medicare claims, this measure requires no additional data collection or submission by IPFs. We are proposing a reporting period beginning with data from CY 2025 performance period/FY 2027 payment determination year.

C. Summary of IPFQR Program Measures for the FY IPFQR Program

We are proposing one new measure for the FY 2027 IPFQR Program. If we finalize adoption of this measure, the FY 2027 IPFQR Program measure set would include 16 mandatory and one voluntary measure. Table 22 sets forth the measures in the FY 2027 IPFQR Program.

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[46] For information about the Cost and Efficiency endorsement review we refer readers to the meeting summary, available at *https://p4qm.org/sites/default/files/Cost%20and%20Efficiency/material/EM-Cost-and-Efficiency-Fall2023-Endorsement-Meeting-Summary.pdf.*

TABLE 22: IPFQR PROGRAM MEASURE SET FOR THE FY 2027 IPFQR PROGRAM

CBE #	Measure ID	Measure
Required Measures		
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
N/A	FAPH	Follow-Up After Psychiatric Hospitalization
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility
N/A	N/A	30-Day Risk-Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge measure[1]
3205*	Med Cont.	Medication Continuation Following Inpatient Psychiatric Discharge
N/A	N/A	Modified COVID-19 Healthcare Personnel (HCP) Vaccination Measure
N/A	Facility Commitment	Facility Commitment to Health Equity
N/A	Screening for SDOH	Screening for Social Drivers of Health
N/A	Screen Positive	Screen Positive Rate for Social Drivers of Health
Voluntary Measure		
N/A	PIX	Psychiatric Inpatient Experience Survey[2]

* Measure is no longer endorsed by the CBE but was endorsed at the time of adoption. We note that although section 1886(s)(4)(D)(i) of the Act generally requires measures specified by the Secretary be endorsed by the entity with a contract under section be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

[1] Measure proposed for adoption in Section V.B.2. of this proposed rule.

[2] We note that the PIX measure will become mandatory for the FY 2028 payment determination, as finalized in the FY 2024 IPF PPS Final Rule (88 FR 51128).

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D. Proposal To Modify Data Submission Requirements for the FY 2027 Payment Determination and Subsequent Years

Section 1886(s)(4)(C) of the Act requires the submission of quality data in a form and manner, and at a time, specified by the Secretary. In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and fiscal year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers (FY 2013 IPPS/LTCH PPS) final rule (77 FR 53655), we specified that data must be submitted between July 1 and August 15 of the calendar year preceding a given payment determination year (for example, data were required to be submitted between July 1, 2015 and August 15, 2015 for the FY 2016 payment determination). In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and fiscal year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status (FY 2014 IPPS/LTCH PPS) final rule (78 FR 50899), we clarified that this policy applied to all future years of data submission for the IPFQR Program unless we changed the policy through future rulemaking.

In the FY 2018 IPF PPS final rule (82 FR 38472 through 38473) we updated this policy by stating that the data submission period will be a 45-day period beginning at least 30 days

following the end of the data collection period and that we will provide notification of the exact dates through subregulatory means.

In the FY 2022 IPF PPS Final Rule (86 FR 42658 through 42661), we finalized voluntary patient-level data reporting for the FY 2023 payment determination and mandatory patient-level data reporting for chart-abstracted measures within the IPFQR Program beginning with FY 2024 payment determination and subsequent years. The measures currently in the IPFQR Program affected by this requirement are set forth in Table 23.

TABLE 23: IPFQR PROGRAM MEASURES REQURING PATIENT-LEVEL DATA SUBMISSION

CBE #	Measure ID	Measure
Required Measures		
0640	HBIPS-2	Hours of Physical Restraint Use (numerator only)
0641	HBIPS-3	Hours of Seclusion Use (numerator only)
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders

As we have gained experience with patient-level data submission for the IPFQR program, during the voluntary data submission period for FY 2023 (which occurred in CY 2022) and the first mandatory data submission period for FY 2024 (which occurred in CY 2023), we have observed that annual data submission periods require IPFs to store large volumes of patient data to prepare for transmission to CMS. Furthermore, the volume of data associated with all IPFs reporting a full year of patient-level data during one data submission period creates the risk that systems will be unable to handle the volume of data.

We have reviewed how other quality reporting programs that require patient-level data submission address these concerns and determined that the Hospital Inpatient Quality Reporting (IQR) Program (78 FR 50811) and the Hospital Outpatient Quality Reporting (OQR) Program (72 FR 66872) both require quarterly submission of patient-level data. As we considered requiring quarterly reporting for the IPFQR Program, we also determined that increasing the frequency of data submission would allow additional analysis of measure trends over time. We believe that having additional data points (from additional quarters of data) could allow for more nuanced analyses of the IPFQR Program's measures. Specifically, we would be able to better identify quarterly highs or lows that may be less apparent when data are combined over a full year. We recognize that, if we update data reporting requirements to require reporting four times per year instead of once per year, then IPFs would need to meet four incremental deadlines instead of one deadline, and that this increases the risk that an individual IPF may fail to submit data specified for the measures and not receive its full market basket update. However, we believe that this risk is low because IPFs already have experience submitting some data required by the IPFQR Program on a more frequent basis. Specifically, the COVID–19 Healthcare Personnel (HCP) Vaccination Measure is currently reported into the CDC's National Healthcare Safety Network (NHSN) for one week per month resulting in a quarterly measure result (as originally adopted in the FY 2022 IPF PPS final rule (86 FR 42636) and restated in the FY 2024 IPF PPS final rule (88 FR 51131 through 51132). In addition, if this proposal for quarterly data submission is finalized, data submission for each calendar quarter would be required during a period of at least 45 days beginning three months after the end of the calendar quarter. Table 24 summarizes these proposed deadlines for the CY 2025 and CY 2026 performance periods:

TABLE 24: QUARTERLY SUBMISSION DEADLINES FOR CY 2025 AND CY 2026 PERFORMANCE PERIODS

Performance Period	Submission Deadline
January 1, 2025- March 31, 2025 (Q1 2025)	November 15, 2025
April 1, 2025 – June 30, 2025 (Q2 2025)	November 15, 2025
July 1, 2025 – September 30, 2025 (Q3 2025)	February 15, 2026
October 1, 2025 – December 31, 2025 (Q4 2025)	May 15, 2026
January 1, 2026- March 31, 2026 (Q1 2026)	August 15, 2026
April 1, 2026 – June 30, 2026 (Q2 2026)	November 15, 2026
July 1, 2026 – September 30, 2026 (Q3 2026)	February 15, 2027
October 1, 2026 – December 31, 2026 (Q4 2026)	May 15, 2027

Furthermore, we are proposing that all data which continue to be reported on an annual basis (that is, non-measure data, aggregate measures, and attestations) would be required to be reported concurrently with the data from the fourth quarter of the applicable year. For example, data reflecting the entirety of CY 2025 (that is, non-measure data, aggregate measures, and attestations) would be required by the Q4 2025 submission deadline (that is, May 15, 2026).

We welcome comments on this proposal.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment (see section VI.C of this proposed rule) on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

The following changes will be submitted to OMB for review under control number 0938–1171 (CMS–10432). We are not proposing any changes that would change any of the data collection instruments that are currently approved under that control number.

In section VI.2 of this proposed rule, we restate our currently approved burden estimates. In section VI.3 of this proposed rule, we estimate the changes in burden associated with update more recent wage rates. Then in section VI.4 of this proposed rule, we estimate the changes in burden associated with the policies proposed in this proposed rule.

A. Wage Estimates

In the FY 2024 IPF PPS final rule, we utilized the median hourly wage rate for Medical Records Specialists, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the IPFQR Program (88 FR 51145). While the most recent data from the BLS reflects a mean hourly wage of $24.56 per hour for all medical records specialists, $26.06 is the mean hourly wage for ''general medical and surgical hospitals,'' which is an industry within medical records specialists.[47] We believe the industry of ''general medical and surgical hospitals'' is more specific to the IPF setting for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities (skilled nursing facilities).'' We calculated the cost of indirect costs, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to IPFs using a wage plus benefits estimate of $52.12 per hour throughout the discussion in this section of this rule for the IPFQR Program.

Some of the activities previously finalized for the IPFQR Program require beneficiaries to undertake tasks such as responding to survey questions on their own time. In the FY 2024 IPF PPS final rule, we estimated the hourly wage rate for these activities to be $20.71/hr (88 FR 51145). We are updating that estimate to a post-tax wage of $24.04/hr.

[47] Medical Records Specialists (*bls.gov*).

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time.[48] To derive the costs for beneficiaries, we used a measurement of the usual weekly earnings of wage and salary workers of $1,118, divided by 40 hours to calculate an hourly pre-tax wage rate of $27.95/hr.[49] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[50] resulting in the post-tax hourly wage rate of $24.04/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Previously Finalized IPFQR Estimates

We are finalizing provisions that impact policies beginning with the FY 2027 payment determination. For the purposes of calculating burden, we attribute the costs to the year in which the costs begin. Under our previously finalized policies, data submission for the measures that affect the FY 2027 payment determination occurs during CY 2026 and generally reflects care provided during CY 2025. If we finalize our proposal to switch to quarterly reporting in section XX.X of this proposed rule, data submission for the FY 2027 payment determination would begin during CY 2025. Our currently approved burden for CY 2025 is set forth in Table 25.

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[48] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[49] *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed January 1, 2024.

[50] *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed January 2, 2024.

TABLE 25: PREVIOUSLY IPFQR PROGRAM FOR CY 2025

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate ($/hr)	Cost per Facility ($)	Total Annual Cost ($)
Hours of Physical Restraint Use	1,596	1,261	2,012,556	0.25	315	503,139	44.86	14,142	22,570,816
Hours of Seclusion Use	1,596	1,261	2,012,556	0.25	315	503,139	44.86	14,142	22,570,816
Follow-Up After Psychiatric Hospitalization	1,596	0	0	0	0	0	44.86	0	0
Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Influenza Immunization	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Screening for Metabolic Disorders	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility	1,596	0	0	0	0	0	44.86	0	0
30-Day Risk-Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge measure[1]	1,596	0	0	0	0	0	44.86	0	0
Medication Continuation Following Inpatient Psychiatric Discharge	1,596	0	0	0	0	0	44.86	0	0
Modified COVID-19 Healthcare Personnel (HCP) Vaccination Measure	1,596	0	0	0	0	0	44.86	0	0
Facility Commitment to Health Equity	1,596	1	1,596	0.167	0	267	44.86	7	11,957

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate ($/hr)	Cost per Facility ($)	Total Annual Cost ($)
Screening for Social Drivers of Health (Data Submission)	798	1	798	0.167	0	133	44.86	7	5,978
Screen Positive Rate for Social Drivers of Health	798	1	798	0.167	0	133	44.86	7	5,978
Non Measure Data Collection	1,596	4	6,384	0.5	2	3,192	44.86	90	143,193
Subtotal for Medical Records Specialists	*1,596*	*6,183*	*9,866,472*	*Varies*	*1,547*	*2,467,949*	*44.86*	*69,376*	*110,712,195*
Screening for Social Drivers of Health (Patient Screening)	1,596	1,261	2,012,556	0.033	42	66,414	20.71	862	1,375,441
Psychiatric Inpatient Experience Survey	798	300	239,400	0.121	36	28,967	20.71	752	599,915
Subtotal for Individuals	*1,596*	*1,561*	*2,251,956*	*Varies*	*78*	*95,382*	*20.71*	*1,614*	*1,975,356*
Totals	**1,596**	**7,744**	**12,118,428**	**3.155**	**1,624**	**2,563,331**	**804.04**	**70,990**	**112,687,551**

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C. Updates Due to More Recent Information

In section VI.A of this proposed rule, we described our updated wage rates which increase from $44.86/hr to $52.12/hr (an increase of $7.26/hr) for activities performed by Medical Records Specialists and from $20.71/hr to $24.04/hr (an increase of $3.33/hr) for activities performed by individuals. The effects of these updates are set forth in Table 26.

TABLE 26: EFFECTS OF WAGE RATE UPDATES

Measure/Response Description	Total Annual Responses	Time Per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Change in Applicable Wage Rate ($/hr)	Change in Cost per Facility ($)	Change in Total Annual Cost ($)
Subtotal for Medical Records Specialists	9,866,472	Varies	1,547	2,467,949	7.26	11,228	17,919,245
Subtotal for Individuals	2,251,956	Varies	78	95,382	3.33	259	414,083
Totals	12,118,428	Varies	1,624	2,563,331	Varies	11,487	18,333,328

D. Updates Due to Proposals in This Proposed Rule

In section V.B.2 of this proposed rule, we are proposing to adopt the 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge measure beginning with the CY 2025 performance period/FY 2027 payment determination. As described in section V.B.2.c. of this preamble, we will calculate the 30-Day Risk-Standardized All-Cause ED Visit Following an Inpatient Psychiatric Facility Discharge measure using Medicare claims that IPFs and other providers submit for payment. Since this is a claims-based measure there is no additional burden outside of submitting a claim. The claim submission is approved by OMB under control number 0938–0050 (CMS–2552–10). This rule does not warrant any changes under that control number.

In Section V.D. of this proposed rule, we are proposing to require IPFs to submit data on chart-abstracted measures quarterly. In CY 2025, this would equate to one additional data submission period (that is, the reporting period which would close on November 15, 2025 as set forth in Table 27). In CY 2026, there would be an additional two data submission periods (for a total of four annually). We estimate that the

increase in burden associated with the increase in data submission periods is approximately equal to the burden of reporting one attestation measure because both of these activities require logging into and interacting with user interfaces within the CMS data reporting system (that is, the Hospital Quality System—HQS). The effects of this increase on the IPFQR Program for CY 2025 are set forth in Table 27. The effects of this increase on the IPFQR Program for CY 2026 are set forth in Table 28.

TABLE 27: CY 2025 EFFECTS OF INCREASING BY ONE DATA SUBMISSION PERIOD

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate ($/hr)	Cost per Facility ($)	Total Annual Cost ($)
Addition of one data submission period (for a total of 2)	1,596	1	1,596	0.167	0.167	267	52.12	9	13,892

TABLE 28: CY 2025 EFFECTS OF INCREASING BY ONE DATA SUBMISSION PERIOD

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate ($/hr)	Cost per Facility ($)	Total Annual Cost ($)
Addition of two data submission periods (for a total of 4)	1,596	2	3,192	0.167	0.334	533	52.12	17	27,783

E. Consideration of Burden Related to Clarification of Eligibility Criteria for the Option To Elect To File an All-Inclusive Cost Report

As discussed in section III.E.4 of this proposed rule, we are clarifying the eligibility criteria to be approved to file all-inclusive cost reports. Only government-owned and tribally owned facilities are able to satisfy these criteria, and thus only these facilities will be permitted to file an all-inclusive cost report for cost reporting periods beginning on or after October 1, 2024.

We do not estimate any change in the burden associated with the hospital cost report (CMS–2552–10) OMB control number 0938–0050. We anticipate that IPFs which are currently filing all-inclusive cost reports, but are not government-owned or tribally owned, would not incur additional burden related to the submission of the cost report. The approved burden estimate associated with the submission of the hospital cost report includes the same amount of burden for the submission of an all-inclusive cost report as for the submission of a cost report with a charge structure.

We recognize that these IPFs would be required to track ancillary costs and charges using a charge structure; however, we expect that any burden associated with this tracking would be part of the normal course of a hospital's activities.

F. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule's information collection requirements to OMB for their review. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *https://www.cms.gov/regulationsand-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1806–P), the ICR's CFR citation, and OMB control number.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

This rule proposes updates to the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2025 (October 1, 2024 through September 30, 2025). We are proposing to apply the 2021-based IPF market basket increase of 3.1 percent, reduced by the productivity adjustment of 0.4 percentage point as required by 1886(s)(2)(A)(i) of the Act for a proposed total FY 2025 payment rate update of 2.7 percent. In this proposed rule, we

are proposing to update the outlier fixed dollar loss threshold amount, update the IPF labor-related share, adopt new CBSA delineations based on OMB Bulletin 23–01, and update the IPF wage index to reflect the FY 2025 hospital inpatient wage index. Section 1886(s)(4) of the Act requires IPFs to report data in accordance with the requirements of the IPFQR Program for purposes of measuring and making publicly available information on health care quality; and links the quality data submission to the annual applicable percentage increase.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. We estimate that the total impact of these changes for FY 2025 payments compared to FY 2024 payments will be a net increase of approximately $70 million. This reflects a $75 million increase from the update to the payment rates (+$85 million from the 4th quarter 2023 IGI forecast of the 2021-based IPF market basket of 3.1 percent, and -$10 million for the productivity adjustment of 0.4 percentage point), as well as a $5 million decrease as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 2.1 percent in FY 2024 to 2.0 percent of total estimated IPF payments in FY 2025.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''significant,'' though not significant under section 3(f)(1) of Executive Order 12866. Nevertheless, because of the potentially substantial impact to IPF providers, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

Nevertheless, because of the potentially substantial impact to IPF providers, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''significant.'' Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

In this section, we discuss the historical background of the IPF PPS and the impact of this proposed rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the RY 2005 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. This budget neutrality factor included the following components: outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the RY 2009 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section III.D.1.d of this proposed rule, we are proposing to update the wage index and labor-related share, as well as update the CBSA delineations based on OMB Bulletin 23–01, in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem base rate and ECT payment per treatment. In addition, as discussed in section III.F of this proposed rule, we are proposing to apply a refinement standardization factor to the Federal per diem base rate and ECT payment per treatment to account for the proposed revisions to the ECT per treatment amount, ED adjustment, and patient-level adjustment factors (as previously discussed in sections III.B, III.C, and III.D of this proposed rule, and summarized in Addendum A), which must be made budget-neutrally. Therefore, the budgetary impact to the Medicare program of this proposed rule would be due to the proposed market basket update for FY 2025 of 3.1 percent (see section III.A.2 of this proposed rule) reduced by the productivity adjustment of 0.4 percentage point required by section 1886(s)(2)(A)(i) of the Act and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2025 impact would be a net increase of $70 million in payments to IPF providers. This reflects an estimated $75 million increase from the update to the payment rates and a $5 million decrease due to the update to the outlier threshold amount to set total estimated outlier payments at 2.0 percent of total estimated payments in FY 2025. This estimate does not include the implementation of the required 2.0 percentage point reduction of the productivity-adjusted market basket update factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section III.B.2. of this proposed rule).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this proposed rule, we compare estimated payments under the proposed IPF PPS rates and factors for FY 2025 versus those under FY 2024. We determined the percent change in the estimated FY 2025 IPF PPS payments compared to the estimated FY 2024 IPF PPS payments for each category of IPFs.

In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the proposed update to the outlier fixed dollar loss threshold amount; the proposed revisions to the patient-level adjustment factors, ED adjustment, and ECT per treatment amount; the updated wage index data including the proposed labor-related share and the proposed changes to the CBSA delineations; and the proposed market basket increase for FY 2025, as reduced by the proposed productivity adjustment according to section 1886(s)(2)(A)(i) of the Act.

To illustrate the impacts of the proposed FY 2025 changes in this proposed rule, our analysis begins with FY 2023 IPF PPS claims (based on the 2023 MedPAR claims, December 2023 update). We estimate FY 2024 IPF PPS payments using these 2023 claims, the finalized FY 2024 IPF PPS Federal per diem base rate and ECT per treatment amount, and the finalized FY 2024 IPF PPS patient and facility level adjustment factors (as published in the FY 2024 IPF PPS final rule (88 FR 51054)). We then estimate the FY 2024 outlier payments based on these simulated FY 2024 IPF PPS payments using the same methodology as finalized in the FY 2024 IPF PPS final rule (88 FR 51090 through 51092) where total outlier payments are maintained at 2 percent of total estimated FY 2024 IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The proposed update to the outlier fixed dollar loss threshold amount.
- The proposed revisions to patient-level adjustment factors, ED adjustment, and the ECT per treatment amount.
- The proposed FY 2025 IPF wage index, the proposed changes to the CBSA delineations, and the proposed FY 2025 labor-related share (LRS).
- The proposed market basket increase for FY 2025 of 3.1 percent reduced by the proposed productivity adjustment of 0.4 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 2.7 percent.

Our proposed column comparison in Table 29 illustrates the percent change in payments from FY 2024 (that is, October 1, 2023, to September 30, 2024) to FY 2025 (that is, October 1, 2024, to September 30, 2025) including all the proposed payment policy changes.

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TABLE 29: FY 2025 IPF PPS PROPOSED PAYMENT IMPACTS

Facility by Type[1]	Number of Facilities	Outlier	Refinement of Patient-Level Adjustments and ECT	Wage Index FY25, LRS, and 5% Cap	Total Percent Change[2]
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
All Facilities	1,430	-0.1	0.0	0.0	2.6
Total Urban	1,171	-0.1	0.0	-0.2	2.4
Urban unit	655	-0.1	0.4	-0.5	2.5
Urban hospital	516	0.0	-0.5	0.2	2.3
Total Rural	259	0.0	0.0	1.3	4.0
Rural unit	199	0.0	0.3	1.1	4.1
Rural hospital	60	0.0	-0.7	1.7	3.7
By Type of Ownership:					
Freestanding IPFs					
Urban Psychiatric Hospitals					
Government	117	-0.1	1.0	-0.6	2.9
Non-Profit	98	0.0	-0.2	-0.1	2.4
For-Profit	301	0.0	-0.9	0.4	2.2
Rural Psychiatric Hospitals					
Government	30	-0.1	1.5	0.0	4.2
Non-Profit	12	-0.1	-1.5	-0.1	1.0
For-Profit	18	0.0	-1.4	2.9	4.1
IPF Units					
Urban					
Government	95	-0.2	0.7	-0.3	2.9
Non-Profit	436	-0.1	0.6	-0.8	2.4
For-Profit	124	0.0	-0.5	0.2	2.4
Rural					
Government	45	0.0	0.0	0.9	3.6
Non-Profit	114	-0.1	0.5	1.2	4.4
For-Profit	40	0.0	0.2	1.2	4.1
By Teaching Status:					
Non-teaching	1,230	-0.1	-0.2	0.3	2.7
Less than 10% interns and residents to beds	104	-0.1	0.6	-0.9	2.3

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Facility by Type[1]	Number of Facilities	Outlier	Refinement of Patient-Level Adjustments and ECT	Wage Index FY25, LRS, and 5% Cap	Total Percent Change[2]
10% to 30% interns and residents to beds	71	-0.1	1.1	-1.2	2.4
More than 30% interns and residents to beds	25	-0.2	1.0	-1.1	2.4
By Region:					
New England	102	-0.1	0.8	-1.3	2.1
Mid-Atlantic	193	-0.1	0.2	-1.5	1.2
South Atlantic	226	0.0	0.4	0.9	4.0
East North Central	228	0.0	0.0	0.2	2.9
East South Central	140	0.0	-0.1	2.5	5.0
West North Central	99	-0.1	1.1	0.3	3.9
West South Central	214	0.0	-1.0	1.7	3.3
Mountain	102	0.0	-0.4	1.1	3.4
Pacific	126	-0.1	-0.5	-1.6	0.5
By Bed Size:					
Psychiatric Hospitals					
Beds: 0-24	87	0.0	-0.8	0.6	2.5
Beds: 25-49	87	0.0	-1.1	1.0	2.6
Beds: 50-75	92	0.0	-0.4	0.8	3.1
Beds: 76 +	310	0.0	-0.4	0.0	2.2
Psychiatric Units					
Beds: 0-24	450	-0.1	0.2	0.4	3.2
Beds: 25-49	234	-0.1	0.5	-0.7	2.4
Beds: 50-75	98	-0.1	0.7	0.2	3.5
Beds: 76 +	72	-0.2	0.5	-1.1	1.9

[1] Providers in this table are classified as urban or rural based on the current CBSA delineations for FY 2024.
[2] This column includes the impact of the updates in columns (3) through (6) above, and of the proposed IPF market basket percentage increase for FY 2025 of 3.1 percent, reduced by 0.4 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act.

3. Impact Results

Table 30 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services file, the IPF PSF, and cost report data from the Healthcare Cost Report Information System:

- Facility Type.
- Location.
- Teaching Status Adjustment.
- Census Region.
- Size.

The top row of the table shows the overall impact on the 1,430 IPFs included in the analysis. In column 2, we present the number of facilities of each type that had information available in the PSF, had claims in the MedPAR dataset for FY 2023. We note that providers are assigned urban or rural status in Table 30 based on the current CBSA delineations for FY 2024.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 2.1 percent in FY 2024. Therefore, we are proposing to adjust the outlier threshold amount to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2025. The estimated change in total IPF payments for FY 2025, therefore, includes an approximate 0.1 percent decrease in payments because we would expect the outlier portion of total payments to decrease from approximately 2.1 percent to 2.0 percent.

The overall impact of the estimated decrease to payments due to updating the outlier fixed dollar loss threshold (as shown in column 3 of Table 30), across all hospital groups, is a 0.1 percent decrease. The largest decrease in payments due to this change is estimated to be 0.2 percent for urban government IPF units, IPFs with more than 30 percent interns and residents to beds, and IPF units with 76+ beds.

In column 4, we present the effects of the proposed revisions to the patient-level adjustment factors, ED adjustment, and ECT per treatment amount and the application of the refinement standardization factor that is discussed in section III.F of this proposed rule. We estimate the largest payment increases would be for rural freestanding government-owned IPFs. Conversely, we estimate that for-profit IPF hospitals in rural areas would experience the largest payment decrease. Payments to IPF units in urban areas would increase by 0.4 percent, and payments to IPF units in rural areas would increase by 0.3 percent.

In column 5, we present the effects of the proposed budget-neutral update to the IPF wage index, the proposed LRS, and the proposed changes to the CBSA delineations for FY 2025. In addition, this column includes the application of the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year as finalized in the FY 2023 IPF PPS final rule (87 FR 46856 through 46859). The change in this column represents the effect of using the concurrent hospital wage data as discussed in section III.D.1.a of this proposed rule. That is, the impact represented in this column reflects the proposed update from the FY 2024 IPF wage index to the proposed FY 2025 IPF wage index, which includes basing the FY 2025 IPF wage index on the FY 2025 pre-floor, pre-reclassified IPPS hospital wage index data, applying a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and updating the LRS from 78.7 percent in FY 2024 to 78.8 percent in FY 2025. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 5; however, there would be distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 2.9 percent for freestanding rural for-profit IPFs, and the largest decrease in payments to be 1.6 percent for IPFs located in the Pacific region.

Overall, IPFs are estimated to experience a net increase in payments of 2.6 percent as a result of the updates in this proposed rule. IPF payments are therefore estimated to increase by 2.4 percent in urban areas and 4.0 percent in rural areas. The largest payment increase is estimated at 5.0 percent for IPFs located in the East South Central region.

4. Effect on Beneficiaries

Under the FY 2025 IPF PPS, IPFs will continue to receive payment based on the average resources consumed by patients for each day. Our longstanding payment methodology reflects the differences in patient resource use and costs among IPFs, as required under section 124 of the BBRA. We expect that updating IPF PPS rates in this rule will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in inpatient psychiatric care and the costs of these resources. We continue to expect that paying prospectively for IPF services under the FY 2025 IPF PPS will enhance the efficiency of the Medicare program.

As discussed in sections V.B.2 of this proposed rule, we expect that the proposed additional IPFQR Program measure will support improving discharge planning and care coordination to decrease the likelihood that a patient will need to seek emergency care within 30 days of discharge from an IPF.

5. Effects of the Updates to the IPFQR Program

In section V.B.2. of this rule, we are proposing the 30-Day Risk-Standardized All-Cause ED Visit Following an Inpatient Psychiatric Facility Discharge measure beginning with data from the CY 2025 performance period for the FY 2027 payment determination. We do not believe this update would impact providers' workflows or information systems to collect or report the data because this measure is calculated by CMS using information that IPFs already submit as part of the claims process. There may be some effects of this measure on IPF workflows and clinical processes to improve care coordination and discharge planning to improve performance on the measure.

We are also proposing to adopt a quarterly data submission requirement for measures for which we require patient-level data. We believe there may be some non-recurrent costs associated with training staff and updating processes to submit these data more frequently. We believe that the recurring costs of these updates will be an increase of 800 hours across all IPFs, equating to change of $41,696.

In accordance with section 1886(s)(4)(A) of the Act, we will apply a 2-percentage point reduction to the FY 2025 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2025, including reporting on the mandatory measures. For the FY 2024 payment determination, of the 1,568 IPFs eligible for the IPFQR Program, 194 IPFs did not receive the full market basket update because of the IPFQR Program; 42 of these IPFs chose not to participate and 152 did not meet the requirements of the program.

We intend to closely monitor the effects of the IPFQR Program on IPFs and help facilitate successful reporting outcomes through ongoing education, national trainings, and a technical help desk.

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this proposed rule, we assume that the total number of unique commenters on the most recent IPF proposed rule will be the number of reviewers of this proposed rule. For this FY 2025 IPF PPS proposed rule, the most recent IPF proposed rule was the FY 2024 IPF PPS proposed rule, and we received 2,506 unique comments on this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed the FY 2024 IPF proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by this proposed rule. We are soliciting comments on this assumption.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule; therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of this proposed rule.

Using the May, 2022 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this proposed rule is $123.06 per hour, including other indirect costs *https://www.bls.gov/oes/current/oes119111.htm.* Assuming an

average reading speed of 250 words per minute, we estimate that it would take approximately 112 minutes (1.87 hours) for the staff to review half of this proposed rule, which contains a total of approximately 56,000 words. For each IPF that reviews the proposed rule, the estimated cost is (1.87 × $123.06) or $230.12. Therefore, we estimate that the total cost of reviewing this proposed rule is $576,680.72 ($230.12 × 2,506 reviewers).

D. Alternatives Considered

The statute gives the Secretary discretion in establishing an update methodology to the IPF PPS. We continue to believe it is appropriate to routinely update the IPF PPS so that it reflects the best available data about differences in patient resource use and costs among IPFs, as required by the statute. Therefore, we are proposing to: update the IPF PPS using the methodology published in the RY 2005 IPF PPS final rule (our ''standard methodology'') pre-floor, pre-reclassified IPPS hospital wage index as its basis, along with the proposed changes to the CBSA delineations. Additionally, we apply a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. Lastly, we are proposing to revise the patient-level adjustment factors, ED adjustment, and to increase the ECT per treatment amount for FY 2025 (reflecting the pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost).

E. Accounting Statement

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 30, we have prepared an accounting statement showing the classification of the expenditures associated with the updates to the IPF wage index and payment rates in this proposed rule. Table 30 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this proposed rule and based on the data for 1,430 IPFs with data available in the PSF, with claims in our FY 2023 MedPAR claims dataset. Lastly, Table 30 also includes our best estimate of the costs of reviewing and understanding this proposed rule.

TABLE 30: Accounting Statement: Classification of Estimated Costs, Savings, and Transfers

Category	Primary estimate ($million/year)	Low estimate	High estimate	Units		
				Year dollars	Discount rate	Period covered
Regulatory Review Costs	0.58	-	-	2022	-	FY 2025
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	70	-	-	FY 2025	-	FY 2025

F. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $47 million in any 1 year).

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards,* IPFs falls into the North American Industrial Classification System (NAICS) code 622210, Psychiatric and Substance Abuse hospitals. The SBA defines small Psychiatric and Substance Abuse hospitals as businesses having less than $47 million.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs' revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities.

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 30, we estimate that the overall revenue impact of this proposed rule on all IPFs is to increase estimated Medicare payments by approximately 2.6 percent. As a result, since the estimated impact of this proposed rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this proposed rule will have a positive revenue impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in section VIII.C.2 of this proposed rule, the rates and policies set forth in this proposed rule will not have an adverse impact on the rural hospitals based on the data of the 199 rural excluded psychiatric units and 60 rural psychiatric hospitals in our database of 1,430 IPFs for which data were available. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandate Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $183 million. This proposed rule does not mandate any requirements for state, local, or tribal governments, or for the private sector. This proposed rule would not impose a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $183 million in any 1 year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule does not impose substantial direct costs on state or local governments or preempt state law.

In accordance with the provisions of Executive Order 12866, this proposed regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 22, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–06764 Filed 3–28–24; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 89 Wednesday,

No. 65 April 3, 2024

Part IV

Department of Commerce

Patent and Trademark Office

37 CFR Parts 1, 41, and 42

Setting and Adjusting Patent Fees During Fiscal Year 2025; Proposed Rule

DEPARTMENT OF COMMERCE

Patent and Trademark Office

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[Docket No. PTO–P–2022–0033]

RIN 0651–AD64

Setting and Adjusting Patent Fees During Fiscal Year 2025

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO) proposes to set or adjust patent fees as authorized by the Leahy-Smith America Invents Act (AIA), as amended by the Study of Underrepresented Classes Chasing Engineering and Science Success Act of 2018 (SUCCESS Act). The proposed fee adjustments are needed to provide the USPTO with sufficient aggregate revenue to recover the aggregate costs of patent operations in future years (based on assumptions and estimates found in the agency's Fiscal Year 2025 Congressional Justification (FY 2025 Budget)), including implementing the USPTO 2022–2026 Strategic Plan (Strategic Plan).

DATES: The USPTO solicits comments from the public on this proposed rule. Written comments must be received on or before June 3, 2024 to ensure consideration.

ADDRESSES: Written comments on proposed patent fees must be submitted through the Federal eRulemaking Portal at *https://www.regulations.gov.* To submit comments via the portal, commenters should go to *https://www.regulations.gov/docket/PTO-P-2022-0033* or enter docket number PTO–P–2022–0033 on the *https://www.regulations.gov* homepage and select the ''Search'' button. The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this document and select the ''Comment'' button, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe portable document format (PDF) or Microsoft Word format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not possible, please contact the USPTO using the contact information below in the **FOR FURTHER INFORMATION CONTACT** section of this document for special instructions.

FOR FURTHER INFORMATION CONTACT: Brendan Hourigan, Director, Office of Planning and Budget, at 571–272–8966, or *Brendan.Hourigan@uspto.gov;* or C. Brett Lockard, Director, Forecasting and Analysis Division, at 571–272–0928, or *Christopher.Lockard@uspto.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Introduction

The USPTO publishes this notice of proposed rulemaking (NPRM or proposed rule) under section 10 of the AIA (section 10), Public Law 112–29, 125 Stat. 284, as amended by the SUCCESS Act, Public Law 115–273, 132 Stat. 4158, which authorizes the Under Secretary of Commerce for Intellectual Property and Director of the USPTO to set or adjust by rule any patent fee established, authorized, or charged under title 35 of the United States Code (U.S.C.) for any services performed, or materials furnished, by the agency. Section 10 prescribes that fees may be set or adjusted only to recover the aggregate estimated costs to the USPTO for processing, activities, services, and materials relating to patents, including administrative costs with respect to such patent fees. Section 10 authority includes flexibility to set individual fees in a way that furthers key policy factors, while considering the cost of the respective services. Section 10 also establishes certain procedural requirements for setting or adjusting fee regulations, such as public hearings and input from the Patent Public Advisory Committee (PPAC) and congressional oversight. PPAC held a public hearing on the USPTO's preliminary patent fee proposals on May 18, 2023, and released a report (PPAC Report) on August 14, 2023, containing its comments, advice, and recommendations on the preliminary fee proposals. The USPTO considered and analyzed the PPAC Report before publishing the fee proposals in this NPRM.

B. Purpose of This Action

Based on a biennial review of fees, costs, and revenues that began in fiscal year (FY) 2021, the USPTO concluded that fee adjustments are necessary to provide the agency with sufficient financial resources to facilitate the effective administration of the U.S. patent system, including implementing the USPTO 2022–2026 Strategic Plan, available on the agency website at *https://www.uspto.gov/StrategicPlan.* The USPTO reviewed and analyzed the overall balance between the agency's estimated revenue and costs over the next five years (based on current projections) under this proposed rule. The proposed fees will help stabilize the USPTO's finances by offsetting the forecasted increase in aggregate costs and maintaining the patent operating reserve in the desired operating range. The patent operating reserve mitigates financing risk and enables the agency to deliver reliable and predictable service levels, while positioning it to undertake initiatives that encourage participation in the innovation ecosystem.

The individual fee proposals align with the USPTO's strategic goals and its fee structure philosophy, including the agency's four key fee setting policy factors: (1) promote innovation strategies; (2) align fees with the full costs of products and services; (3) facilitate effective administration of the U.S. patent system; and (4) offer application processing options as discussed in detail in Part IV: Rulemaking Goals and Strategies. The proposed fee adjustments will enable the USPTO to accomplish its mission to drive U.S. innovation, inclusive capitalism, and global competitiveness. The USPTO's goal is to drive innovation, entrepreneurship, and creativity for the benefit of all Americans and people around the world.

C. Summary of Provisions Impacted by This Action

The USPTO proposes to set or adjust 455 patent fees for undiscounted, small, and micro entities (any reference herein to ''undiscounted entity'' includes all entities other than those with established entitlement to either a small or micro entity fee discount, see Part II: Legal Framework for more information), including the introduction of 73 new fees.

Overall, the routine fees to obtain a patent (*i.e.,* filing, search, examination, and issue fees) will increase under this NPRM relative to the current fee schedule to ensure financial sustainability and accommodate increases needed to improve the predictability and reliability of patent intellectual property (IP) protection (discussed in detail below). Applicants who meet the eligibility criteria for small or micro entity discounts will continue to pay a reduced fee for the fees eligible for discount under AIA section 10(b). Additional information describing the proposed fee adjustments is included in Part V: Individual Fee Rationale in this rulemaking and in the

''Table of Patent Fees—Current, Proposed, and Unit Cost'' (Table of Patent Fees) available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.*

D. Summary of Costs and Benefits of This Action

This proposed rule is economically significant and requires a Regulatory Impact Analysis (RIA) under Executive Order 12866 Regulatory Planning and Review, (Sept. 30, 1993). The USPTO prepared an RIA to analyze the costs and benefits of the NPRM over a five-year period, FY 2025–2029. The RIA includes an analysis of how well the four alternatives align with the rulemaking strategies and goals, which are comprised of strategic priorities (goals, objectives, and key performance strategies) from the Strategic Plan; and fee setting policy factors. From this conceptual framework, the USPTO assessed the absolute and relative qualitative costs and benefits of each alternative. Consistent with OMB Circular A–4, ''Regulatory Analysis,'' this proposed rule involves a transfer payment from one group to another. The USPTO recognizes that it is very difficult to precisely monetize and quantify social costs and benefits resulting from deadweight loss of a transfer rule such as this proposed rule. The costs and benefits identified and analyzed in the RIA are strictly qualitative. Qualitative costs and benefits have effects that are difficult to express in either dollar or numerical values. Monetized costs and benefits, on the other hand, have effects that can be expressed in dollar values. The USPTO did not identify any monetized costs and benefits of this proposed rule, but found this proposed rule has significant qualitative benefits and only minimal costs.

The qualitative costs and benefits that the RIA assesses are: (1) fee schedule design—a measure of how well the fee schedule aligns to the key fee setting policy factors; and (2) securing aggregate revenue to recover aggregate cost—a measure of whether the alternative provides adequate revenue to support the core mission and strategic priorities described in the NPRM, Strategic Plan, and FY 2025 Budget. Based on the costs and benefits identified and analyzed in the RIA, the fee schedule proposed in this NPRM offers the highest net benefits. As described throughout this document, the proposed fee schedule maintains the existing balance of below cost entry fees (*e.g.,* filing, search, and examination) and above cost maintenance fees as one approach to foster innovation. Further, as detailed in Part V: Individual Fee Rationale, the proposed fee changes are targeted in support of one or more fee setting policy factors. Lastly, this proposed rule secures the aggregate revenue needed to maintain patent operations and achieve the strategic priorities encompassed in the rulemaking goals and strategies (see Part IV: Rulemaking Goals and Strategies). The proposed fee schedule produces sufficient aggregate revenue to fund the strategic objectives to issue and maintain robust and reliable patents; improve patent application pendency; optimize the patent application process to enable efficiencies for applicants and other stakeholders; and enhance internal processes to prevent fraudulent and abusive behaviors that do not embody the USPTO's mission. Table 1 summarizes the RIA results. Additional details describing the costs and benefits can be found in the RIA, available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.*

TABLE 1—PROPOSED PATENT FEE SCHEDULE COSTS AND BENEFITS, CUMULATIVE FY 2025–2029

Qualitative costs and benefits	
Costs:	
Fee Schedule Design	Minimal.
Benefits:	
Secure Aggregate Revenue to Recover Aggregate Costs.	Significant.
Fee Schedule Design	Significant.
Net Benefit	Significant benefit.

II. Legal Framework

A. Leahy-Smith America Invents Act—Section 10

The AIA was enacted into law on September 16, 2011. Public Law 112–29, 125 Stat. 284. Section 10(a) of the AIA authorizes the Director of the USPTO to set or adjust by rule any patent fee established, authorized, or charged under 35 U.S.C. for any services performed or materials furnished by the agency. Fees under 35 U.S.C. may be set or adjusted only to recover the aggregate estimated costs to the USPTO for processing, activities, services, and materials related to patents, including administrative costs to the agency with respect to such patent operations. See 125 Stat. at 316. Provided that fees in the aggregate achieve overall aggregate cost recovery, the Director may set individual fees under section 10 at, below, or above their respective cost. Section 10(e) requires the Director to publish the final fee rule in the **Federal Register** and the USPTO's *Official Gazette* at least 45 days before the final fees become effective.

Section 10 authorized the USPTO to set or adjust patent fees within the regulatory process. The USPTO has used the AIA's fee setting authority to achieve its key fee setting policy factors and to generate the aggregate revenue needed to recover the aggregate costs of operations and strategic patent priorities in final rules published in FY 2013 (Setting and Adjusting Patent Fees, 78 FR 4212 (Jan. 18, 2013)), FY 2018 (Setting and Adjusting Patent Fees During Fiscal Year 2017, 82 FR 52780 (Nov. 14, 2017)), and FY 2020 (Setting and Adjusting Patent Fees During Fiscal Year 2020, 85 FR 46932 (Aug. 3, 2020) (FY 2020 Final Rule)).

B. The Study of Underrepresented Classes Chasing Engineering and Science Success Act of 2018

The SUCCESS Act was enacted into law on October 31, 2018. See Public Law 115–273, 132 Stat. 4158. Section 4 of the SUCCESS Act amended section 10(i)(2) of the AIA by striking ''7-year'' and inserting ''15-year'' in reference to the expiration of fee setting authority. Therefore, updated section 10(i) terminates the Director's authority to set or adjust any fee under section 10(a) upon expiration of the 15-year period that began on September 16, 2011, and ends on September 16, 2026.

C. Unleashing American Innovators Act of 2022

On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023, which included the Unleashing American Innovators Act (UAIA). The UAIA increased fee discounts for small entities from 50% to 60% and fee discounts for micro entities from 75% to 80% for fees for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents. The UAIA also increased fee discounts for small entities from 75% to 80% for filing a basic, nonprovisional utility application electronically. See Consolidated Appropriations Act, 2023, Public Law 117–328; Reducing Patent Fees for Small Entities and Micro Entities Under the Unleashing American Innovators Act of 2022, 88 FR 17147 (Mar. 22, 2023).

D. Small Entity Fee Reduction

Section 10(b) of the AIA, as amended by the UAIA, requires the USPTO to reduce by 60% the fees for small entities that are set or adjusted under section 10(a) for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents.

E. Micro Entity Fee Reduction

Section 10(g) of the AIA amended 35 U.S.C. chapter 11, by adding section 123 concerning micro entities. The AIA, as amended by the UAIA, provides that the USPTO must reduce by 80% the fees for micro entities for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents.

F. Patent Public Advisory Committee Role

The Secretary of Commerce established PPAC under the American Inventors Protection Act of 1999. See 35 U.S.C. 5. PPAC advises the Director of the USPTO on the management, policies, goals, performance, budget, and user fees of patent operations.

When adopting fees under section 10, the Director must provide PPAC the proposed fees at least 45 days prior to publishing in the **Federal Register**. PPAC then has 30 days to deliberate, consider, and comment on the proposal, as well as hold public hearing(s) on the proposed fees. Then, before the USPTO issues any final fees, PPAC must make a written report available to the public of the comments, advice, and recommendations of the committee regarding the proposed fees. The USPTO must consider and analyze any comments, advice, or recommendations received from PPAC before finally setting or adjusting fees.

Consistent with this framework, on April 20, 2023, the Director notified PPAC of the USPTO's intent to set or adjust patent fees and submitted a preliminary patent fee proposal with supporting materials. The preliminary patent fee proposal and associated materials are available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.* PPAC held a public hearing at the USPTO's headquarters in Alexandria, Virginia, on May 18, 2023, where members of the public were given an opportunity to provide oral testimony. Transcripts of the hearing are available for review on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/PPAC_Hearing_Transcript-20230518.pdf.* Members of the public were also given an opportunity to submit written comments for PPAC to consider, and these comments are available on *Regulations.gov* at *https://www.regulations.gov/document/PTO-P-2023-0017-0001.* On August 14, 2023, PPAC issued a written report setting forth in detail their comments, advice, and recommendations regarding the preliminary proposed fees. The report is available on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/PPAC-Report-on-2023-Fee-Proposal.docx.* The USPTO considered and analyzed all comments, advice, and recommendations received from PPAC before publishing this NPRM. Further discussion of the PPAC Report can be found in Part IV: Rulemaking Goals and Strategies and Part V: Individual Fee Rationale.

III. Estimating Aggregate Costs and Revenues

Section 10 prescribes that patent fees may be set or adjusted only to recover the aggregate estimated costs to the USPTO for processing, activities, services, and materials relating to patents, including administrative costs with respect to such patent fees. The following is a description of how the USPTO calculates aggregate costs and revenue.

Step 1: Estimating Prospective Aggregate Costs

Estimating prospective aggregate costs is accomplished primarily through the annual USPTO budget formulation process. The annual budget is a five-year plan for carrying out base programs and new initiatives to deliver on the USPTO's statutory mission and implement strategic goals and objectives. First, the USPTO projects the level of demand for patent products and services. Demand for products and services depends on many factors that are subject to change, including domestic and global economic activity. The USPTO also considers overseas patenting activities, policies and legislation, and known process efficiencies. Because filing, search, and examination costs are the largest share of the total patent operating costs, a primary production workload driver is the number of patent application filings (*i.e.,* incoming work to the USPTO). The USPTO looks at indicators such as the expected growth in Real Gross Domestic Product (RGDP), a leading indicator of incoming patent applications, to estimate prospective workload. RGDP is reported by the Bureau of Economic Analysis (*www.bea.gov*) and is forecasted each February by the OMB (*www.omb.gov*) in the Economic and Budget Analyses section of the Analytical Perspectives and twice annually by the Congressional Budget Office (CBO) (*www.cbo.gov*) in the Budget and Economic Outlook.

The expected production workload must then be compared to the current examination production capacity to determine any required staffing and operating cost (*e.g.,* salaries, workload processing contracts, and publication) adjustments. The USPTO uses a patent pendency model to estimate patent production output based on actual historical data and input assumptions, such as incoming patent applications and overtime hours. An overview of the model, including a description of inputs, outputs, key data relationships, and a simulation tool is available at *https://www.uspto.gov/learning-and-resources/statistics/patent-pendency-model.*

Next, the USPTO calculates budgetary spending requirements based on the prospective aggregate costs of patent operations. First, the USPTO estimates the prospective costs of status quo operations (base requirements). Then, the base requirements are adjusted for anticipated pay increases and inflationary increases for the budget year and four outyears. The USPTO then estimates the prospective costs for expected changes in production workload and new initiatives over the same period. The USPTO reduces cost estimates for completed initiatives and known cost savings expected over the same five-year horizon. A detailed description of the budgetary requirements, aggregate costs, and related assumptions for the Patents program is available in the FY 2025 Budget.

The USPTO estimates that the Patents program will cost $3.973 billion in FY 2025, including $2.835 billion for patent examining; $90 million for patent trial and appeals; $159 million for patent information resources; $24 million for activities related to IP protection, policy, and enforcement; and $866 million for general support costs necessary for patent operations (*e.g.,* the patent share of rent, utilities, legal, financial, human resources, other administrative services, and Office-wide information technology (IT) infrastructure and IT support costs). See Appendix II of the FY 2025 Budget. In addition, the USPTO will transfer $2 million to the Department of Commerce Inspector General for audit support.

Table 2 below provides key underlying production workload projections and assumptions from the FY 2025 Budget used to calculate aggregate costs. Table 3 (see Step 2) presents the total budgetary requirements (prospective aggregate costs) for FY 2025 through FY 2029 and the estimated collections and operating reserve balances that would result from the proposed adjustments contained in this NPRM. These projections are based on point-in-time estimates and assumptions that are subject to change. There is considerable uncertainty in

out-year budgetary requirements. There are risks that could materialize over the next several years (*e.g.,* adjustments to examination capacity, recompetition of contracts, changes in workload, inflationary increases, etc.) that could increase the USPTO's budgetary requirements in the short- to medium-term. These estimates are refreshed annually in the production of the USPTO's budget.

TABLE 2—PATENT PRODUCTION WORKLOAD PROJECTIONS, FY 2025–2029

Utility, plant, and reissue (UPR)	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Applications *	609,400	615,400	623,600	629,600	642,200
Application growth rate	2.1%	1.0%	1.3%	1.0%	2.0%
Production units **	557,000	577,300	602,300	621,100	639,000
Unexamined patent application backlog	817,900	820,200	811,600	789,400	780,000
Examination capacity ***	8,833	9,276	9,589	9,867	10,135
Performance measures (UPR):					
Average first action pendency (Months)	20.7	20.7	21.0	20.6	21.3
Average total pendency (months)	26.1	27.2	26.6	26.4	25.7

* In this table, the patent application filing data includes requests for continued examination.

** Each serial new (*i.e.,* non-request for continued examination) application carries 1 production unit or 2.0 counts, a fraction of which is awarded for each major Office action type. In most but not all cases, requests for continued examination carry a fraction of a production unit (*e.g.,* 1.75 counts) and the credit for a first action is reduced by a corresponding amount.

*** In this table, Examination Capacity is the UPR examiners onboard at end-of-year, as described in the FY 2025 Budget.

Step 2: Estimating Prospective Aggregate Revenue

As described above in Step 1, the USPTO's prospective aggregate costs (as presented in the FY 2025 Budget) include budgetary requirements related to planned production, anticipated new initiatives, and a contribution to the patent operating reserve required for the USPTO to maintain patent operations and realize its strategic goals and objectives for the next five years. The prospective aggregate costs become the target aggregate revenue level that the new fee schedule must generate in a given year over the five-year planning horizon. To estimate aggregate revenue, the USPTO references the production models used to estimate aggregate costs and analyzes relevant factors and indicators to calculate or determine prospective fee workloads (*e.g.,* number of applications and requests for services and products).

Economic activity is an important consideration when developing workload and revenue forecasts for patent products and services because economic conditions affect patenting activity. Major economic indicators include the overall condition of the U.S. and global economies, spending on research and development activities, and investments that lead to the commercialization of new products and services. These indicators correlate with patent application filings, which are a key driver of patent fees. Economic indicators also provide insight into market conditions and the management of IP portfolios, which influence application processing requests and post-issuance decisions to maintain patent protection. When developing fee workload forecasts, the USPTO considers other influential factors including overseas activity, policies and legislation, court decisions, process efficiencies, and anticipated applicant behavior.

Anticipated applicant behavior in response to fee changes is measured using an economic principle known as elasticity, which for the purpose of this proposal measures how sensitive applicants and patentees are to changes in fee amounts. The higher the elasticity measure (in absolute value), the greater the applicant response to the relevant fee change. If elasticity is low enough (*i.e.,* demand is *inelastic* or the elasticity measure is less than one in absolute value), a fee increase will lead to only a relatively small decrease in patent activities, and overall revenues will still increase. Conversely, if elasticity is high enough (*i.e.,* demand is *elastic* or the elasticity measure is greater than one in absolute value), a fee increase will lead to a relatively large decrease in patenting activities such that overall revenues will decrease. When developing fee forecasts, the USPTO accounts for how applicant behavior will change at different fee amounts projected for the various patent services. The USPTO previously analyzed elasticity for nine broad patent fee categories: filing/search/examination fees, excess independent claims fees, excess total claims fees, application size (excess page) fees, issue fees, request for continued examination (RCE) fees, appeal fees, AIA trial fees, and maintenance fees, including distinctions by entity size where applicable. Additional information about how the USPTO estimates elasticity is provided in ''Setting and Adjusting Patent Fees during Fiscal Year 2020—Description of Elasticity Estimates,'' available on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/Elasticity_Appendix.docx.*

Patent fees are collected for patent-related services and products at different points in time within the patent application examination process and over the life of the pending patent application and granted patent. Maintenance fee payments account for about half of all patent fee collections and subsidize the cost of filing, search, and examination activities. Changes in application filing levels immediately impact current year fee collections, because fewer patent application filings mean the USPTO collects fewer fees. The resulting reduction in production activities also creates an out-year revenue impact because less production output in one year results in fewer issue and maintenance fee payments in future years.

The USPTO's five-year estimated aggregate patent fee revenue (see table 3) is based on the number of patent applications it expects to receive for a given fiscal year, work it expects to process in a given fiscal year (an indicator of patent issue fee workloads), expected examination and process requests for the fiscal year, and the expected number of post-issuance decisions to maintain patent protection over that same fiscal year. Within the iterative process for estimating aggregate revenue, the USPTO adjusts individual fee rates up or down based on cost and policy decisions, estimates the effective dates of new fee rates, and then multiplies the resulting fee rates by workload volumes (including elasticity adjustments) to calculate a revenue estimate for each fee. For the aggregate

revenue estimates shown below, the USPTO assumes that all proposed fee rates will become effective on January 18, 2025. Using these figures, the USPTO sums the individual fee revenue estimates, and the result is a total aggregate revenue estimate for a given year (see table 3). The aggregate revenue estimate also includes collecting $50 million annually in other income associated with recoveries and reimbursable agreements (offsets to spending).

TABLE 3—PATENT FINANCIAL OUTLOOK, FY 2025–2029

	Dollars in millions				
	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Projected fee collections	3,972	4,238	4,338	4,305	4,314
Other income	50	50	50	50	50
Total projected fee collections and other income	4,022	4,288	4,388	4,355	4,364
Budgetary requirements	3,975	4,102	4,268	4,431	4,600
Funding to (+) and from (−) operating reserve	47	186	120	(76)	(236)
End-of-year operating reserve balance	840	1,028	1,148	1,074	837
Over/(under) minimum level	522	700	807	720	469
Over/(under) optimal level	(35)	126	209	99	(175)

IV. Rulemaking Goals and Strategies

A. Fee Setting Strategy

The strategy of this proposed rule is to establish a fee schedule that generates sufficient multi-year revenue to recover the aggregate costs of maintaining USPTO patent operations. The overriding principles behind this strategy are to operate within a sustainable funding model that supports the USPTO's strategic goals and objectives, such as optimizing patent application pendency through the promotion of efficient operations and filing behaviors, issuing robust and reliable patents, and encouraging access to the patent system for all stakeholders.

The USPTO assessed this proposed rule for alignment with four key fee setting policy factors that promote a particular aspect of the U.S. patent system: (1) Promoting innovation strategies seeks to ensure barriers to entry into the U.S. patent system remain low, and innovation is incentivized by granting inventors certain short-term exclusive rights to stimulate additional inventive activity; (2) Aligning fees with the full costs of products and services recognizes that some applicants may use particular services in a more costly manner than other applicants (*e.g.,* patent applications cost more to process when more claims are filed); (3) Facilitating the effective administration of the U.S. patent system seeks to encourage patent prosecution strategies that promote efficient patent prosecution, resulting in compact prosecution and reduction in the time it takes to obtain a patent; and (4) Recognizing that patent prosecution is not a one-size-fits-all process and, where feasible, offering application processing options. Part V: Individual Fee Rationale describes the reasoning for setting and adjusting individual fees, including the design benefits of the proposed fee schedule. The RIA, available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting,* also discusses fee schedule design benefits.

B. Fee Setting Considerations

The balance of this sub-section presents the specific fee setting considerations the USPTO reviewed in developing the proposed patent fee schedule: (1) historical cost of providing individual services; (2) the balance between projected costs and revenue to meet the USPTO's operational needs and strategic goals; (3) ensuring sustainable funding; and (4) PPAC's comments, advice, and recommendations on the USPTO's initial fee setting proposal. Collectively, these considerations inform USPTO's chosen rulemaking strategy.

1. Historical Cost of Providing Individual Services

The USPTO sets individual fee rates to further key policy considerations while considering the cost of a particular service. For instance, the USPTO has a longstanding practice of setting basic filing, search, and examination (''front-end'') fees below the actual cost of processing and examining applications to encourage innovators to take advantage of patent rights and protections.

The USPTO considers unit cost data provided by its Activity Based Information (ABI) program to decide how to best align fees with the full cost of products and services. Using historical cost data and forecasted application demands, the USPTO can align fees to the costs of specific patent products and services. Additional information on the USPTO's costing methodology in addition to the last three years of historical cost data is provided in the document titled ''Setting and Adjusting Patent Fees during Fiscal Year 2025—Activity Based Information and Patent Fee Unit Expense Methodology,'' available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.* Part V: Individual Fee Rationale describes the reasoning and anticipated benefits for setting some individual fees at cost, below cost, or above cost such that the USPTO recovers the aggregate costs of providing services through aggregate fee collections.

2. Balancing Projected Costs and Revenue

In developing this proposed patent fee schedule, the USPTO considered its current estimates of future year workload demands, fee collections, and costs to maintain core USPTO operations and meet its strategic goals, as found in the FY 2025 Budget and the Strategic Plan. The USPTO's strategic goals include: (1) driving inclusive U.S. innovation and global competitiveness, (2) promoting the efficient delivery of reliable IP rights, (3) promoting the protection of IP against new and persistent threats, (4) bringing innovation to impact, and (5) generating impactful employee and customer experiences by maximizing agency operations. The following subsections provide details regarding updated revenue and cost estimates, cost-saving efforts taken by the USPTO, and planned strategic improvements.

a. Updated Revenue and Cost Estimates

Projected revenue from the current fee schedule is insufficient to meet future budgetary requirements (costs) due largely to unforeseen economic and

policy factors since the USPTO last exercised its rulemaking authority to set patent fees in the FY 2020 Final Rule. As further discussed below, increased fee discounts for small and micro entities under the UAIA have reduced revenue estimates. Higher-than-expected inflation in the broader U.S. economy and government-wide pay raises have increased the USPTO's forecasted operating costs. Also, the USPTO has undertaken efforts to increase special pay rates and offer other incentives to recruit and retain examiners and other employees in patent specific job series in order to remain competitive in the job market for science, technology, engineering, and mathematics (STEM) workers. Absent the proposed increase in fees, the USPTO will be unable to collect sufficient fees at current fee rates to recover aggregate operating costs necessary to finance ongoing operations.

On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023, which included the UAIA. The law reduced barriers to entry into the patent system by increasing small entity discounts from 50% to 60% and micro entity discounts from 75% to 80%. The USPTO estimated as part of its Fiscal Year 2024 Congressional Justification (FY 2024 Budget) that these discounts would reduce projected fee collections by $74 million in FY 2023 (partial year impact) and at least $100 million per year beginning in FY 2024 (full year impact). In addition to increased entity discounts, the UAIA increases costs through its provision that requires that the USPTO establish a new Southeast Regional Office and four new community outreach offices—including one in northern New England. The USPTO must also conduct a study to determine whether additional offices are required to achieve AIA mandates and to increase participation of underrepresented inventors in the patent system.

Higher-than-expected inflation in 2021 and 2022 in the broader U.S. economy increased the USPTO's operating costs above previous estimates for labor and nonlabor activities such as benefits, service contracts, and equipment. Salaries and benefits comprise 70% of all patent-related costs, and employee pay raises enacted across all U.S. government agencies—including the USPTO—in 2023 and 2024 were much larger than previously budgeted. Federal General Schedule (GS) pay was raised by 4.6% in 2023 and 5.2% in 2024; before 2023 the last time GS pay was raised by at least 4% was in 2004. The FY 2025 Budget includes an estimated 2.0% civilian pay raise planned in calendar year (CY) 2025 and assumed 3.0% civilian pay raises in CY 2026–29, as well as inflationary increases for other labor and nonlabor activities.

Similarly, the USPTO seeks to adjust the patent special rate table (pay) for the first time since 2007. In 2007 the special rate table was set 11.4% to 31.4% above the GS pay table for the Washington, DC area because patent-related job fields require a highly educated and technical STEM workforce. This specialization has historically posed recruitment challenges for the agency, and the increased pay rates kept the USPTO competitive with private sector compensation opportunities. The differential above the general schedule has diminished over the years—to 0.0% to 20.5% in 2023 because of cost-of-living-adjustments to the GS pay scale that were not similarly applied to the special rate table—reducing the USPTO's competitive edge amongst both private and other Federal agencies. The objective of the special rate table change is to provide competitive compensation to patent employees, thereby reducing attrition and enhancing recruitment of qualified talent.

The USPTO's recruitment and retention efforts go beyond adjustments to examiner pay. In support of its strategic goal of generating impactful employee and customer experiences by maximizing agency operations, the USPTO strives to be a model employer through its diversity, equity, inclusion, and accessibility (DEIA) practices. The agency will build upon its existing diversity and foster greater inclusion to empower the USPTO workforce to serve the IP community successfully. The USPTO will research and implement leading-edge practices related to hiring, development, advancement, accessibility, and retention, based on behavioral science research and data, to better integrate DEIA practices throughout the agency.

b. Cost-Saving Measures

The USPTO recognizes that fees cannot simply increase for every improvement deemed desirable. The USPTO has a responsibility to stakeholders to pursue strategic opportunities for improvement in an efficient, cost-conscious manner. Likewise, the USPTO recognizes its obligation to gain operational efficiency and reduce spending when appropriate.

The USPTO's FY 2025 Budget submission includes cost reducing measures such as releasing leased space in Northern Virginia and a moderate reduction in overall IT spending. In FY 2025, the USPTO estimates $4,569 million in total spending for patent and trademark operations. This is a $122 million net increase from the agency's FY 2024 estimated spending level of $4,447 million. The net increase includes a $224 million upward adjustment for prescribed inflation and other adjustments, and a $102 million downward adjustment in program spending and other realized efficiencies. This estimate builds on the $40 million in annual real estate savings assumed in the FY 2024 Budget submission to include additional annual cost savings of $12 million through releasing more leased space in Northern Virginia. The combined reduction in real estate space amounts to almost 1 million square feet and an estimated annual cost savings of approximately $52 million. Also, the USPTO is actively pursuing IT cost containment. The FY 2025 budget includes a relatively flat IT spending profile despite upward pressure from inflation, supply chain disruptions, and government-wide pay raises; ongoing IT improvements that offer business value to fee-paying customers; and data storage costs increasing proportionally with the USPTO's forecasted growth in patent and trademark applications. The USPTO will achieve this cost containment goal via modern equipment in a new data center that will cost less to maintain and by retiring legacy IT systems. Both of these cost containment measures will further improve the USPTO's cybersecurity posture and increase system resiliency.

c. Efficient Delivery of Reliable IP Rights: Quality, Backlog, and Pendency

The USPTO continuously works to improve patent quality, particularly the predictability, reliability, and robustness of issued patents. See the USPTO's Quality Metrics web page, *https://www.uspto.gov/patents/quality-metrics,* for more information on patent quality including (1) statutory compliance measures, (2) process measures, and (3) perception measures. The USPTO's strategic goal to ''promote the efficient delivery of reliable IP rights'' recognizes the importance of innovation as the foundation of American economic growth and global competitiveness as well as the role the USPTO plays in encouraging these principles. The USPTO is committed to improving pendency to deliver timely, efficient services that help innovators bring their ideas and products to impact more quickly and efficiently. The USPTO diligently works to balance timely examination with improvements in patent quality; particularly, the

robustness and reliability of issued patents while remaining mindful that patent applications are becoming increasingly more complex and that technologies are converging. To address these challenges, the USPTO must continue to develop and equip examiners with additional guidance, training, tools, advanced technology, and procedural resources.

The USPTO is pursuing initiatives to enhance patent quality and the clarity and completeness of the official record during prosecution of an application, including encouraging applicants to begin filing patent applications in DOCX format, automating pre-examination procedures, expanding examiner training, and working on additional guidance for examiners and the PTAB. Current guidance initiatives include refresher guidance on obviousness under 35 U.S.C. 103 and enablement under 35 U.S.C. 112, and new guidance on how examiners should analyze inventorship issues for artificial intelligence (AI)-assisted inventions. See Updated Guidance for Making a Proper Determination of Obviousness, 89 FR 14449 (February 27, 2024); Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 FR 1563 (December 21, 2023); Inventorship Guidance for AI-Assisted Inventions, 89 FR 10043 (February 13, 2024). The USPTO is also increasing patent examination quality and efficiency via initiatives such as the Global Dossier Initiative (see *https://www.uspto.gov/patents/basics/international-protection/global-dossier-initiative*), and by providing examiners with advanced technologies and tools for identifying prior art, such as the artificial intelligence (AI)-based ''More Like This'' and ''Similarity Search'' features in the Patents End-to-End (PE2E) search suite (see 1494 Off. Gaz. Pat. Office 251 (January 11, 2022) and 1504 Off. Gaz. Pat. Office 359 (November 15, 2022)). More information on the USPTO's AI initiatives, including the Artificial Intelligence (AI) and Emerging Technologies Partnership, is available at *https://www.uspto.gov/initiatives/artificial-intelligence.*

The USPTO recognizes that optimal pendency helps inventors and investors bring innovation to impact. The growing demand for patent services requires that the USPTO embrace new ways of delivering these critical IP services. Therefore, the USPTO is also working to identify policies, process changes, and technologies to improve patent pendency. Some of these efforts will focus on operational improvements to the patent examination process, including aligning the patent workforce with the incoming workload in the most efficient manner. Other efforts will target improvements to how applicants and other customers engage with the USPTO and navigate the prosecution process. For example, the USPTO has enhanced its website to increase access to our resources and enhance customer service for inventors and practitioners, including modernizing and updating the Patent Basics and Patents Petitions pages, adding a Virtual Assistant on select pages, and providing an updated and modern general website search tool. The USPTO has also upgraded its computer systems, including transitioning from legacy systems to Patent Center for the electronic filing and management of patent applications in November 2023. Patent Center, a web-based platform that allows users to file and manage patent applications and requests, provides improved system performance and a more intuitive user interface for an enhanced user experience. The USPTO is committed to continuously improving the customer experience on our websites to enhance and modernize accessibility, design, and overall satisfaction in our digital space. For information on additional enhancements to our online services, visit our web improvements page at *https://www.uspto.gov/about-us/website-improvements.* Effecting the changes in the examination process needed to ensure the issuance of reliable patents, while also issuing those patents in a timely manner, means recognizing a potential increase in the core operating costs for future years.

Another major component of the overall patent process that has seen an increase in operating costs is the work carried out by the Patent Trial and Appeal Board (PTAB) and the Central Reexamination Unit (CRU). These units play a key role in providing an efficient system for amending or voiding any patent claims that overreach and stunt innovation, inclusive capitalism, and global competitiveness. To ensure that post-issuance challenges to patent rights through the PTAB and the CRU help protect innovation and investments to commercialize innovation, the USPTO will invest in new tools and resources that increase communication, knowledge sharing, and collective problem solving. These strategic investments will enable the USPTO to identify and continue to implement guidelines and best practices to serve the patent system.

3. Sustainable Funding

All aspects of estimating the five-year forecast for aggregate cost, aggregate revenue, and the patent operating reserve are inherently uncertain because they are based on numerous, multifaceted planning assumptions predicated on external indicators of economic IP activity to forecast demand, as well as internal workload drivers derived from production models. Maintaining a viable operating reserve is a key consideration as the USPTO sets patent fees. To mitigate the risk of uncertain demand, the USPTO maintains a patent operating reserve. The U.S. Government Accountability Office (GAO) considers operating reserves a best practice for user fee-funded government agencies like the USPTO. The patent operating reserve enables the USPTO to align fees and costs over a longer horizon and to improve its preparation for, and adjustment to, fluctuations in actual fee collections and spending.

The USPTO manages the operating reserve within a range of acceptable balances and assesses its options when projected balances fall either below or above that range. Minimum planning targets are intended to address immediate, unplanned changes in the economic or operating environments as the reserve builds to the optimal level. The minimum and optimal planning targets are reviewed every three years to ensure the reserve operating range (between minimum and optimal targets) mitigates the severity of an array of financial risks. Based on the current risk environment, including various risk factors such as economic and funding uncertainty and the high percentage of fixed costs in the Patents program, the USPTO established a minimum planning level of 8% of total spending—about one month's operating expenses (estimated at $318 million and $368 million between FY 2025 through FY 2029)—and an optimal long-range target of 22% of total spending—about three months' operating expenses (estimated at $875 million and $1,012 million between FY 2025 through FY 2029).

Based on current cost and revenue assumptions in the FY 2025 Budget, the USPTO forecast that in FY 2024 estimated aggregate costs will exceed aggregate revenue and the operating reserve will be used to maintain operations. The fee proposals contained in this NPRM are projected to increase patent fee collections to the point that they exceed spending requirements, and forecasted excess fee collections will replenish the patent operating reserve each year from FY 2025 through FY

2027. Based on this forecast, the USPTO will achieve its optimal level of three months operating requirements for the patent operating reserve in FY 2026. The USPTO then expects to use the patent operating reserve to fund operating expenses in FY 2028 and FY 2029 as the current projection for fee collection growth slows but projected patent spending requirements continue to increase.

These projections are based on point-in-time estimates and assumptions that are subject to change. For instance, the budget includes assumptions about filing levels, renewal rates, whether the President will authorize or Congress will mandate employee pay raises, the productivity of the workforce, and many other factors. A change in any of these factors could have a significant cumulative impact on reserve balances. As seen in table 3, set forth in Part III: Estimating Aggregate Costs and Revenue, the operating reserve balance can change significantly over a five-year planning horizon, underscoring the USPTO's financial vulnerability to varying risk factors and the importance of fee setting authority.

The USPTO will continue to evaluate long-term planning assumptions to determine the appropriate course of action beyond FY 2027 to ensure the Patents program is not vulnerable to changes in the economy that reduce annual revenue, unexpected cost increases, and other financial risks. The USPTO will also continue to assess the patent operating reserve balance against its target balance annually, and at least every three years, the USPTO will evaluate whether the minimum and optimal target balance remain sufficient to provide the stable funding the USPTO needs. Per the USPTO's operating reserve policy, if the operating reserve balance is projected to exceed the optimal level by 10% for two consecutive years, the USPTO will consider fee reductions. The USPTO will continue to regularly review its operating budgets and long-range plans to ensure the prudent use of patent fees.

4. Comments, Advice, and Recommendations From PPAC

In the report prepared in accordance with the AIA fee setting authority (available on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/PPAC-Report-on-2023-Fee-Proposal.docx*) PPAC supports the USPTO in seeking adequate revenue to recover the costs for the USPTO fulfill its role in supporting the country's innovation ecosystem. In addition, PPAC recognizes that ''the USPTO is in the best position to assess its own needs and balance the tradeoffs in setting individual fees.'' PPAC Report at 6. PPAC expressed general support for the increase in patent fees, noting that timely, high-quality search and examination requires an appropriately compensated work force with adequate time to complete the search and examination process, as well as reliable, state of the art IT infrastructure. However, PPAC expressed concerns over some of the individual proposed fee adjustments and their potential impacts on patent applicants and holders. In general, PPAC urged the USPTO to provide more detail and justification on how additional revenue will be used to increase patent quality and reliability. The USPTO has included additional information in this NPRM to further address some of the concerns of PPAC and the public. See Part V: Individual Fee Rationale.

Regarding the proposed changes to fees for excess claims, PPAC expressed support for the proposed fee increases. However, they also emphasized their belief that the public wants more certainty that the revenue generated from an increased fee will go toward examination and giving examiners additional time to evaluate such cases. The USPTO appreciates this concern and the current patent examination production time approach provides examiners with additional time to review excess claims. The proposed fees would contribute to recovering the costs to the USPTO for this additional examination time.

PPAC expressed support for the proposed decreases to fees for extensions of time for provisional applications. PPAC also expressed support for the proposals to increase suspension of action fees and fees for unintentional delay petitions. Part V: Individual Fee Rationale provides more details on these proposals.

In general, PPAC expressed support for the USPTO's proposal to implement a tiered fee structure for information disclosure statements (IDSs). PPAC recommended a legislative proposal to clarify inequitable conduct rules, which may have a significant impact on applicant behavior. They noted that under the current inequitable conduct case law, there is increased pressure on practitioners to cite every possible reference if they do not want to risk the practitioner's right to practice or the enforceability of the patent. The USPTO appreciates this suggestion and will give it further consideration. PPAC also recommended that if any additional fees are paid, the additional money should go to allowing examiners more time to consider the additional references. The USPTO notes that it is current USPTO policy to provide examiners with additional time to review large IDSs and the proposed fees would pay for this additional time. Only 13% of applications contain 50 or more applicant-provided citations, and thus would incur one of these proposed fees. The proposal would place the service costs of large IDSs on those applicants who file them.

PPAC supports the proposal to create a third tier for requests for continued examination (RCEs). PPAC notes that the proposed increases would ''allow the costs of continued examinations to be recovered directly from those applicants requesting multiple RCEs, instead of relying on other fees to subsidize the costs.'' PPAC Report at 4.

The report noted opposition to the proposed fee for electronically submitted assignments. PPAC argues that transparency of patent ownership is key to patent data integrity and a fee for assignment recordation would be an impediment to keeping assignment data up to date. The USPTO's initial fee proposal was designed to reduce the number of frivolous assignment submissions. However, the USPTO agrees with PPAC's assessment that keeping up-to-date assignment data outweighs the processing efficiency gains the USPTO expects from the proposal. Therefore, the USPTO is dropping its proposal to raise the recordation fee for an electronically submitted assignment. PPAC expressed conditional support for the continuing applications proposal if the USPTO drops the year three provision and only requires the proposed fee for year seven or after. PPAC's rationale for this modification is that three years is too short of a period, as there may not be an Office action at this point in prosecution, particularly if the application is in the national stage of an international application filed under the Patent Cooperation Treaty (PCT) or is classified in an art area with significant backlog. In response to these concerns the USPTO notes that as of April 2023, traditional total pendency is 2.1 years, which is below the three-year threshold for the first tier of the proposal. However, in view of PPAC's concerns about pendency, and the admittedly longer pendency for PCT applications, the USPTO proposes to modify the tiers to slide the threshold dates later in time. This NPRM therefore proposes the first tier at five years and the second tier at eight years. See Parts V: Individual Fee Rationale and VI: Discussion of Specific Rules for further details regarding the modification of this proposal.

Regarding the proposed fee for the After Final Consideration Pilot Program (AFCP 2.0), PPAC expressed the view that this proposal is problematic as it requires paying a fee with no guarantee of an interview. PPAC offered support for an AFCP 2.0 fee if: (1) the program is changed such that the applicant is guaranteed an interview; or (2) under the current program, a fee is assessed only if the interview is granted. The USPTO recognizes PPAC's concern but notes that the AFCP 2.0 program is costly to the agency and is heavily used by applicants; more than half of after-final responses come via this program. The costs of this program are currently subsidized by other fees. While the USPTO appreciates that some applicants may be unwilling to pay for a program that may not result in a favorable outcome or an interview with the examiner, the USPTO must make its patentability decisions in accordance with the appropriate legal standards that govern the USPTO and incurs costs to provide the service regardless of the outcome. The USPTO notes that a significant portion of the cost for AFCP 2.0 comes from the initial consideration of the request by the patent examiner. If the USPTO is unable to recover the cost of the AFCP 2.0 program from participants, it will need to consider terminating the program due to its cost. See Part V: Individual Fee Rationale for additional details regarding this proposal.

PPAC expressed a lack of support for the proposal to increase fees for design applications, recommending the USPTO prioritize addressing pendency issues before applying increased fees, as many design applicants are already paying expedited fees beyond the basic filing, search, and examination fees, given the current pendency. PPAC also suggests that the USPTO's concerns about recovering its costs in the design area could be addressed by a change in the law that allows for the implementation of maintenance fees for design patents. The USPTO acknowledges PPAC's concern regarding design application pendency and recognizes that some design applicants are paying expedited fees. Recovering more of the design costs from design applicants better aligns fees to the cost of services performed by the USPTO, and it also incents design applicants to make more appropriate economic decisions. With respect to PPAC's concern about expedited fees, in FY 2022 about 19% of design applicants requested expedited handling. See Part V: Individual Fee Rationale for additional details regarding the rationale for increasing design patent fees.

Regarding the patent term adjustment (PTA) proposal, PPAC offered support for increasing the fee if the proposal is modified such that no fee is assessed by the USPTO if a PTA adjustment is made due to a USPTO calculation error. The USPTO notes that a fee for this applicant-requested service has been in place since calendar year 2000 and has only increased $10 since enacted. Moreover, this fee helps recover a portion of the costs for applicant-requested manual redeterminations of PTA under 35 U.S.C. 154(b). While there are about 500 service requests each year, many concern the IDS safe harbor under 37 Code of Federal Regulations (CFR) 1.704(d)(1) and thus could have been avoided if the applicant had used the USPTO-provided form (PTO/SB/133) to invoke the safe harbor. With respect to PPAC's suggestion of adding a refund component to the proposal, the USPTO's rationale for this fee increase is to recover a greater percentage of the costs associated with the service that are incurred regardless of the outcome.

PPAC expressed general support for the patent term extension (PTE) proposal but suggested the USPTO consider if such a large increase in the fees is optimal, particularly the initial fee given start-up companies may be resource constrained. By law, this service is only available to owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products, and is designed to restore some patent term that was lost while awaiting premarket government approval from a regulatory agency. Because such development and premarketing activities are extremely expensive, it is unlikely that any resource-constrained companies would qualify for PTE services.

PPAC expressed a lack of support for the terminal disclaimer proposal, noting disagreement with the USPTO's justification and suggesting that the fee will place an unfair burden on filers with limited resources who may be tempted to give up patent term in exchange for a less expensive and more compact prosecution. While the USPTO appreciates PPAC's concerns, the agency believes that under-resourced applicants are unlikely to be affected by these fees, as a double patenting rejection necessitating a terminal disclaimer would not be made unless they had sufficient resources to file multiple applications with closely-related subject matter. This presumption is supported by data collected by the USPTO that shows only about 1% of terminal disclaimers are filed by micro entities.

PPAC expressed a lack of support for the proposed fee for requesting additional words in an inter partes or post-grant petition, noting that it may favor well-resourced petitioners given the added expense to prepare longer papers. After careful consideration of the comments and recommendations provided in the PPAC Report and in testimony at the public hearing, the USPTO has decided to withdraw this proposal.

PPAC expressed a lack of support for the proposal to establish a new fee for parties requesting a review of a PTAB decision by the Director. PPAC felt a fee was not warranted because a review by the Director ensures the PTAB decisions are consistent. PPAC also expressed concern that adding a fee for this previously free service may adversely affect individual inventors and small company applicants. In response to these concerns, the USPTO has provided additional justification and data. Part V: Individual Fee Rationale offers this additional information.

In summary, the USPTO appreciates the general support by PPAC and its stakeholders for an increase in patent fees sufficient for aggregate fees to recover aggregate costs. After careful consideration of the comments, concerns, and suggestions provided in the report, and keeping in mind the goals of this proposed rule, the USPTO elected to make changes to three of the fee proposals initially presented to PPAC. The fee structure proposed herein will ultimately allow the USPTO to maintain patent operations and continue its path towards achieving the goals and objectives laid out in the Strategic Plan. The USPTO looks forward to receiving additional comments on this revised proposal during the public comment period.

C. Summary of Rationale and Purpose of the Proposed Rule

The USPTO estimates that the proposed patent fee schedule will produce sufficient aggregate revenues to recover the aggregate costs of patent operations and ensure financial sustainability for effective administration of the patent system. This proposed rule aligns with the USPTO's four key fee setting policy factors and supports the USPTO's mission-focused strategic goals.

V. Individual Fee Rationale

The USPTO projects that aggregate revenue generated from the proposed patent fees will recover the prospective

aggregate costs of patent operations as laid out in the FY 2025 Budget. As detailed previously, PPAC recognizes the importance of ensuring the USPTO's financial sustainability, stating that, ''[t]o support its role in the country's innovation system, the USPTO requires adequate funding.'' PPAC Report at 5. PPAC also acknowledges the need to fund additional strategic investments, commenting that ''[t]imely, high-quality search and examination require an appropriately compensated work force with adequate time to complete the same, supported by state of the art and reliable IT infrastructure.'' PPAC Report at 5–6.

The USPTO did not set each individual proposed fee necessarily equal to the estimated costs of performing activities related to the fee. Instead, as described in Part IV: Rulemaking Goals and Strategies, some proposed fees are set at, above, or below their unit costs to balance four key fee setting policy factors: (1) promoting innovation strategies; (2) aligning fees with the full costs of products and services; (3) facilitating effective administration of the U.S. patent system; and (4) offering application processing options. For example, the agency sets many initial filing fees below unit cost to promote innovation strategies by removing barriers to entry to the patent system. To balance the aggregate revenue loss of fees set below cost, the USPTO must set other fees above cost in areas less likely to reduce inventorship (*e.g.,* maintenance).

For some fees proposed in this NPRM, such as extension of time fees, the USPTO does not maintain individual historical cost data for services provided; instead, the agency considers the policy factors described in Part IV: Rulemaking Goals and Strategies to inform fee setting. For example, facilitating effective administration of the U.S. patent system enables the USPTO to: (1) foster an environment where USPTO personnel can provide and applicants can receive prompt, quality interim and final decisions; (2) encourage the prompt conclusion of prosecuting an application, resulting in pendency reduction and faster dissemination of patented information; and (3) help recover costs for activities that strain the patent system.

The proposed fee changes are grouped into three categories: (A) an across-the board-adjustment to patent fees; (B) an adjustment to front-end fees; and (C) targeted fees. Part VI: Discussion of Specific Rules contains a complete listing of fees set or adjusted in the proposed patent fee schedule, including small and micro entity fees. This information is also listed in the Table of Patent Fees available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.*

This proposed rule includes one procedural amendment (D) expanding the applicability of the rule allowing applicants to obtain a refund of search and excess claims fees paid in an application through express abandonment.

A. Across-the-Board Adjustment to Patent Fees

The broader U.S. economy has experienced higher-than-expected inflation the last two years and, in turn, increased USPTO operating costs relative to baseline estimates for labor and nonlabor activities such as benefits, service contracts, and equipment. Also, the agency's estimates of future costs in the FY 2025 Budget include a 2.0% civilian pay raise planned in CY 2025 and an assumption of 3.0% civilian pay raises in CY 2026–29, as well as inflationary increases for other labor and nonlabor activities. To keep the USPTO on a stable financial track sufficient to recover the aggregate costs of patent operations and to support the agency's strategic objectives, the USPTO proposes adjusting, by approximately 5%, all patent fees not covered by the targeted adjustments discussed in section C. The USPTO estimates that new fees would not be implemented until FY 2025, more than four years after the agency's last fee adjustment in October 2020. A 5% across-the-board increase in 2025 would be equivalent to just a 1.2% annual increase, well below the prevailing inflation rate the last few years. The agency is not proposing a larger across-the-board increase in line with inflation because the across-the-board adjustment is intended to supplement the additional revenue collected from the targeted adjustments. Also, the USPTO will continue its ongoing efforts to improve operational efficiency and reduce spending when appropriate.

The 5% across-the-board adjustment strikes an appropriate balance between projected aggregate revenue and aggregate costs based on the assumptions used to develop the point-in-time estimates that support this NPRM. If changes to the assumptions underlying the USPTO's cost and revenue estimates result in significant changes to the financial outlook, the agency will refine the size of the across-the-board adjustment, either upward or downward, such that fees are set at a level that secures aggregate cost recovery and ensures a reasonable pace for operating reserve growth to the optimal level.

For patent fees with small and micro entity fee reductions, the proposed undiscounted fee is rounded up or down to the nearest $5 by applying standard arithmetic rules. The resulting proposed fee amounts are more convenient to patent users and permit the USPTO to set small and micro entity fees at whole dollar amounts when applying applicable fee reductions. Therefore, some smaller fees will not change since a 5% increase would round down to the current fee, while other fees would change by slightly more or less than 5%, depending on rounding. For patent fees that do not have small and micro entity fee reductions, the proposed fees are rounded to the nearest dollar by applying standard arithmetic rules. The proposed fee adjustments in this category are listed in the Table of Patent Fees available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.*

B. Adjustment to Front-End Patent Fees

The USPTO proposes to adjust all filing, search, and examination fees not covered by the targeted adjustments as discussed in section C by an additional 5% on top of the 5% across-the-board adjustment, for a total front-end increase of 10%. The current fee schedule, implemented by the FY 2020 Final Rule, set filing, search, and examination fees below the costs of performing these services to achieve low barriers to entry into the innovation ecosystem. These front-end fees are subsidized by other fee collections, primarily maintenance fees. This proposal will marginally recover some, but not all, additional filing, search, and examination costs earlier in the patent life cycle, thus mitigating the risk of potentially lower maintenance fee payments in the future while remaining consistent with a low barrier to entry policy.

Similar to the across-the-board adjustment, for fees that have small and micro entity fee reductions, the undiscounted fee is rounded up or down to the nearest $5 by applying standard arithmetic rules. Therefore, the proposed fee rates may not be precisely 10% higher than the current fee rates. The proposed fee adjustments in this category are listed in the Table of Patent Fees available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.*

C. Targeted Adjustments to Patent Fees

The USPTO proposes the following fee adjustments for the reasons stated below. The proposed fees are based on changes in undiscounted fee amounts; the percentage changes for small and micro entity fees would be the same as the percentage change for the undiscounted fee rate, and the dollar change would be 40% or 20% of the undiscounted change. A discussion of the rationale for each fee is divided into 14 categories according to function, as follows:

1. After Final Consideration Pilot Program 2.0

TABLE 4—AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Consideration of AFCP 2.0 request	Undiscounted	New	$500	n/a	n/a	n/a
Consideration of AFCP 2.0 request	Small	New	200	n/a	n/a	n/a
Consideration of AFCP 2.0 request	Micro	New	100	n/a	n/a	n/a

The USPTO proposes a new fee for participation in the AFCP 2.0. The agency created this program in May 2013 and has renewed it repeatedly. There is currently no fee for participation in this program. See After Final Consideration Pilot Program 2.0, 78 FR 29117 (May 17, 2013), and the program's section of the USPTO website at *https://www.uspto.gov/patents/initiatives/after-final-consideration-pilot-20.*

Under customary examination practice, after the close of prosecution, amendments that will place the application either in condition for allowance or in better form for appeal may be entered, and the applicant may also hold an interview with the examiner. See 37 CFR 1.116(b) and section 714.12 of Manual of Patent Examining Procedure (MPEP) (9th ed., Rev. 07.2022, February 2023), which may be viewed on or downloaded from the USPTO website at *https://www.uspto.gov/MPEP* or *https://mpep.uspto.gov.* The AFCP 2.0 was designed to encourage continued collaboration between examiners and applicants after close of prosecution and reduce pendency by avoiding RCEs and continued prosecution applications (CPA). The program requires that applicants submit a response with a nonbroadening amendment to at least one independent claim, and in return, affords the examiner additional time to consider the response. See Guidelines for Consideration of Responses After Final Rejection under 37 CFR 1.116(b) under the AFCP 2.0, available on the USPTO website at *https://www.uspto.gov/sites/default/files/patents/init_events/afcp_guidelines.pdf.* If the response will require further search and/or consideration that would take longer than the allotted time, the examiner will not admit the request under the program. Otherwise, if the response meets the program requirements, the examiner will consider the response, and will either: (1) mail a notice of allowance if the application is in condition for allowance or (2) contact the applicant to schedule an interview to discuss the amendment if the application is not in condition for allowance.

The AFCP 2.0 program offers several benefits to participating applicants. Under customary practice, after a final rejection, applicants have no right to unrestricted further prosecution. The AFCP 2.0 provides a participating applicant an opportunity to potentially have the examiner consider an amendment that would otherwise not be considered at this stage, possibly precluding the need to file an RCE or a CPA. This consideration saves applicants the higher fees associated with those filings and, in the case of the RCEs, saves applicants from patent term adjustment consequences. See MPEP section 2731 for more information on patent term adjustment. Moreover, participation in the program is not necessary to hold an interview after final rejection, or to have an amendment filed and entered after close of prosecution, see MPEP sections 713.09 and 714.13. An AFCP 2.0 request should be filed only when an applicant would like to file a substantive amendment after close of prosecution that may require additional time for an examiner to consider and/or search.

The AFCP 2.0 is a popular program; since 2016, applicants have filed more than 60,000 requests annually. These requests make up over half of the USPTO's after-final responses during this time. Due to its popularity, costs to administer the AFCP 2.0 are significant. In FY 2022, the USPTO estimates more than $15 million in incurred costs associated with examiners considering the AFCP 2.0 submissions. This cost is in addition to the cost for examiners to initially consider the AFCP 2.0 request and any consultation costs with supervisors and primary examiners. These examination costs represent time that could otherwise be used to examine new applications.

The USPTO is reconsidering the policy choice of continuing to offer the AFCP 2.0 program for free without recouping costs from applicants utilizing it. As noted by the Government Accountability Office (GAO) in Federal User Fees: A Design Guide, Report No. GAO–08–386SP (May 2008), available at *https://www.gao.gov/products/gao-08-386sp:*

> If those benefiting from a service do not bear the full social cost of the service, they may seek to have the government provide more of the service than is economically efficient. User fees may also foster production efficiency by increasing awareness of the costs of publicly provided services and therefore increasing incentives to reduce costs where possible.

Thus, without a fee to recover the cost of the program, the agency is considering not renewing (*i.e.,* terminating) the program. A large part of the AFCP 2.0's popularity is due to economic inefficiencies where participants receive program benefits for only a fraction of the program's costs (because applicants pay only indirectly via future maintenance fees). That said, the USPTO also recognizes that the program has some indirect benefits to the patent system by reducing overall pendency. If there is sufficient public support for the proposed fees, the improved economic efficiencies of aligning fees with direct beneficiaries (program participants), together with indirect benefits, would favor continuing the program. Accordingly, the USPTO is proposing to charge fees for filing a request for consideration under the AFCP 2.0: $500 for undiscounted applications, $200 for applications receiving a small entity discount, and $100 for applications receiving a micro entity discount.

At this time, the USPTO is not proposing any further changes to the AFCP 2.0. For example, the agency will not change the program to guarantee an

examiner interview if an AFCP 2.0 request is admitted under the program. The USPTO appreciates that some applicants may be unwilling to pay for a program that might not result in a favorable outcome or guarantee an examiner interview. Regardless of the outcome, the agency incurs costs to provide the service and must make its patentability decisions in accordance with appropriate legal standards. A significant portion of the AFCP 2.0's cost is initial consideration of the request by the patent examiner. Moreover, as noted previously, applicants may file amendments and participate in interviews after a final rejection without filing an AFCP 2.0 request. Further, a majority of the AFCP 2.0 requests (60% for utility and 80% for design) meet program requirements, meaning that either the application is allowed or an interview is granted.

The USPTO expects the percentage of compliant AFCP 2.0 requests to increase as applicants become more selective with the amendments filed, due to the fee. Accordingly, the agency does not expect a significant percentage of applicants to pay the fee without an opportunity for either allowance of the application or an interview with an examiner. Also, since undiscounted entities have historically filed 83% of all AFCP 2.0 requests, the USPTO does not anticipate the proposed fees having a disproportionate impact on small or micro entities.

2. Continuing Application Fees

TABLE 5—CONTINUING APPLICATION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Filing an application or presentation of benefit claim more than five years after earliest benefit date.	Undiscounted ...	New	$2,200	n/a	n/a	n/a
Filing an application or presentation of benefit claim more than five years after earliest benefit date.	Small	New	880	n/a	n/a	n/a
Filing an application or presentation of benefit claim more than five years after earliest benefit date.	Micro	New	440	n/a	n/a	n/a
Filing an application or presentation of benefit claim more than eight years after earliest benefit date.	Undiscounted	New	3,500	n/a	n/a	n/a
Filing an application or presentation of benefit claim more than eight years after earliest benefit date.	Small	New	1,400	n/a	n/a	n/a
Filing an application or presentation of benefit claim more than eight years after earliest benefit date.	Micro	New	700	n/a	n/a	n/a

The USPTO is proposing new fees in § 1.17(w) for presenting certain benefit claims in nonprovisional applications. These new fees would apply to nonprovisional applications (''later-filed'' applications) that have an actual filing date more than five years, or more than eight years, later than the earliest filing date for which benefit is claimed under 35 U.S.C. 120, 121, 365(c), or 386(c), and § 1.78(d) (the ''Earliest Benefit Date'' (EBD)). When the later-filed application is a utility or plant patent application, the EBD is also the date from which the 20-year patent term is calculated under 35 U.S.C. 154(a)(2). The EBD is also known as the ''patent term filing date.'' For more information about benefit claims, see MPEP 210 and 211 *et seq.,* for more information about the patent term filing date see MPEP 804 subsection I.B.1(a), and for more information about patent term, see MPEP 2701.

The proposed fee set forth in § 1.17(w)(1) would be due when the later-filed application's EBD is more than five years, and no more than eight years, earlier than its actual filing date, and would be $2,200 for undiscounted applications, $880 for applications receiving a small entity discount, and $440 for applications receiving a micro entity discount. The proposed fee set forth in § 1.17(w)(2) would be due when the later-filed application's EBD is more than eight years earlier than its actual filing date, and would be $3,500 for undiscounted applications, $1,400 for applications receiving a small entity discount, and $700 for applications receiving a micro entity discount.

Payment of these fees would be required at the time a prompting benefit claim (*i.e.,* a benefit claim that causes the EBD of the later-filed application to be more than five or eight years earlier than its actual filing date) is presented in the later-filed application. If the prompting benefit claim is presented at the time of filing the later-filed application, the applicable § 1.17(w) fee would be due at filing. If the prompting benefit claim is presented at a later time, the applicable § 1.17(w) fee would be due concurrently with the presentation of the prompting benefit claim. If the later presentation of the prompting benefit claim is by way of a petition for acceptance of an unintentionally delayed benefit claim under § 1.78(e), the applicable § 1.17(w) fee would be due in addition to the petition fee under § 1.17(m).

Because the proposed fees in § 1.17(w) are based on the application's EBD, presenting multiple benefit claims at the same time will not incur multiple fees. However, if benefit claims are presented at multiple times during an application's pendency, a second fee may be due if the later-presented benefit claim changes the application's EBD to be more than eight years earlier than the actual filing date. In this situation, the amount due under § 1.17(w)(2) for the later presentation will reflect any prior payment under § 1.17(w)(1) for the earlier presentation. For instance, if the fee under § 1.17(w)(1) was paid at the time of filing, and a prompting benefit claim requiring payment of the § 1.17(w)(2) fee is presented at a later time, the additional amount owed is the difference between the current fee amount stated in § 1.17(w)(2) and the amount of the previous payment under § 1.17(w)(1).

The following examples illustrate the most common situations anticipated to require payment of the proposed fees under § 1.17(w). For purposes of these examples, the agency assumes that all requirements for claiming benefit under 35 U.S.C. 119, 120, 121, 365(c), or 386(c), and § 1.78 are satisfied, and that all fees are paid at the undiscounted rates listed in table 5, supra.

Example 1: Application A is a nonprovisional application filed on July 7, 2025. The Application Data Sheet (ADS) present upon A's filing contains a benefit claim under 35 U.S.C. 120 to nonprovisional application N filed on February 3, 2020, which is the only benefit claim in the application. A's EBD is February 3, 2020, which is more than five years, and no more than eight

years, earlier than A's actual filing date of July 7, 2025. In this example, the § 1.17(w)(1) fee of $2,200 is due upon A's filing.

Example 2: Application B is a nonprovisional application filed on July 8, 2025. The ADS present upon B's filing contains a benefit claim under 35 U.S.C. 120 to nonprovisional application O filed on February 4, 2021, and a benefit claim under 35 U.S.C. 119(e) to provisional application P filed on March 11, 2020. The USPTO's records indicate that O also contains a benefit claim under 35 U.S.C. 119(e) to provisional application P. In this situation, P's filing date is not the EBD, because § 1.17(w) does not encompass benefit claims under 35 U.S.C. 119(e). Instead, B's EBD is February 4, 2021, which is less than five years earlier than B's actual filing date of July 8, 2025. In this example, no fee would be due under § 1.17(w).

Example 3: Application C is a nonprovisional application filed on July 9, 2025. The ADS present upon C's filing contains benefit claims under 35 U.S.C. 120 to nonprovisional application Q filed on February 5, 2020, and to nonprovisional application R filed on March 12, 2019. C's EBD is March 12, 2019, which is more than five years, and no more than eight years, earlier than C's actual filing date of July 9, 2025. In this example, the § 1.17(w)(1) fee of $2,200 is due upon C's filing.

Example 4: Application D is a nonprovisional application filed on August 10, 2028. The ADS present upon D's filing does not contain any benefit claims. Two months after D's filing, the applicant files a second ADS containing a benefit claim under 35 U.S.C. 120 to nonprovisional application S filed on February 6, 2020, which is the only benefit claim in the application. Because this newly added benefit claim causes D's EBD to become February 6, 2020, which is more than eight years earlier than D's actual filing date of August 10, 2028, the § 1.17(w)(2) fee of $3,500 is due upon filing of the second ADS.

Example 5: Application E is a nonprovisional application filed on August 11, 2028. The ADS present upon E's filing does not contain any benefit claims. Eighteen months after E's filing, the applicant files a second ADS containing a benefit claim under 35 U.S.C. 120 to nonprovisional application T filed on February 7, 2020, which is the only benefit claim in the application. Because this newly added benefit claim causes E's EBD to become February 7, 2020, which is more than eight years earlier than E's actual filing date of August 11, 2028, the § 1.17(w)(2) fee of $3,500 is due upon filing of the second ADS. In addition, because this benefit claim is delayed (not submitted within the required time period in § 1.78(d)), a petition for acceptance of an unintentionally delayed benefit claim under § 1.78(e) and the petition fee under § 1.17(m) are also required.

Example 6: Application F is a nonprovisional application filed on August 14, 2028. The ADS present upon F's filing contains a benefit claim under 35 U.S.C. 120 to nonprovisional application U filed on April 18, 2023, which is the only benefit claim in the application. F's EBD is April 18, 2023, which is more than five years, and no more than eight years, earlier than F's actual filing date of August 14, 2028. Accordingly, the § 1.17(w)(1) fee of $2,200 is due upon F's filing. Two months after F's filing, the applicant files a second ADS containing a benefit claim under 35 U.S.C. 120 nonprovisional application V filed on February 10, 2020. This newly added benefit claim causes F's EBD to become February 10, 2020, which is more than eight years earlier than F's actual filing date of August 14, 2028, and thus prompts the fee in § 1.17(w)(2). Because the fee in § 1.17(w)(1) was previously paid, the previous payment is subtracted from the amount now due under § 1.17(w)(2). Accordingly, the amount due upon filing of the second ADS is $1,300 (the current fee amount of $3,500 set forth in § 1.17(w)(2) less the $2,200 previously paid under § 1.17(w)(1)).

The proposed fees will recover more costs related to continuing applications from filers of such applications, encourage more efficient filing and prosecution behaviors, and partially offset foregone maintenance fee revenue resulting from later-filed continuing applications.

Continuing applications, which include continuation, divisional, and continuation-in-part applications filed under the conditions specified in 35 U.S.C. 120, 121, 365(c), or 386(c) and § 1.78, represent a large and increasing share of patent applications. From FY 2010 to FY 2022, total serialized filings rose about 44%, including a moderate increase in noncontinuing applications (about 25%) and a large increase in continuing applications (about 100%), due almost entirely to increased continuation filings. Since FY 2010, divisional and continuation-in-part applications remained flat at annual levels of about 22,000 and 19,000, respectively. However, continuation applications have tripled, from about 40,000 in FY 2010 to about 122,800 in FY 2022, and now represent about 34% of serialized filings.

The volume and rapid increase of continuing applications negatively impacts the USPTO's workload and docketing practices. For example, it is difficult for the agency to balance patent resources between the examination of ''new'' (*i.e.,* noncontinuing) applications disclosing new technology and innovations, and continuing applications, which, in some cases, are a repetition of previously examined applications either issued as patents or that have become abandoned. See *e.g.,* FY 2021 pendency statistics review presented at the PPAC quarterly meeting on Nov. 18, 2021, available on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/20211115-PPAC-FY21-pendency-stats-review.pdf* (note that about 80% of continuations have a patented parent).

Continuing applications filed long after their EBD are less likely to have a patent term long enough for the USPTO to recover the costs of its search and examination. The patent fee structure is designed to encourage innovation by maintaining low barriers to entry, which the agency accomplishes by keeping initial filing fees for utility, plant, and design applications below the costs for preexamination, search, and examination. The USPTO recovers the remaining cost of performing the work from maintenance fee payments made after issuance of a utility patent. See *e.g.,* the FY 2022 Agency Financial Report at 45–46, available on the USPTO website at *https://www.uspto.gov/AnnualReport.* Maintenance fees are due 3.5 years, 7.5 years, and 11.5 years from the issue date of a utility patent. See 35 U.S.C. 41(b)(1). During FY 2022, maintenance fees collected from utility patentees represented 53.8% of patent revenue, about one-third of which derived from payment of the 11.5-year fee. This revenue is vital to providing the necessary aggregate financing to fund patent operations. Thus, the fees proposed in this NPRM help compensate the USPTO for foregone maintenance fee revenue from continuing applications filed long enough after their EBD for their term to be less than 11.5 years.

If future workloads for continuing applications were to remain steady at FY 2022 levels, about 16% of continuing applications (approximately 22,000) would pay the proposed § 1.17(w)(1) fee, and an additional 11% of continuing applications (approximately 15,000) would pay the proposed § 1.17(w)(2) fee. Based on FY

2022 data, of the applications that would be affected by this proposal, about 69% are undiscounted, about 30% receive a small entity discount, and about 1% receive a micro entity discount. The USPTO also anticipates that the proposed fees will be relatively technology-neutral, with the most affected area being Technology Center 3700 (which examines technologies including mechanical engineering, manufacturing, gaming, and medical devices/processes) because it receives a much higher proportion of late-filed continuing applications than other areas.

3. Design Application Fees

TABLE 6—DESIGN APPLICATION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Basic filing fee—Design	Undiscounted	$220	$300	$80	36	$250
Basic filing fee—Design	Small	88	120	32	36	250
Basic filing fee—Design	Micro	44	60	16	36	250
Basic filing fee—Design CPA	Undiscounted	220	300	80	36	930
Basic filing fee—Design CPA	Small	88	120	32	36	930
Basic filing fee—Design CPA	Micro	44	60	16	36	930
Design search fee or Design CPA search fee	Undiscounted	160	300	140	88	574
Design search fee or Design CPA search fee	Small	64	120	56	88	574
Design search fee or Design CPA search fee	Micro	32	60	28	88	574
Design examination fee or Design CPA examination fee.	Undiscounted	640	700	60	9	835
Design examination fee or Design CPA examination fee.	Small	256	280	24	9	835
Design examination fee or Design CPA examination fee.	Micro	128	140	12	9	835
Design issue fee	Undiscounted	740	1,300	560	76	574
Design issue fee	Small	296	520	224	76	574
Design issue fee	Micro	148	260	112	76	574
Hague design issue fee	Undiscounted	740	1,300	560	76	n/a
Hague design issue fee	Small	296	520	224	76	n/a
Hague design issue fee	Micro	148	260	112	76	n/a
International Design Application First Part U.S. Designation Fee.	Undiscounted	1,020	1,300	280	27	n/a
International Design Application First Part U.S. Designation Fee.	Small	408	520	112	27	n/a
International Design Application First Part U.S. Designation Fee.	Micro	204	260	56	27	n/a
(Part II Designation Fee) Issue Fee Paid Through the International Bureau in an International Design Application.	Undiscounted	740	1,300	560	76	n/a
(Part II Designation Fee) Issue Fee Paid Through the International Bureau in an International Design Application.	Small	296	520	224	76	n/a
(Part II Designation Fee) Issue Fee Paid Through the International Bureau in an International Design Application.	Micro	148	260	112	76	n/a

The USPTO is proposing increases in the fees for filing, search, examination, and issuance of design patent applications. These proposals adjust the fees to account for inflationary cost increases, and to recover a larger portion of design costs from design applicants.

The proposed design fee increases will affect national design application filings and international design application filings that designate the United States under the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, July 2, 1999 (''Hague Agreement'').

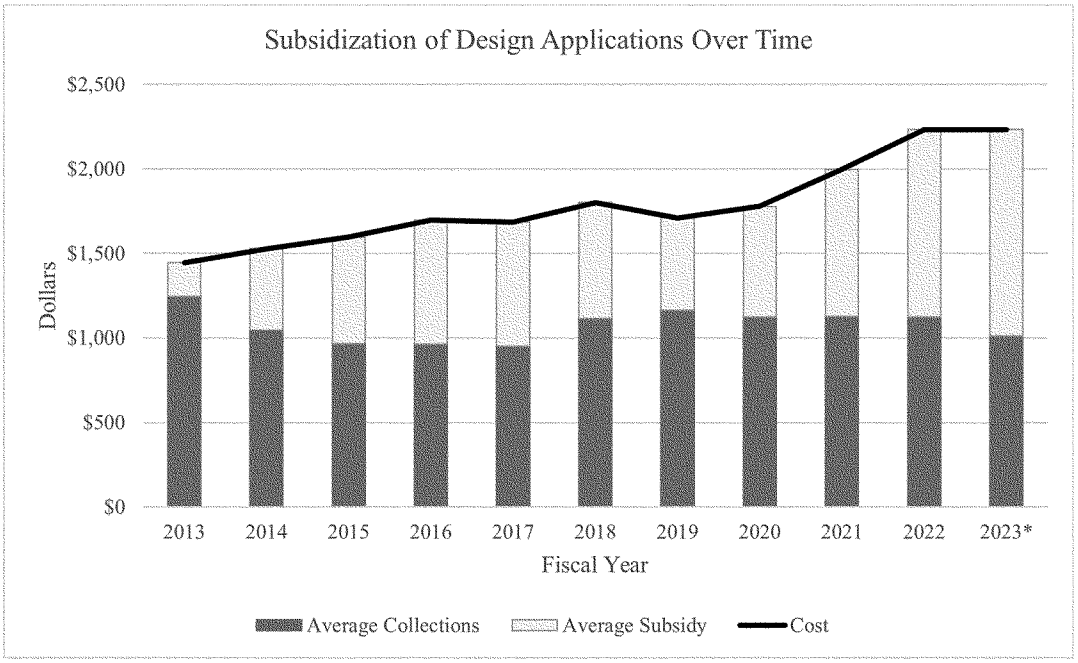
As shown in the table above, the combined total of filing, search, examination, and issue fees for a design application that proceeds to issuance would increase from $1,760 to $2,600 for undiscounted applications, from $704 to $1,040 for applications receiving a small entity discount, and from $352 to $520 for applications receiving a micro entity discount. Note that under the Hague Agreement and its implementing regulations in the United States, including § 1.1031, the required fees (known as ''designation fees'') for international design application filings that designate the United States are set by reference to the national fees. Thus, the first part of the designation fee corresponds to the sum of the filing fee, search fee, and examination fee, and the second part of the designation fee corresponds to the issue fee. See MPEP 2910 for more information about international design application fees.

Despite these increases, the proposed fees will not achieve full recovery of design costs. On an individual basis, the proposed fees including the issue fee do not fully recover the cost of examining and issuing a design application even when the applicant paid the undiscounted rate. On an aggregate basis, design fee payments will not fully recover design costs because most design applications qualify for discounted fees. For example, of the design applications filed in FY 2023, 28% paid the micro entity fee amount, 38% paid the small entity fee amount, and only 34% paid the undiscounted fee amounts. The USPTO is required by law to reduce most patent fees by 60% for small entities and by 80% for micro entities. See Part II: Legal Framework, supra. As a result of the heavy use of these discounts by design applicants, the USPTO's collections from design fees have been significantly below design costs for more than 10 years. For example, based on the most recently

available cost data (FY 2022), the unit cost for a design application was $2,233, and for a design Continued Prosecution Application, $2,913. The collections (in the same year) from design fees averaged only $1,125 per application, resulting in an average shortfall of about $1,108 per application. Assuming the unit cost remains the same in FY 2023, the average shortfall would increase to about $1,220 per application based on FY 2023 collections from design fees, which averaged only $1,013 per application.

Because USPTO operations are financed solely by user fees, the agency must make up the shortfall in the design area through fees set in other patent areas. While the USPTO has raised design fees twice in the last 10 years, those increases were not large enough to eliminate the shortfall over the long term. Thus, design costs continue to be subsidized by other fees, primarily utility patent maintenance fees. This subsidy has grown in recent years, as shown in figure 1. The graph depicts average fee collections per design application (''average collections'') in dark gray, and the average shortfall or subsidy per design application (''average subsidy'') in light gray. The average subsidy in FY 2022 was $1,108, and in FY 2023 was $1,220 (estimated based on FY 2022 unit cost).

Figure 1: Subsidization of Design Applications Over Time



* FY 2022 cost is assumed for FY 2023 because the FY 2023 data is not yet available.

The patent fee structure is designed to encourage innovation by maintaining low barriers to entry into the patent system. The USPTO accomplishes this goal by keeping initial filing fees for utility, plant, and design applications below the agency's costs for preexamination, search, and examination, and by recovering remaining costs of performing the work from maintenance fee payments made after issuance of a utility patent. See *e.g.,* the FY 2022 Agency Financial Report at 45–46, available on the USPTO website at *https://www.uspto.gov/AnnualReport.* Although the USPTO is not permitted to establish maintenance fees for design or plant patents (see 35 U.S.C. 41(b)(3)), the maintenance fees it collects from utility patentees represented 53.8% of patent revenue in FY 2022. This revenue is vital to providing the necessary aggregate revenue to recover the aggregate cost of patent operations.

Because design fee payors do not bear the full costs of design services, a disconnect between fees and costs, as currently exists in the design patent area, can lead to overuse of discounted services. See *e.g.,* Federal User Fees: A Design Guide, Report No. GAO–08–386SP (May 2008), available at *https://www.gao.gov/products/gao-08-386sp,* and the Patent and Trademark Office: New User Fee Design Presents Opportunities to Build on Transparency and Communication Success, Report No. GAO–12–514R (April 2012), available at *https://www.gao.gov/products/gao-12-514r.*

Historically, this difference between design fees and design costs did not result in a significant subsidy because the annual volume of design applications was much lower than the annual volume of issued utility patents. Since 2014, however, the number of design applications has surged 50% (from 36,254 in FY 2014 to 54,476 in FY 2022) while the number of issued utility patents (and thus the volume of potential future maintenance fees) has increased only 7% (from 303,930 in FY 2014 to 325,455 in FY 2022). See *e.g.,* FY 2022 Workload Table 1, available on the USPTO website at *https://www.uspto.gov/AnnualReport.* Moreover, virtually all growth in design application filings is attributable to applications in which discounted fees are paid. From FY 2014 to FY 2022, the number of undiscounted design applications filed did not increase, but the number of small entity applications increased 24%, and the number of micro entity applications increased 313%. As a result, the entity spread for design applications changed dramatically. For example, in FY 2014, the entity spread for design applications was 50% undiscounted, 40% small

entity, and 10% micro entity; during FY 2022, the entity spread for design applications was 35% undiscounted, 35% small entity, and 30% micro entity. In contrast, the entity spread in utility application filings has remained the same from FY 2014 to FY 2022, at about 72% undiscounted, 24% small entity, and 4% micro entity.

The combination of these factors makes it challenging for the USPTO to balance the setting of design fees that appropriately encourage innovation while also incenting design applicants to make appropriate economic decisions and not overuse design services. For example, based on the FY 2022 unit cost and assuming that filing volume and entity spread remain stable, recovering the full cost of design services from design applicants would require total fees of about $4,000 for undiscounted applications. Abruptly raising fees to these levels could discourage innovation, so the USPTO is proposing a more moderate increase to $2,600 for undiscounted applications. After considering all relevant factors, the agency believes the proposed design fee increases strike a balance that still encourages innovation while bringing in increased revenue to recover more design costs.

4. Excess Claims Fees

TABLE 7—EXCESS CLAIMS FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Each independent claim in excess of three	Undiscounted	$480	$600	$120	25	n/a
Each independent claim in excess of three	Small	192	240	48	25	n/a
Each independent claim in excess of three	Micro	96	120	24	25	n/a
Each reissue independent claim in excess of three	Undiscounted	480	600	120	25	n/a
Each reissue independent claim in excess of three	Small	192	240	48	25	n/a
Each reissue independent claim in excess of three	Micro	96	120	24	25	n/a
Each claim in excess of 20	Undiscounted	100	200	100	100	n/a
Each claim in excess of 20	Small	40	80	40	100	n/a
Each claim in excess of 20	Micro	20	40	20	100	n/a
Each reissue claim in excess of 20	Undiscounted	100	200	100	100	n/a
Each reissue claim in excess of 20	Small	40	80	40	100	n/a
Each reissue claim in excess of 20	Micro	20	40	20	100	n/a
Each reexamination independent claim in excess of three and also in excess of the number of such claims in the patent under reexamination.	Undiscounted	480	600	120	25	n/a
Each reexamination independent claim in excess of three and also in excess of the number of such claims in the patent under reexamination.	Small	192	240	48	25	n/a
Each reexamination independent claim in excess of three and also in excess of the number of such claims in the patent under reexamination.	Micro	96	120	24	25	n/a
Each reexamination claim in excess of 20 and also in excess of the number of claims in the patent under reexamination.	Undiscounted	100	200	100	100	n/a
Each reexamination claim in excess of 20 and also in excess of the number of claims in the patent under reexamination.	Small	40	80	40	100	n/a
Each reexamination claim in excess of 20 and also in excess of the number of claims in the patent under reexamination.	Micro	20	40	20	100	n/a

Under § 1.16(h) and (i), the USPTO charges a fee for filing, or later presenting at any other time, each independent claim in excess of three, as well as each claim (whether dependent or independent) in excess of 20. The agency proposes to increase the § 1.16(h) and (i) excess claims fees. The § 1.16(j) multiple dependent claim fee is part of the across-the-board adjustment and not included in this targeted proposal as well as the counterpart excess claims fees applicable to reexamination proceedings and applications that are the national stage of an international application filed under the Patent Cooperation Treaty. These changes would provide more revenue to help recover the additional search and examination costs associated with excess claims, as well as prosecution costs not covered by front-end fees. These changes would also promote compact prosecution, and the USPTO believes applicants motivated by costs would be incentivized to not file excess claims. In FY 2021, only about 15% of applications contained more than 20 total claims, and about 8% of applications contained more than three independent claims.

The USPTO has increased excess claim fees several times during the last 20 years, which has been very effective at reducing excess claims from their peak in the early 2000s. A high frequency of applications filed with exactly 20 claims and a very low frequency of applications with claim counts exceeding 20 to help promote compact prosecution. In absence of the agency's proposed increases to excess claims fees, it anticipates that excess claims numbers would increase in response to proposed fees for certain continuing applications discussed previously in this proposal.

Continuing application and excess claim fees are naturally linked and likely to have counterbalancing effects. For example, an increase in continuing applications could result from raising only excess claims fees, and an increase in excess claims could result from raising only the fee for continuing applications (even in specific, lesser-occurring situations). The proposed increases in excess claims fees are intended to avert the latter scenario.

An applicant who files a nonprovisional utility application having three independent claims and 40 claims total—double the § 1.16(i) total claim-count threshold—is required to pay the § 1.16(i) fee for 20 excess claims.

Under the USPTO's proposed fee rates, an application with double the 20 total claim-count threshold would require an excess claims fee payment that equals the combined proposed fee amounts for filing, search, and examination. In other words, a double-sized application (three independent claims and 40 claims total) would require double the combined total in applicable fees for filing, search, and examination.

5. Extension of Time for Provisional Application Fees

TABLE 8—EXTENSION OF TIME FOR PROVISIONAL APPLICATION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Extension for response within first month, provisional application.	Undiscounted ...	$220	$50	−$170	−77	n/a
Extension for response within first month, provisional application.	Small	88	20	−68	−77	n/a
Extension for response within first month, provisional application.	Micro	44	10	−34	−77	n/a
Extension for response within second month, provisional application.	Undiscounted ...	640	100	−540	−84	n/a
Extension for response within second month, provisional application.	Small	256	40	−216	−84	n/a
Extension for response within second month, provisional application.	Micro	128	20	−108	−84	n/a
Extension for response within third month, provisional application.	Undiscounted	1,480	200	−1,280	−86	n/a
Extension for response within third month, provisional application.	Small	592	80	−512	−86	n/a
Extension for response within third month, provisional application.	Micro	296	40	−256	−86	n/a
Extension for response within fourth month, provisional application.	Undiscounted ...	2,320	400	−1,920	−83	n/a
Extension for response within fourth month, provisional application.	Small	928	160	−768	−83	n/a
Extension for response within fourth month, provisional application.	Micro	464	80	−384	−83	n/a
Extension for response within fifth month, provisional application.	Undiscounted ...	3,160	800	−2,360	−75	n/a
Extension for response within fifth month, provisional application.	Small	1,264	320	−944	−75	n/a
Extension for response within fifth month, provisional application.	Micro	632	160	−472	−75	n/a

The USPTO proposes a separate extension of time (EOT) fee structure for provisional applications in which fees would be decreased from current amounts by an average of 81%. Under EOT practice, if an applicant is required to reply within a nonstatutory or shortened statutory time period, the applicant may normally petition to extend the time period for reply with the requisite fee. The time extension may be up to the earlier of the expiration of any maximum period set by statute or five months after the time period set for reply, if a petition for an EOT under § 1.136(a), including the EOT fee set in § 1.17(a), is filed.

Currently, the EOT fees specified in § 1.17(a) apply equally to both provisional and nonprovisional applications. The USPTO proposes an average 81% EOT fee decrease in provisional applications under a new paragraph (u) of § 1.17, with an additional proposal that § 1.136(a) be amended to refer to EOT fees under both § 1.17(a) and new § 1.17(u). For patent applications other than provisional applications, the EOT fee structure retained under § 1.17(a) would be increased by 5%, in accordance with the across-the-board proposal.

With fees reduced by 81% on average, the proposed separate EOT fee structure for provisional applications would benefit filers in all entity status categories. The agency envisions that micro entity provisional application filers would benefit most. As explained in the Director's April 20, 2023, letter to PPAC:

''The USPTO's fee review concluded that applicants who have certified micro entity status in provisional applications are more than twice as likely to request EOT as compared to other applicants. Thus, we are proposing reduced EOT fees for provisional applications by an average of 81% to reduce financial and entry barriers and further foster inclusive innovation.''

Some micro entity applicants need time extensions to accommodate attempts to meet additional formality requirements associated with establishing micro entity status. Another consideration favoring this proposal is that provisional applications are not examined; therefore, there is less urgency to expedite processing.

6. Information Disclosure Statement Size Fees

TABLE 9—INFORMATION DISCLOSURE STATEMENT SIZE FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided items of information to exceed 50 but not exceed 100.	Undiscounted	New	$200	n/a	n/a	n/a
Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided items of information to exceed 100 but not exceed 200.	Undiscounted ...	New	$500, less any amount previously paid.	n/a	n/a	n/a
Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided items of information to exceed 200.	Undiscounted ...	New	$800, less any amounts previously paid.	n/a	n/a	n/a

Sections 1.97 and 1.555 provide applicants and patent owners the opportunity to submit an information disclosure statement (IDS) containing items of information for consideration by the examiner. In a patent application, to be considered, the IDS must meet the timing requirements of § 1.97 and the content requirements of § 1.98. In a reexamination proceeding, the IDS must meet the content requirements of § 1.98(a). There are no specific regulatory limits to the number of items of information that may be included in an IDS. Most applications contain relatively few items of information submitted by applicants for consideration. Approximately 77% of applications have fewer than 25 applicant-cited items of information submitted during prosecution.

The USPTO receives large IDS submissions in a small percentage of applications. Based on the agency's most recent data, in approximately 13% of applications applicants submit over 50 total items of information and in 8% of applications applicants submit over 100 items of information. In an even smaller subset of applications, the number of applicant-submitted items can be quite large, sometimes in the thousands or even tens of thousands.

In many instances, these large IDS submissions contain clearly irrelevant, marginally relevant, or cumulative information. It is onerous for examiners and hinders the USPTO's statutory obligation to timely examine applications under 35 U.S.C. 154 to consider large numbers of clearly irrelevant, marginally relevant, or cumulative information. Additionally, large IDS submissions are costly for the agency to consider. Therefore, the USPTO suggests, as a best practice, that applicants and patent owners avoid filing large IDS submissions by eliminating clearly irrelevant, marginally relevant, or cumulative information. See MPEP 2004, item 13.

In 2006, the USPTO attempted to address large IDS submissions by proposing new requirements, including that IDSs with more than twenty citations be accompanied by an explanation of relevance. See Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 FR 38808 (July 10, 2006). The proposal was not adopted; instead, to provide some relief for examiners burdened with large IDS submissions, the agency began providing examiners additional time to consider large IDS submissions in applications.

On average, the USPTO provides examiners approximately 80,000 additional hours each year to consider large IDS submissions in applications, costing the agency $10 million annually. As there is currently no fee for large IDS submissions, this cost is subsidized generally by patent fees, primarily maintenance fees collected for patents that resulted from applications that did not contain large IDS submissions.

Accordingly, to have applicants and patent owners filing large IDS submissions cover more of the associated costs, the USPTO proposes to amend § 1.17 to implement a new IDS size fee based on the cumulative number of items of information submitted by an applicant or patent owner during the pendency of the application or reexamination proceeding. The proposed IDS size fee sets forth: (1) a first amount ($200) for a cumulative number of applicant-provided or patent-owner provided items of information in excess of 50; (2) a second amount ($500) for a cumulative number of applicant-provided or patent-owner provided items of information in excess of 100 but not exceeding 200, less any amount previously paid; and (3) a third amount ($800) for a cumulative number of applicant-provided or patent owner provided items of information in excess of 200, less any amounts previously paid.

For example, if an applicant submits a single IDS during prosecution with 101 items of information, the applicant would pay $500 under the proposed new § 1.17(v)(2) for exceeding 100 items of information, but not exceeding 200. In another example, if an applicant files a first IDS with 51 items of information, they would pay $200 under proposed new § 1.17(v)(1) for exceeding 50 items of information, but not exceeding 100. Subsequently, in that same application, if the applicant files a second IDS with 50 items of information, the cumulative number of items of information in the application would be 101. The applicant would then pay $500 under proposed new § 1.17(v)(2) for exceeding 100 items of information, but not exceeding 200, less the $200 previously paid under proposed new § 1.17(v)(1), for a total of $300.

Further, in that same application, if the applicant files a third IDS with 100 items of information, the cumulative number of items of information in the application would be 201. The applicant would then pay $800 under proposed new § 1.17(v)(3) for exceeding 200 items of information, less the $200 previously paid under proposed new § 1.17(v)(1) and less the $300 previously paid under proposed new § 1.17(v)(2), for a total of $300. Thus, in this example, the applicant would pay a combined IDS size fee of $800 for the three IDSs filed during the pendency of the application.

Additionally, the USPTO is proposing to amend § 1.98(a) to include a new content requirement for an IDS that will facilitate implementation of the proposed IDS size fee. Specifically, the USPTO is proposing to require that an IDS contain a clear written assertion by applicant and patent owner that the IDS is accompanied by the appropriate IDS size fee, or that no IDS size fee is required. This assertion is necessary because it ensures the record is clear as

to which fee the applicant or patent owner believes may be due (or that no fee may be due), with the IDS so the examiner can promptly ascertain whether the IDS is compliant. There would be no specific language required for the written assertion, but it should be readily identifiable on the IDS and clearly convey the applicable IDS size fee.

The agency envisions modifying USPTO Form PTO/SB/08 to include the requisite written assertion stylized as a set of check boxes corresponding to each potential IDS size fee, along with an additional box indicating that no IDS size fee is due. Since the form must be signed in accordance with § 1.33(b), certifications under §§ 1.4 and 11.18 apply. Applicants and patent owners would be strongly advised to use the PTO/SB/08 form, but it will not be required. The USPTO does not foresee general authorizations to charge fees or a specific authorization to charge any applicable IDS size fee as a compliant written assertion under the proposed requirement. It would be the applicant's and patent owner's responsibility to track the cumulative number of items of information submitted in the application and provide a written assertion of any applicable IDS size fee due. In accordance with § 1.97(i), an IDS filed in an application without the written assertion or the necessary IDS size fee will be placed in the file, but not considered by the agency. The applicant may then file a new IDS accompanied by the written assertion or necessary IDS size fee, but the date the new IDS is filed will be the date of the IDS for purposes of determining compliance with § 1.97. See MPEP 609.05(a). An IDS filed in a reexamination proceeding without the written assertion or the necessary IDS size fee will be placed in the file and will remain of record, but the IDS will not be considered.

Applicants are reminded that the duty of disclosure under §§ 1.56 and 1.555 only requires the submission of information material to patentability to the USPTO. Material information is described in §§ 1.56(b) and 1.555(b) as information that is not cumulative to information already of record and (1) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the USPTO, or (ii) asserting an argument of patentability. The United States Court of Appeals for the Federal Circuit uses an even higher standard for materiality than the § 1.56(b) and 1.555(b) standards by requiring ''but-for'' materiality, such that the USPTO would not have allowed a claim had it been aware of the undisclosed information. Neither the § 1.56(b) and 1.555(b) standards nor the Federal Circuit's ''but-for'' standard require the submission of clearly irrelevant or marginally relevant information.

The USPTO does not believe the proposed IDS size fee will have a large impact on patent applicants or owners. As stated previously, a majority of applicants do not submit large amounts of information for consideration. Based on current IDS filing volume, only 13% of applications will require the first-tier IDS size fee for submitting over 50 items of information. Even fewer applications will be subject to the succeeding two tiers, as only approximately 8% of applications contain over 100 items of information, and about 4% contain over 200 items of information. Additionally, the fee should not disproportionately impact small and micro entities. During FY 2022, small entities accounted for only 25% of applications that would incur a fee, while micro entities made up less than 1%. By placing more of the service costs for considering IDS submissions totaling over 50 items of information on the applicants who file such IDS submissions, less costs will be borne across the patent system.

7. Patent Term Adjustment Fees

TABLE 10—PATENT TERM ADJUSTMENT FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Filing an application for patent term adjustment	Undiscounted ...	$210	$300	$90	43	$745

The USPTO is proposing a fee increase from $210 to $300 for filing an application for patent term adjustment under § 1.705(b), which allows patentees of utility and plant patents to request reconsideration of the patent term adjustment indicated on the face of the patent. This proposal adjusts the fee for inflation and supports the USPTO's fee setting policy of aligning fees with costs.

This service and fee were introduced in September 2000 as part of a rule package implementing the patent term adjustment provisions of 35 U.S.C. 154(b), which were created by the Uruguay Round Agreements Act (Pub. L. 103–465, 108 Stat. 4809 (1994)) and amended by the American Inventors Protection Act of 1999 (Pub. L. 106–113, 113 Stat. 1501, 1501A–552 through 1501A–591 (1999)). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56366 (Sept. 18, 2000). Under 35 U.S.C. 154(b), patent term adjustment is a complex statutory scheme that compensates utility and plant patent owners for certain application processing delays that would otherwise reduce a patent's term. See MPEP 2730 through 2732 for more information regarding grounds for adjustment, the adjustment period, and reductions in the adjustment period due to applicant failures to engage in reasonable efforts to conclude prosecution of an application.

In accordance with these laws and their implementing regulations, the USPTO determines applicable patent term adjustment at the time of issuing each utility and plant patent and indicates such adjustment on the face of the patent. These determinations are performed using a computer program that relies upon information in the agency's patent application data repository—formerly Patent Application Locating and Monitoring, now the One Patent Service Gateway (OPSG). This information includes the type of document (*e.g.,* an amendment or a notice of allowance) and the relevant date (*e.g.,* for an amendment, the date of receipt in the USPTO). Applicants may use Patent Center to check the accuracy of the data entered in the OPSG throughout the examination process and are encouraged to notify the agency of any detected errors prior to allowance. See *e.g.,* MPEP 2733 for guidance about checking records and reporting errors (note, Patent Center replaced the Patent Application Information Retrieval system discussed in the MPEP).

If the patentee disagrees with the adjustment indicated on the patent, they may file a request for reconsideration of patent term adjustment under § 1.705(b) which must filed within two months of the date the patent was granted. The

request (also called an application) must include the patentee's requested patent term adjustment and a supporting statement of facts and be accompanied by the fee specified in § 1.18(e). In response to a request, the USPTO will conduct a manual redetermination of the patent term adjustment, which may result in (1) an amount of patent term adjustment that is the amount of patent term adjustment requested by the applicant; (2) the same amount of patent term adjustment as indicated in the patent (*i.e.,* no change); or (3) a different amount of patent term adjustment that may be higher or lower than the patent term adjustment indicated on the patent. More information regarding determination and reconsideration of patent term adjustment is available in MPEP 2733 and 2734.

When introduced in 2000, the agency set the fee for requests for reconsideration of patent term adjustment at $200, and since then has increased this fee only $10. See Changes To Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56366 (Sep. 18, 2000); FY 2020 Final Rule. If the agency had adjusted the fee for inflation as measured by the Consumer Price Index since the fee's introduction, it would be $351 as of June 2023. The USPTO's proposed increase to $300 is 15% below the inflation-adjusted original fee. Thus, the proposed fee represents a partial recovery of the inflation-adjusted original fee. Moreover, the proposed fee will remain significantly less than the unit cost of this service ($745 in FY 2022). While this fee does not qualify for entity discounts, the proposed increase will not disproportionately impact small and micro entities. Based on data from FY 2021 and FY 2022, small entities file about 19% of PTA reconsideration requests, and micro entities only 1%.

This service has a low volume of about 500 requests each year, meaning that patentees are requesting reconsideration of patent term adjustment in only 0.15% of issued patents (since FY 2019, the USPTO has issued over 325,000 utility and plant patents annually). This low volume is due partly to the USPTO's improvements to its computer program over the years, and partly to applicant diligence when submitting and reviewing papers. For example, as described previously, applicants are encouraged to bring any detected errors in OPSG data to the agency's attention before allowance. In addition, applicants can improve the accuracy of the USPTO's records (which, in turn, improves the accuracy of the computer program's determinations) by using the proper document codes when filing papers. See *e.g.,* Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements, 88 FR 39172 (Jun. 15, 2023), which explains how using the agency's form and document code when filing a ''safe harbor'' statement for an IDS enhances the accuracy of the USPTO's automated process for calculating patent term adjustment when the ''safe harbor'' provisions of § 1.704(d) are involved.

8. Patent Term Extension Fees

TABLE 11—PATENT TERM EXTENSION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Application for extension of term of patent	Undiscounted	$1,180	$6,700	$5,520	468	$2,581
Initial application for interim extension (see 37 CFR 1.790).	Undiscounted	440	1,320	880	200	2,347
Subsequent application for interim extension (see 37 CFR 1.790).	Undiscounted	230	680	450	196	2,347
Supplemental redetermination after notice of final determination.	Undiscounted	New	1,440	n/a	n/a	n/a

The USPTO is proposing fee increases for filing applications for patent term extension and applications for interim extensions under 35 U.S.C. 156, and is also proposing a new fee for requesting a supplemental redetermination of the patent term extension in a pending application for patent term extension. These proposals adjust fees for inflation and reflect the full cost of these services and also supports the agency's fee setting policy of aligning fees with costs.

The patent term extension service and fee were introduced in October 1984 as part of initial operating guidelines established after enactment of the patent term extension provisions of 35 U.S.C. 156 in the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417, 98 Stat. 1585 (1984)) (Hatch-Waxman Act). See Guidelines for Extension of Patent Term under 35 U.S.C. 156, 1047 OG 16 (Oct. 9, 1984). In brief, patent term extensions under 35 U.S.C. 156 enable owners of patents claiming certain products subject to premarket regulatory review to restore to the terms of those patents some of the time lost while awaiting premarket government approval for the products from a regulatory agency. The products eligible for patent term extension services under 35 U.S.C. 156 include human drug products, medical devices, animal drugs, and food or color additive products, all of which are regulated by the FDA, and veterinary biological products, which are regulated by the United States Department of Agriculture (USDA). See MPEP 2750 for more information regarding the legislative history and scope of the Hatch-Waxman Act with respect to patent term extensions.

In accordance with this law and its implementing regulations, the patent owner must file an application for patent term extension with the USPTO within a short time after the product receives permission for commercial marketing or use from the applicable regulatory agency (the FDA or USDA). See MPEP 2754 *et seq.* Upon receipt, the USPTO reviews the application, the applicant, the patent, and the claimed product or process and then works with the applicable regulatory agency to evaluate compliance with the statutory requirements for a patent term extension under 35 U.S.C. 156. While it is the USPTO's responsibility to decide whether an applicant has satisfied statutory requirements and whether the patent qualifies for patent term extension, the applicable regulatory agency possesses expertise and records regarding some statutory requirements and has certain direct responsibilities under 35 U.S.C. 156 for determining length of the regulatory review period. See MPEP 2756 for a more detailed explanation of how the USPTO works with these regulatory agencies to determine a patent's eligibility for patent term extension under 35 U.S.C. 156. Once the USPTO has received the necessary information from the regulatory agency, it determines the

applicable patent term extension (if any) and formulates a Notice of Final Determination or determination of ineligibility, reviews any responses or reconsideration requests received from the patent owner, and then prepares a Final Determination or certificate as appropriate. See MPEP 2755 through 2759 for an explanation of this process. Because of the coordination and communication required between the USPTO and the appropriate regulatory agency, and the complexity of the legal determinations involved, it often takes two or more years to reach a Final Determination or determination of ineligibility. The time required varies greatly depending on the individual circumstances of each application.

When introduced in 1984, the fee for this service was set at $750 and since then has increased to only $1,180. See *e.g.,* Guidelines for Extension of Patent Term Under 35 U.S.C. 156, 1047 OG 16 (Oct. 9, 1984), Rules for Extension of Patent Term, 52 FR 9386 (Mar. 24, 1987), and FY 2020 Final Rule. If the original fee were adjusted for inflation as measured by the CPI, it would be $2,173 as of June 2023. Moreover, the complexity and cost of this service has increased over time due to the subject matter and legal expertise required to evaluate the statutory requirements. Thus, the USPTO is proposing to raise the fee for this service from $1,180 to $6,700.

While the proposed fee is greater than the reported unit cost, the USPTO did not begin formally tracking the unit cost of this service (as a separate service through the ABI program) until midway through FY 2021. Prior to FY 2018 the service volume was quite low at about 42 applications each year. Since then, volume has averaged 100-plus applications each year. Accordingly, because the ABI for patent term extension is based on limited data, the currently reported unit cost is believed to be significantly lower than the actual cost of providing the service. As the amount of service information increases with time, the USPTO expects that the unit cost determined by the ABI program will more closely align with the actual cost.

The USPTO is also proposing a new service fee that would apply to the approximate one-third of applications for patent term extension in which the user files a response that includes a terminal disclaimer after receiving the Notice of Final Determination. The submission of terminal disclaimers at this late stage in the review process affects the patent term, requiring the USPTO to engage in a substantial amount of rework to recalculate the applicable patent term extension and make a supplemental redetermination of the appropriate extension in view of the disclaimer. These submissions became more common after the Federal Circuit's decision in *Gilead Sciences, Inc.* v. *Natco Pharma Ltd.,* 753 F.3d 1208 (Fed. Cir. 2014), which made it clear that the extended term of a patent can be affected by a terminal disclaimer filed against a later-issued but earlier-expiring reference patent, and after a 2015 presentation by USPTO personnel at a public meeting discussing the *Gilead* decision. See Safekeeping of 35 U.S.C. 156 Extensions presentation from the USPTO Biotechnology/Chemical/Pharmaceutical Customer Partnership Meeting on April 7, 2015, available at *https://www.aipla.org/docs/default-source/committee-documents/bcp-files/pte-for-4-7-15-bcp.pdf?sfvrsn=868807b4_2.* These submissions are expected to become more common in the future, because of *In re Cellect,* 81 F.4th 1216, 2023 U.S.P.Q.2d 1011 (Fed. Cir. 2023), in which the Federal Circuit explained that patent term adjustment and patent term extension are treated differently with respect to nonstatutory double patenting and terminal disclaimers. Currently, beneficiaries of this rework receive this additional service for free because the cost is subsidized by other users (*e.g.,* by unrelated fee collections from other patent applicants and owners). In accordance with user fee design principles, the USPTO is proposing a new fee of $1,440 to cover the costs of this service, to be paid by users who benefit from it.

The USPTO is also proposing to increase the fees for filing applications for interim patent term extensions under § 1.790. This service and fees were introduced in 1994 in response to an amendment of the Hatch-Waxman Act that added 35 U.S.C. 156(d)(5). See MPEP 2750 and Guidelines for Interim Extension Under 35 U.S.C. 156(d)(5) of a Patent Term Prior To Regulatory Approval of a Product for Commercial Marketing or Use—Public Law 103–179 (Dec. 3, 1993), 1159 OG 12 (Feb. 1, 1994). Interim patent extension under 35 U.S.C. 156(d)(5) is available for a patent claiming a product which is undergoing the approval phase of regulatory review as defined in 35 U.S.C. 156(g), if the patent is expected to expire before approval is granted. The application of an interim patent extension is very similar to an application for patent term extension, with a similar evaluation process, except the USPTO is not required to seek the advice of the regulatory agency. See MPEP 2755.02 for more information regarding this service.

The interim extension service has a very low volume of about 20 or fewer applications each year, but it is costly and requires special handling due to the subject matter and legal expertise required to evaluate the statutory requirements. The USPTO is proposing to raise the fees from $440 to $1,320 for the initial (first) application for an interim extension of patent term, and from $230 to $680 for each subsequent application. This fee increase will help recover the agency's costs of performing this service. Upon its introduction in 1993, the fees for this service were set at $400 for an initial application and $200 for subsequent applications, and have increased by only $40 and $30, respectively, since. See FY 2020 Final Rule. The proposed fee amounts remain significantly less than the agency's costs of providing the service; as of FY 2022, the unit cost was $2,347.

No patent term extension-related fees are eligible for entity discounts. The users of these services are typically large pharmaceutical and medical device companies due to the expense required to develop and obtain marketing approval for such inventions, in addition to limits on service availability set forth in 35 U.S.C. 156. For example, over the last 40 years, 81% of applications for patent term extension concerned human drug products, 15% concerned medical devices, 3% concerned animal drugs, and about 1% concerned food or color additive products or veterinary biological products. See *e.g.,* the USPTO website at *https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156,* which provides a list of patents that have been extended via this service. Additionally, the costs for regulatory approval of these products are extremely high. For example, as reported by the CBO, three recent studies estimated the average research and development costs per new drug to range from $0.8 billion to $2.3 billion. See Congressional Budget Office, Research and Development in the Pharmaceutical Industry, Report No. 57126 pp. 15 and 16 (April 2021), available at *https://www.cbo.gov/publication/57126.* It is not clear whether the figures reported in these studies included FDA user fees, which are currently between $1.6 million and $3.2 million as a one-time sum, with an additional annual program fee of $393,933. See *e.g.,* the FDA's user fee page for prescription drugs at *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.* Thus, when compared to

either FDA user fees or the research and development costs required to develop a new drug and obtain marketing approval, the proposed fees to obtain a patent term extension for the patent covering such a new drug are quite small.

9. Request for Continued Examination Fees

TABLE 12—REQUEST FOR CONTINUED EXAMINATION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Request for continued examination (RCE)—1st request (see 37 CFR 1.114).	Undiscounted	$1,360	$1,500	$140	10	$3,059
Request for continued examination (RCE)—1st request (see 37 CFR 1.114).	Small	544	600	56	10	3,059
Request for continued examination (RCE)—1st request (see 37 CFR 1.114).	Micro	272	300	28	10	3,059
Request for continued examination (RCE)—2nd request (see 37 CFR 1.114).	Undiscounted	2,000	2,500	500	25	2,191
Request for continued examination (RCE)—2nd request (see 37 CFR 1.114).	Small	800	1,000	200	25	2,191
Request for continued examination (RCE)—2nd request (see 37 CFR 1.114).	Micro	400	500	100	25	2,191
Request for continued examination (RCE)—3rd and subsequent request (see 37 CFR 1.114).	Undiscounted	2,000	3,600	1,600	80	2,169
Request for continued examination (RCE)—3rd and subsequent request (see 37 CFR 1.114).	Small	800	1,440	640	80	2,169
Request for continued examination (RCE)—3rd and subsequent request (see 37 CFR 1.114).	Micro	400	720	320	80	2,169

For utility and plant applications where prosecution is closed (*e.g.,* a final rejection has been mailed), the applicant may file an RCE and pay a specified fee within the requisite time period. Applicants typically file an RCE when they choose to continue prosecution before an examiner, rather than appeal a rejection or abandon the application. Prior to application abandonment, applicants may also file a continuing application to extend prosecution rather than file an RCE. The USPTO's proposal would split the existing RCE fees into three parts—a fee for a first RCE, a higher fee for a second RCE, and a still higher fee for third and subsequent RCEs filed in a single patent application.

Since FY 2013, the USPTO has split RCE fees into two parts: (1) a fee for a first RCE; and (2) a second, higher fee for a second or subsequent RCE. See Setting and Adjusting Patent Fees, 78 FR 4212 (Jan. 18, 2013). The USPTO's FY 2017 fee setting rulemaking maintained the undiscounted fee for a first RCE well below cost but set the undiscounted fee for second and subsequent RCEs at 19% above cost. See Setting and Adjusting Patent Fees During Fiscal Year 2017, 82 FR 52780 (Nov. 14, 2017). The initial RCE fee from FY 2017 would have required an applicant without any entity status discount to file four RCEs to mostly recover the USPTO's costs for treating all RCE filings.

These costs have increased annually since FY 2017. In fact, the current undiscounted fee for second and subsequent RCEs is set so far below cost that no amount of RCE filings would recapture the USPTO's costs of providing the service. Under this proposal to trifurcate the RCE fee structure, the undiscounted fee for a first RCE would be more than 50% below cost, and the undiscounted fee for a second RCE would be just above cost. The undiscounted fee for third and subsequent RCEs would be enough above cost that a third RCE from an applicant with no entity status discount, combined with the fees for filing the first two RCEs, would cover agency costs for treating all three RCEs.

Of course, applicants do not file multiple RCEs all at once, and the USPTO's costs typically rise over time due to inflationary factors. Under the proposed new trifurcated fee structure, by the time an applicant pays the third and subsequent RCE fee, it—when combined with the first two RCE fees—would likely not cover the USPTO's costs for treating all three RCEs. In addition, RCEs filed by applicants with an established entitlement to an entity status discount would never approach covering the agency's costs, regardless of the number of RCEs filed.

During FY 2011, when the agency's fee schedule set only one RCE fee, RCE filings comprised about 30% of all RCE and utility patent application filings collectively. In FY 2018, RCE filings comprised 29% of the total despite the bifurcated fee structure introduced in FY 2013. The RCE filing percentage declined to 25% in FY 2021 and 23% in FY 2022. It is unlikely these recent decreases resulted from the bifurcated fee structure, as the RCE filing percentage was hardly affected in the years immediately following FY 2013.

By reducing RCE filings in favor of appeal or reaching agreement with an examiner, the proposed higher fee for RCEs filed subsequent to the first RCE should help promote more compact prosecutions. Higher fees for successively filed RCEs also address the inequities of providing further subsidies to those who make greater use of the patent system. As explained in the USPTO's FY 2013 rulemaking at 78 FR 4212, 4245 (Jan. 18, 2013), because the USPTO set the fee for the first RCE below the cost to process it, the agency must recoup that cost elsewhere. Since most applicants resolve their issues with the first RCE, the agency determined that applicants that file more than one RCE are using the patent system more extensively than those who file zero or only one RCE. Therefore, the USPTO determined that the cost to review applications with multiple RCEs should not be subsidized with other back-end fees to the same extent as applications with a first RCE, newly filed applications, or other continuing applications. This proposal would promote compact prosecution and more appropriately dispense the low barrier to entry feature of below cost front end fees.

In FY 2011, around 70% of RCE applications were for first RCEs, with

the remaining 30% for a second or subsequent RCE. Based on FY 2021 and FY 2022 data, approximately 72% of current RCE filings are first RCEs, 19% are second RCEs, and the remaining 9% are third or subsequent RCEs. If this proposal has its intended effect, less than 9% of RCE filings would qualify for the highest fee tier for third and subsequent RCEs.

As previously described, the undiscounted fee for a first RCE would be more than 50% below cost, and the undiscounted fee for a second RCE would be above cost. Accordingly, undiscounted fees paid for two RCEs would be 24% below cost for treating two RCEs. Under this proposal, it is not until the third and subsequent undiscounted RCEs, combined with fees for the first two RCEs, that the USPTO would recover its costs.

An applicant in a position to file a third RCE likely has undergone years of patent prosecution, and they could avoid the higher fee by appealing the examiner's rejection(s) should no agreement be reached to put the application in condition for allowance. Prolonged, years-long prosecution could result in patent expiration prior to maintenance fee payment, especially the third scheduled maintenance fee—another factor in the USPTO's proposal to limit excessive RCE filings.

That said, some applicants may see value in prolonged prosecution. Whereas the scope of an issued patent is fixed and avoiding patent infringement can be assessed by competitors, a patent that may result in the future from a pending application is harder to assess in that regard. Accordingly, the USPTO does not expect to eliminate third and subsequent RCE filings but envisions that the higher fee will help reduce their number.

10. Suspension of Action Fees

TABLE 13—SUSPENSION OF ACTION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
First request for suspension of action	Undiscounted	$220	$300	$80	36	n/a
First request for suspension of action	Small	88	120	32	36	n/a
First request for suspension of action	Micro	44	60	16	36	n/a
Subsequent request for suspension of action	Undiscounted	220	450	230	105	n/a
Subsequent request for suspension of action	Small	88	180	92	105	n/a
Subsequent request for suspension of action	Micro	44	90	46	105	n/a

The USPTO proposes to create a new tiered fee structure for requests for suspension of action under § 1.103(a). Specifically, the agency seeks to increase the undiscounted fee for a first suspension request to $300 and establish a new fee of $450 (undiscounted) for the second or subsequent requests in the same application. The fee increase for the first request is targeted at shifting the cost of the service to those applicants requesting suspensions, thereby reducing subsidization from other fees. This increase will not affect fees for suspensions of action requested at the time of filing CPA under § 1.103(b) or an RCE under § 1.103(c).

Currently, § 1.103(a) permits applicants to request a suspension of action for a period not exceeding six months for good and sufficient cause. The patent examiner typically decides the first request for suspension. Second and subsequent requests require Technology Center director approval. Due to the heightened approval level, these requests cost the USPTO more to process. As such, in order to recoup the additional cost of the second and subsequent requests, the agency is proposing to charge a higher fee for these requests. Additionally, as more requests for suspension are requested and granted, the longer the pendency of the application.

The USPTO receives approximately 2,500 requests for suspension under § 1.103(a) each year. Of those requests, 86% are filed by undiscounted entities, 12% by small entities, and 2% by micro entities. Given the availability of entity discounts, the USPTO believes this fee increase will generally have a negligible impact on small and micro entities.

11. Terminal Disclaimer Fees

TABLE 14—TERMINAL DISCLAIMER FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Terminal disclaimer, filed prior to the first action on the merits.	Undiscounted	$170	$200	$30	18	n/a
Terminal disclaimer, filed prior to a final action or allowance.	Undiscounted	170	500	330	194	n/a
Terminal disclaimer, filed after final or allowance	Undiscounted	170	800	630	371	n/a
Terminal disclaimer, filed on or after a notice of appeal.	Undiscounted	170	1,100	930	547	n/a
Terminal disclaimer, filed in a patented case or in an application for reissue.	Undiscounted	170	1,400	1,230	724	n/a

The USPTO proposes to create a new tiered fee structure for terminal disclaimers, specifically splitting § 1.20(d) into two parts.

The first part, in proposed § 1.20(d)(1), would apply only to statutory disclaimers under 35 U.S.C. 253(a) and § 1.321(a). As explained in MPEP 1490, a statutory disclaimer is a statement in which a patent owner relinquishes legal rights to one or more claims of a patent. The proposed fee for filing such a statutory disclaimer would be increased slightly (from $170 to $179) as part of the across-the-board fee increase.

The second part, in proposed § 1.20(d)(2), would apply only to

terminal disclaimers under 35 U.S.C. 253(b) and § 1.321. As explained in MPEP 1490, a terminal disclaimer is a statement in which a patentee or applicant disclaims or dedicates to the public the entire term or any terminal part of the term of a patent, or of a patent to be granted when filed in an application. The proposed fees for filing such terminal disclaimers would be increased as described in this section and would vary depending on the stage of examination of the application in which the terminal disclaimer is filed. In particular, proposed § 1.20(d)(2) would create five tiers of fees for filing terminal disclaimers, beginning at $200 for the first tier and increasing by $300 for each subsequent tier.

1. The first-tier fee of $200 is set forth in proposed § 1.20(d)(2)(i), and would be required upon the filing of a terminal disclaimer in a non-reissue application before the mailing of a first Office action on the merits.

2. The second-tier fee of $500 is set forth in proposed § 1.20(d)(2)(ii) and would be required upon the filing of a terminal disclaimer in a non-reissue application after the period specified in § 1.20(d)(2)(i) and before the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application.

3. The third-tier fee of $800 is set forth in proposed § 1.20(d)(2)(iii) and would be required upon the filing of a terminal disclaimer in a non-reissue application after the period specified in § 1.20(d)(2)(ii) and before any submission of a notice of appeal under § 41.31.

4. The fourth-tier fee of $1,100 is set forth in proposed § 1.20(d)(2)(iv) and would be required upon the filing of a terminal disclaimer in a non-reissue application on or after the submission of a notice of appeal under § 41.31.

5. The fifth-tier fee of $1,400 is set forth in proposed § 1.20(d)(2)(v) and would be required upon the filing of a terminal disclaimer in a patent, or in an application for reissue of a patent.

These fee increases and the tiered structure in proposed § 1.20(d)(2) are focused on encouraging applicants to promptly address double patenting issues that arise during prosecution, which will then promote more efficient patent examination by reducing unnecessary costs. The proposals will also foster greater public certainty by providing earlier notice of when the patent term will end.

Patent applications and patents are subject to the doctrine of nonstatutory double patenting to prevent both the unjust timewise extension of the right to exclude and multiple infringement suits by different parties. These situations may arise from the granting of multiple patents with patentably indistinct claims where the patents have a common owner, applicant, or inventor, or where the patents are not commonly owned but are subject to a joint research agreement. See MPEP 804 for a more extensive discussion of the doctrine of nonstatutory double patenting. An applicant may avoid or overcome a nonstatutory double patenting rejection by filing a terminal disclaimer in the application or proceeding in which the rejection is anticipated or actually made. As explained in MPEP 804.02, the use of a terminal disclaimer in overcoming a nonstatutory double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public.

Filing terminal disclaimers early in prosecution reduces the amount of time examiners must spend on nonstatutory double patenting analyses. Because double patenting rejections are made on a claim-by-claim basis, an examiner must compare each claim of the application being examined against each claim of the reference patent or application. As explained in MPEP 804 subsection II.B, this comparison includes construing the reference claims and determining whether an anticipation analysis or obviousness analysis is appropriate for each examined claim. Examiners may spend a substantial amount of time on these analyses and must repeat the process for each reference patent or application used in a double patenting rejection. If an applicant files terminal disclaimers prior to the first action on the merits, the examiner can avoid the time-intensive double patenting analyses that would otherwise be required. Further, if an applicant does not file a terminal disclaimer after a rejection has been made, the examiner will often have to repeat the analysis one or more times. Double patenting rejections may need to be modified throughout prosecution based on amendments to the claims under examination and, in the case of a provisional rejection, amendments to the claims of the reference application. If a terminal disclaimer is not promptly filed, the examiner may have to repeat the analysis in a final rejection and at appeal, and the time spent repeating this analysis detracts from the total time available to review the application for other issues such as patentability over the art and compliance with 35 U.S.C. 112.

Terminal disclaimers filed in patents and applications for reissue are subject to the highest fee tier in proposed § 1.20(d)(2)(v) to more strongly encourage the earlier filing of such disclaimers given the public interest in knowing exactly when the term will end, particularly as disclaimer filings during this time period are often motivated by the patent owner's plans to assert the patent. Relatively few disclaimers are filed during this time period (approximately 40 to 80 a year, or about 1% of all terminal disclaimers). Moreover, terminal disclaimers in patented cases require additional processing such as printing the terminal disclaimer data in the *Official Gazette;* and incorporating the notice of the terminal disclaimer published in the *Official Gazette* into the specification of the patent as required by § 1.321(a). See MPEP 1490(IV) for more information about this additional processing by the USPTO's Certificates of Correction Branch.

Other than requiring payment of the fifth-tier fee in § 1.20(d)(2)(v), this proposed rule will not change the processing of terminal disclaimers after issuance or the conditions under which a terminal disclaimer may be filed in a patent when the patent is involved in a post-grant proceeding at the USPTO such as a reexamination or a proceeding before the Patent Trial and Appeal Board under part 42 of 37 CFR (*e.g., inter partes* review). See MPEP 1490(III) for more information about filing a disclaimer in a patent or reexamination proceeding.

Based on workload numbers from the last five full fiscal years (FY 2018 through FY 2022), about 63,000 terminal disclaimers are filed annually. Of these, about 6% would incur the first-tier fee in § 1.20(d)(2)(i), about 65% would incur the second-tier fee in § 1.20(d)(2)(ii), about 28% would incur the third-tier fee in § 1.20(d)(2)(iii), slightly less than 1% would incur the fourth-tier fee in § 1.20(d)(2)(iv), and approximately 0.1% would incur the fifth-tier fee in proposed § 1.20(d)(2)(v). After implementation of the proposed fees, the USPTO anticipates that applicants will file earlier terminal disclaimers, particularly those currently filed in the time periods that fall into the third and fourth tiers.

While these fees do not qualify for entity discounts, the proposed fees are not expected to disproportionately impact small and micro entities based on current trends in filing continuation applications and terminal disclaimers. For instance, because about 80% of

continuation applications have a patented parent, in general they may be more likely than non-continuing applications to raise double patenting issues requiring filing of a terminal disclaimer. Thus, it is reasonable to expect that terminal disclaimer filings would be somewhat proportional to continuation filings (the correlation is not exact, because double patenting may also arise in noncontinuing applications, as explained in MPEP 804). This expectation is supported by the USPTO's workload data for FY 2021 and FY 2022, which indicate that small entities file about 25% of continuation applications and about 26% of terminal disclaimers each year. Micro entities are much less affected, in that they file about 8% of continuation applications but only about 1% of terminal disclaimers each year. Thus, the anticipated impact of the proposed terminal disclaimer fees on small entities is the same as what would be expected based on their respective share of continuation application filings, and micro entities are much less likely to be impacted.

The USPTO also anticipates that the proposed fees will be relatively technology-neutral. Slightly higher impacts may occur in technology areas examined in Technology Center 1600 (biotechnology and organic chemistry) and Technology Center 2400 (computer networks, multiplex, cable, and cryptography/security).

12. Unintentional Delay Petition Fees

TABLE 15—UNINTENTIONAL DELAY PETITION FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Petition for the delayed payment of the fee for maintaining a patent in force, delay less than or equal to two years.	Undiscounted ...	$2,100	$2,200	$100	5	$161
Petition for the delayed payment of the fee for maintaining a patent in force, delay less than or equal to two years.	Small	840	880	40	5	161
Petition for the delayed payment of the fee for maintaining a patent in force, delay less than or equal to two years.	Micro	420	440	20	5	161
Petition for the delayed payment of the fee for maintaining a patent in force, delay greater than two years.	Undiscounted ...	2,100	3,000	900	43	n/a
Petition for the delayed payment of the fee for maintaining a patent in force, delay greater than two years.	Small	840	1,200	360	43	n/a
Petition for the delayed payment of the fee for maintaining a patent in force, delay greater than two years.	Micro	420	600	180	43	n/a
Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay less than or equal to two years.	Undiscounted ...	2,100	2,200	100	5	376
Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay less than or equal to two years.	Small	840	880	40	5	376
Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay less than or equal to two years.	Micro	420	440	20	5	376
Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay greater than two years.	Undiscounted ...	2,100	3,000	900	43	n/a
Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay greater than two years.	Small	840	1,200	360	43	n/a
Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay greater than two years.	Micro	420	600	180	43	n/a
Petition for the delayed submission of a priority or benefit claim, delay less than or equal to two years.	Undiscounted ...	2,100	2,200	100	5	376
Petition for the delayed submission of a priority or benefit claim, delay less than or equal to two years.	Small	840	880	40	5	376

TABLE 15—UNINTENTIONAL DELAY PETITION FEES—Continued

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Petition for the delayed submission of a priority or benefit claim, delay less than or equal to two years.	Micro	420	440	20	5	376
Petition for the delayed submission of a priority or benefit claim, delay greater than two years.	Undiscounted	2,100	3,000	900	43	n/a
Petition for the delayed submission of a priority or benefit claim, delay greater than two years.	Small	840	1,200	360	43	n/a
Petition for the delayed submission of a priority or benefit claim, delay greater than two years.	Micro	420	600	180	43	n/a
Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years.	Undiscounted	2,100	2,200	100	5	n/a
Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years.	Small	840	880	40	5	n/a
Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years.	Micro	420	440	20	5	n/a
Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years.	Undiscounted	2,100	3,000	900	43	n/a
Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years.	Small	840	1,200	360	43	n/a
Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years.	Micro	420	600	180	43	n/a

During FY 2020, the USPTO issued a notice to clarify when additional information is required to support a petition for unintentional delay. See Clarification of the Practice for Requiring Additional Information in Petitions Filed in Patent Applications and Patents Based on Unintentional Delay, 85 FR 12222 (March 2, 2020) (2020 Notice). Petitions based on unintentional delay include petitions seeking revival of an abandoned application, acceptance of a delayed maintenance fee payment, and acceptance of a delayed priority or benefit claim. The 2020 Notice clarified that ''any applicant filing a petition to revive an abandoned application under § 1.137 more than two years after the date of abandonment, any patentee filing a petition to accept a delayed maintenance fee under § 1.378 more than two years after the date of expiration for nonpayment of a maintenance fee, and any applicant or patent owner filing a petition to accept a delayed priority or benefit claim under § 1.55(e) or § 1.78(c) and (e) more than two years after the due date of the priority or benefit claim should expect to be required to provide an additional explanation of the circumstances surrounding the delay that establishes that the entire delay was unintentional.'' *Id* at 12223.

As the evidentiary requirements for these petitions have increased, the costs to review and treat these petitions have also increased due to the higher level of review needed to consider the additional explanation. Accordingly, the USPTO seeks to create a new higher fee for petitions based on unintentional delay over two years to recover their additional associated costs. The higher fee should encourage timely petition filings and avoid delays in the examination process. The new higher fee would apply to petitions under § 1.78(c) and (e) to accept a delayed benefit claim submitted more than two years after the date the benefit claim was due; under § 1.55(e) to accept a delayed priority claim more than two years after the date the foreign priority claim was due; under § 1.137 to revive an abandoned application or reexamination proceeding more than two years after the date of abandonment; under § 1.378 to seek reinstatement of an expired patent more than two years after the date of expiration for nonpayment of a maintenance fee; and under § 1.1051 to excuse an applicant's failure to act within prescribed time limits in an international design application.

The USPTO receives approximately 12,000 petitions each year based upon the unintentional standard (FY 2021, 12,752 petitions; FY 2022, 11,755 petitions). About 10% of these petitions (1,200) have a delay of more than two years. Therefore, the higher cost for petitions having a delay of greater than two years should not have a significant impact on patent applicants overall. The increased fee will help ensure those applicants requesting the service pay its costs, thereby reducing subsidization from other patent applicants.

13. America Invents Act Trial Fees

TABLE 16—AIA TRIAL FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Inter partes review request fee—Up to 20 claims	Undiscounted	$19,000	$23,750	$4,750	25	$21,980
Inter partes review post-institution fee—Up to 20 claims.	Undiscounted	22,500	28,125	5,625	25	37,563

TABLE 16—AIA TRIAL FEES—Continued

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Inter partes review request of each claim in excess of 20.	Undiscounted ...	375	470	95	25	n/a
Inter partes post-institution request of each claim in excess of 20.	Undiscounted	750	940	190	25	n/a
Post-grant or covered business method review request fee—Up to 20 claims.	Undiscounted ...	20,000	25,000	5,000	25	37,683
Post-grant or covered business method review post-institution fee—Up to 20 claims.	Undiscounted	27,500	34,375	6,875	25	49,198
Post-grant or covered business method review request of each claim in excess of 20.	Undiscounted	475	595	120	25	n/a
Post-grant or covered business method review post-institution request of each claim in excess of 20.	Undiscounted	1,050	1,315	265	25	n/a

The USPTO proposes increasing existing fees for AIA trial proceedings by 25%. Under 35 U.S.C. 311(a) and 321(a), the USPTO Director must establish reasonable fees for inter partes and post-grant review in relation to their aggregate costs. The proposed fee increases will better align the fee rates charged to petitioners with the actual costs borne by the USPTO in providing these proceedings. This proposed change will help the PTAB maintain the appropriate level of judicial and administrative resources to continue providing high-quality and timely decisions for AIA trials.

14. Request for Review of a PTAB Decision by the Director

TABLE 17—REQUEST FOR REVIEW OF A PTAB DECISION BY THE DIRECTOR FEES

Description	Entity type	Current fee	Proposed fee	Dollar change	Percent change	FY 2022 unit cost
Request for review of a PTAB decision by the Director.	Undiscounted ...	New	$440	n/a	n/a	n/a

The USPTO proposes to charge a new fee in AIA trial proceedings under part 42 to parties requesting Director Review of the PTAB's: (1) decision whether to institute a trial; (2) final written decision; or (3) decision granting a request for rehearing from either the Board's decision whether to institute trial or the Board's final written decision. The proposed fee is set at the same rate as a petition to the Chief Judge in ex parte appeals and is designed to partially recover the USPTO's costs for conducting Director Reviews. The proposed fee is part of the agency's ongoing efforts to formalize the Director Review process developed in response to the Supreme Court's decision in *United States* v. *Arthrex, Inc.* and furthers the USPTO's goals of promoting innovation through consistent, transparent decision-making and the issuance and maintenance of reliable patents.

More specifically, the Director of the USPTO is a statutory member of the PTAB. See 35 U.S.C. 6(a). On June 21, 2021, the Supreme Court issued a decision in *United States* v. *Arthrex, Inc.,* and explained that ''constitutional principles chart a clear course: Decisions by [administrative patent judges (APJs)] must be subject to review by the Director.'' See 141 S. Ct. 1970, 1986 (2021). Following the statutory authority provided to the Director by Congress and the constitutional principles explained by the Supreme Court, the USPTO set forth an interim process for Director Review, which has been updated periodically. The agency sought public feedback on the interim process and is using feedback to promulgate rules.

As a part of the interim process, when the USPTO receives a Director Review request from a party to an AIA proceeding, the request is processed and routed to an advisory committee that assists with Director Review. The committee includes at least 11 representatives from various USPTO business units who serve at the Director's discretion. Members independently review each request and associated case materials, and the committee meets regularly to recommend which requests for review should be granted. The Director considers each request, its case materials, and the committee's recommendation in determining whether to grant or deny review. When the Director determines to grant review, personnel from various USPTO business units assist in case processing and in issuing and publicizing the Director Review decision.

Given the number of agency personnel involved in Director Review, the USPTO expects its costs to be significantly higher than the proposed fee. The agency plans to formally capture and evaluate these costs in the future.

D. Amendment to Obtaining a Refund Through Express Abandonment

The USPTO proposes amending paragraph (d) of § 1.138, which permits an applicant to obtain a refund of the search and excess claims fees that were paid in an application by submitting a petition and declaration of express abandonment before an examination has been made of the application. The current rule permits such refunds only in nonprovisional applications filed under 35 U.S.C. 111(a) and § 1.53(b). The proposed amendment would expand the applicability of the rule to permit such refunds in national stage applications filed under 35 U.S.C. 371.

The amendment would also clarify that refunds of search and excess claim fee payments under these provisions are limited to the search and excess claim fees set forth in § 1.16 (which apply to applications filed under 35 U.S.C. 111(a) and § 1.53(b)) and search and excess claim fees set forth in § 1.492 (which apply to national stage

applications filed under 35 U.S.C. 371). No refunds would be permitted of any search fees paid under § 1.445 during the international stage of an application filed under the PCT, even if such an application later enters the national stage under 35 U.S.C. 371.

The petition process and the conditions under which a refund will be granted will not otherwise change. See MPEP 711.01 subsection III for more information. The proposed amendment would put national stage applications on the same footing as applications filed under 35 U.S.C. 111(a) when an application is expressly abandoned prior to examination.

VI. Discussion of Specific Rules

The following part shows the Code of Federal Regulations proposed fee amendments. The discussion below includes all proposed fee amendments and all proposed changes to the CFR text.

Title 37 of the CFR, parts 1, 41, and 42, are proposed to be amended as follows:

Section 1.16

Section 1.16 is proposed to be amended by revising paragraphs (a) through (s) and (u) to set forth national application filing, search, examination, and related fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.16 are shown in table 18.

TABLE 18—SECTION 1.16 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.16(a)	1011	Basic filing fee—Utility (paper filing also requires non-electronic filing fee under 1.16(t)).	Undiscounted	$320	$350
1.16(a)	2011	Basic filing fee—Utility (paper filing also requires non-electronic filing fee under 1.16(t)).	Small	128	140
1.16(a)	3011	Basic filing fee—Utility (paper filing also requires non-electronic filing fee under 1.16(t)).	Micro	64	70
1.16(a)	4011	Basic filing fee—Utility (electronic filing for small entities)	Small	64	70
1.16(b)	1012	Basic filing fee—Design	Undiscounted	220	300
1.16(b)	2012	Basic filing fee—Design	Small	88	120
1.16(b)	3012	Basic filing fee—Design	Micro	44	60
1.16(b)	1017	Basic filing fee—Design CPA	Undiscounted	220	300
1.16(b)	2017	Basic filing fee—Design CPA	Small	88	120
1.16(b)	3017	Basic filing fee—Design CPA	Micro	44	60
1.16(c)	1013	Basic filing fee—Plant	Undiscounted	220	240
1.16(c)	2013	Basic filing fee—Plant	Small	88	96
1.16(c)	3013	Basic filing fee—Plant	Micro	44	48
1.16(d)	1005	Provisional application filing fee	Undiscounted	300	315
1.16(d)	2005	Provisional application filing fee	Small	120	126
1.16(d)	3005	Provisional application filing fee	Micro	60	63
1.16(e)	1014	Basic filing fee—Reissue	Undiscounted	320	350
1.16(e)	2014	Basic filing fee—Reissue	Small	128	140
1.16(e)	3014	Basic filing fee—Reissue	Micro	64	70
1.16(e)	1019	Basic filing fee—Reissue (Design CPA)	Undiscounted	320	350
1.16(e)	2019	Basic filing fee—Reissue (Design CPA)	Small	128	140
1.16(e)	3019	Basic filing fee—Reissue (Design CPA)	Micro	64	70
1.16(f)	1051	Surcharge—Late filing fee, search fee, examination fee, inventor's oath or declaration, or application filed without at least one claim or by reference.	Undiscounted	160	170
1.16(f)	2051	Surcharge—Late filing fee, search fee, examination fee, inventor's oath or declaration, or application filed without at least one claim or by reference.	Small	64	68
1.16(f)	3051	Surcharge—Late filing fee, search fee, examination fee, inventor's oath or declaration, or application filed without at least one claim or by reference.	Micro	32	34
1.16(g)	1052	Surcharge—Late provisional filing fee or cover sheet	Undiscounted	60	65
1.16(g)	2052	Surcharge—Late provisional filing fee or cover sheet	Small	24	26
1.16(g)	3052	Surcharge—Late provisional filing fee or cover sheet	Micro	12	13
1.16(h)	1201	Each independent claim in excess of three	Undiscounted	480	600
1.16(h)	2201	Each independent claim in excess of three	Small	192	240
1.16(h)	3201	Each independent claim in excess of three	Micro	96	120
1.16(h)	1204	Each reissue independent claim in excess of three	Undiscounted	480	600
1.16(h)	2204	Each reissue independent claim in excess of three	Small	192	240
1.16(h)	3204	Each reissue independent claim in excess of three	Micro	96	120
1.16(i)	1202	Each claim in excess of 20	Undiscounted	100	200
1.16(i)	2202	Each claim in excess of 20	Small	40	80
1.16(i)	3202	Each claim in excess of 20	Micro	20	40
1.16(i)	1205	Each reissue claim in excess of 20	Undiscounted	100	200
1.16(i)	2205	Each reissue claim in excess of 20	Small	40	80
1.16(i)	3205	Each reissue claim in excess of 20	Micro	20	40
1.16(j)	1203	Multiple dependent claim	Undiscounted	860	905
1.16(j)	2203	Multiple dependent claim	Small	344	362
1.16(j)	3203	Multiple dependent claim	Micro	172	181
1.16(k)	1111	Utility search fee	Undiscounted	700	770
1.16(k)	2111	Utility search fee	Small	280	308
1.16(k)	3111	Utility search fee	Micro	140	154
1.16(l)	1112	Design search fee or Design CPA search fee	Undiscounted	160	300

TABLE 18—SECTION 1.16 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.16(l)	2112	Design search fee or Design CPA search fee	Small	64	120
1.16(l)	3112	Design search fee or Design CPA search fee	Micro	32	60
1.16(m)	1113	Plant search fee	Undiscounted	440	485
1.16(m)	2113	Plant search fee	Small	176	194
1.16(m)	3113	Plant search fee	Micro	88	97
1.16(n)	1114	Reissue search fee or Reissue (Design CPA) search fee	Undiscounted	700	770
1.16(n)	2114	Reissue search fee or Reissue (Design CPA) search fee	Small	280	308
1.16(n)	3114	Reissue search fee or Reissue (Design CPA) search fee	Micro	140	154
1.16(o)	1311	Utility examination fee	Undiscounted	800	880
1.16(o)	2311	Utility examination fee	Small	320	352
1.16(o)	3311	Utility examination fee	Micro	160	176
1.16(p)	1312	Design examination fee or Design CPA examination fee	Undiscounted	640	700
1.16(p)	2312	Design examination fee or Design CPA examination fee	Small	256	280
1.16(p)	3312	Design examination fee or Design CPA examination fee	Micro	128	140
1.16(q)	1313	Plant examination fee	Undiscounted	660	725
1.16(q)	2313	Plant examination fee	Small	264	290
1.16(q)	3313	Plant examination fee	Micro	132	145
1.16(r)	1314	Reissue examination fee or Reissue (Design CPA) examination fee.	Undiscounted	2,320	2,550
1.16(r)	2314	Reissue examination fee or Reissue (Design CPA) examination fee.	Small	928	1,020
1.16(r)	3314	Reissue examination fee or Reissue (Design CPA) examination fee.	Micro	464	510
1.16(s)	1082	Design application size fee—for each additional 50 sheets that exceeds 100 sheets.	Undiscounted	420	440
1.16(s)	2082	Design application size fee—for each additional 50 sheets that exceeds 100 sheets.	Small	168	176
1.16(s)	3082	Design application size fee—for each additional 50 sheets that exceeds 100 sheets.	Micro	84	88
1.16(s)	1083	Plant application size fee—for each additional 50 sheets that exceeds 100 sheets.	Undiscounted	420	440
1.16(s)	2083	Plant application size fee—for each additional 50 sheets that exceeds 100 sheets.	Small	168	176
1.16(s)	3083	Plant application size fee—for each additional 50 sheets that exceeds 100 sheets.	Micro	84	88
1.16(s)	1085	Provisional application size fee—for each additional 50 sheets that exceeds 100 sheets.	Undiscounted	420	440
1.16(s)	2085	Provisional application size fee—for each additional 50 sheets that exceeds 100 sheets.	Small	168	176
1.16(s)	3085	Provisional application size fee—for each additional 50 sheets that exceeds 100 sheets.	Micro	84	88
1.16(s)	1084	Reissue application size fee—for each additional 50 sheets that exceeds 100 sheets.	Undiscounted	420	440
1.16(s)	2084	Reissue application size fee—for each additional 50 sheets that exceeds 100 sheets.	Small	168	176
1.16(s)	3084	Reissue application size fee—for each additional 50 sheets that exceeds 100 sheets.	Micro	84	88
1.16(s)	1081	Utility application size fee—for each additional 50 sheets that exceeds 100 sheets.	Undiscounted	420	440
1.16(s)	2081	Utility application size fee—for each additional 50 sheets that exceeds 100 sheets.	Small	168	176
1.16(s)	3081	Utility application size fee—for each additional 50 sheets that exceeds 100 sheets.	Micro	84	88
1.16(u)	1054	Non-DOCX Filing Surcharge Fee	Undiscounted	400	420
1.16(u)	2054	Non-DOCX Filing Surcharge Fee	Small	160	168
1.16(u)	3054	Non-DOCX Filing Surcharge Fee	Micro	80	84

Section 1.17

Section 1.17 is proposed to be amended by revising paragraphs (a), (c) through (i), (k), (m), and (o) through (t); and adding paragraphs (u), (v), (w), and (x) to set forth application processing fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.17 are shown in table 19.

The USPTO proposes to revise the introductory text of paragraph (a) to exclude provisional applications filed under 1.53(c).

The USPTO proposes to revise paragraph (e)(2) to include only the second request for continued examination and adding paragraph (e)(3) to create a fee for third and subsequent requests for continued examination. The USPTO proposes to revise paragraph (g) by splitting it into two paragraphs (g)(1) and (2). Proposed paragraph (g)(1) would be the same as existing paragraph (g) except for the removal of § 1.103(a) from its coverage. Proposed new paragraphs (g)(2)(i) and (ii) would specify the fees for filing a first request pursuant to § 1.103(a) respectively. The USPTO proposes to add paragraphs (m)(1) through (3) to

create tiered fees for unintentionally delayed petitions based on the length of the delay.

The USPTO proposes to add paragraphs (u) through (x). Paragraph (u) creates a lower fee for extension fees pursuant to § 1.136(a) in provisional applications filed under § 1.53(c). Paragraph (v) creates fees for information disclosure statements filed under § 1.97. Paragraph (w) creates fees for presenting a benefit claim in a nonprovisional application under 35 U.S.C. 120, 121, 365(c), or 386(c) and § 1.78(d). Paragraph (x) creates a fee for the After Final Consideration Pilot Program 2.0.

TABLE 19—SECTION 1.17 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.17(a)(1)	1251	Extension for response within first month, except provisional applications.	Undiscounted	$220	$230
1.17(a)(1)	2251	Extension for response within first month, except provisional applications.	Small	88	92
1.17(a)(1)	3251	Extension for response within first month, except provisional applications.	Micro	44	46
1.17(a)(2)	1252	Extension for response within second month, except provisional applications.	Undiscounted	640	670
1.17(a)(2)	2252	Extension for response within second month, except provisional applications.	Small	256	268
1.17(a)(2)	3252	Extension for response within second month, except provisional applications.	Micro	128	134
1.17(a)(3)	1253	Extension for response within third month, except provisional applications.	Undiscounted	1,480	1,555
1.17(a)(3)	2253	Extension for response within third month, except provisional applications.	Small	592	622
1.17(a)(3)	3253	Extension for response within third month, except provisional applications.	Micro	296	311
1.17(a)(4)	1254	Extension for response within fourth month, except provisional applications.	Undiscounted	2,320	2,435
1.17(a)(4)	2254	Extension for response within fourth month, except provisional applications.	Small	928	974
1.17(a)(4)	3254	Extension for response within fourth month, except provisional applications.	Micro	464	487
1.17(a)(5)	1255	Extension for response within fifth month, except provisional applications.	Undiscounted	3,160	3,320
1.17(a)(5)	2255	Extension for response within fifth month, except provisional applications.	Small	1,264	1,328
1.17(a)(5)	3255	Extension for response within fifth month, except provisional applications.	Micro	632	664
1.17(c)	1817	Request for prioritized examination	Undiscounted	4,200	4,410
1.17(c)	2817	Request for prioritized examination	Small	1,680	1,764
1.17(c)	3817	Request for prioritized examination	Micro	840	882
1.17(d)	1819	Correction of inventorship after first action on merits	Undiscounted	640	670
1.17(d)	2819	Correction of inventorship after first action on merits	Small	256	268
1.17(d)	3819	Correction of inventorship after first action on merits	Micro	128	134
1.17(e)(1)	1801	Request for continued examination (RCE)—1st request (see 37 CFR 1.114).	Undiscounted	1,360	1,500
1.17(e)(1)	2801	Request for continued examination (RCE)—1st request (see 37 CFR 1.114).	Small	544	600
1.17(e)(1)	3801	Request for continued examination (RCE)—1st request (see 37 CFR 1.114).	Micro	272	300
1.17(e)(2)	1820	Request for continued examination (RCE)—2nd request (see 37 CFR 1.114).	Undiscounted	2,000	2,500
1.17(e)(2)	2820	Request for continued examination (RCE)—2nd request (see 37 CFR 1.114).	Small	800	1,000
1.17(e)(2)	3820	Request for continued examination (RCE)—2nd request (see 37 CFR 1.114).	Micro	400	500
1.17(e)(3)	New	Request for continued examination (RCE)—3rd and subsequent request (see 37 CFR 1.114).	Undiscounted	2,000	3,600
1.17(e)(3)	New	Request for continued examination (RCE)—3rd and subsequent request (see 37 CFR 1.114).	Small	800	1,440
1.17(e)(3)	New	Request for continued examination (RCE)—3rd and subsequent request (see 37 CFR 1.114).	Micro	400	720
1.17(f)	1462	Petitions requiring the petition fee set forth in 37 CFR 1.17(f) (Group I).	Undiscounted	420	440
1.17(f)	2462	Petitions requiring the petition fee set forth in 37 CFR 1.17(f) (Group I).	Small	168	176
1.17(f)	3462	Petitions requiring the petition fee set forth in 37 CFR 1.17(f) (Group I).	Micro	84	88
1.17(g)(1)	1463	Petitions requiring the petition fee set forth in 37 CFR 1.17(g) (Group II), except suspension of action.	Undiscounted	220	230

TABLE 19—SECTION 1.17 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.17(g)(1)	2463	Petitions requiring the petition fee set forth in 37 CFR 1.17(g) (Group II), except suspension of action.	Small	88	92
1.17(g)(1)	3463	Petitions requiring the petition fee set forth in 37 CFR 1.17(g) (Group II), except suspension of action.	Micro	44	46
1.17(g)(2)(i)	New	First request for suspension of action	Undiscounted	220	300
1.17(g)(2)(i)	New	First request for suspension of action	Small	88	120
1.17(g)(2)(i)	New	First request for suspension of action	Micro	44	60
1.17(g)(2)(ii)	New	Subsequent request for suspension of action	Undiscounted	220	450
1.17(g)(2)(ii)	New	Subsequent request for suspension of action	Small	88	180
1.17(g)(2)(ii)	New	Subsequent request for suspension of action	Micro	44	90
1.17(h)	1464	Petitions requiring the petition fee set forth in 37 CFR 1.17(h) (Group III).	Undiscounted	140	145
1.17(h)	2464	Petitions requiring the petition fee set forth in 37 CFR 1.17(h) (Group III).	Small	56	58
1.17(h)	3464	Petitions requiring the petition fee set forth in 37 CFR 1.17(h) (Group III).	Micro	28	29
1.17(i)(1)	1053	Non-English translation	Undiscounted	140	145
1.17(i)(1)	2053	Non-English translation	Small	56	58
1.17(i)(1)	3053	Non-English translation	Micro	28	29
1.17(i)(1)	1830	Processing fee, except in provisional applications	Undiscounted	140	145
1.17(i)(1)	2830	Processing fee, except in provisional applications	Small	56	58
1.17(i)(1)	3830	Processing fee, except in provisional applications	Micro	28	29
1.17(i)(2)	1808	Other publication processing fee	Undiscounted	140	147
1.17(i)(2)	2808	Other publication processing fee	Small	140	147
1.17(i)(2)	3808	Other publication processing fee	Micro	140	147
1.17(i)(2)	1803	Request for voluntary publication or republication	Undiscounted	140	147
1.17(i)(2)	2803	Request for voluntary publication or republication	Small	140	147
1.17(i)(2)	3803	Request for voluntary publication or republication	Micro	140	147
1.17(k)	1802	Request for expedited examination of a design application	Undiscounted	1,600	1,680
1.17(k)	2802	Request for expedited examination of a design application	Small	640	672
1.17(k)	3802	Request for expedited examination of a design application	Micro	320	336
1.17(m)(1)	New	Petition for the delayed payment of the fee for maintaining a patent in force, delay greater than two years.	Undiscounted	2,100	3,000
1.17(m)(1)	New	Petition for the delayed payment of the fee for maintaining a patent in force, delay greater than two years.	Small	840	1,200
1.17(m)(1)	New	Petition for the delayed payment of the fee for maintaining a patent in force, delay greater than two years.	Micro	420	600
1.17(m)(2)	1558	Petition for the delayed payment of the fee for maintaining a patent in force, delay less than or equal to two years.	Undiscounted	2,100	2,200
1.17(m)(2)	2558	Petition for the delayed payment of the fee for maintaining a patent in force, delay less than or equal to two years.	Small	840	880
1.17(m)(2)	3558	Petition for the delayed payment of the fee for maintaining a patent in force, delay less than or equal to two years.	Micro	420	440
1.17(m)(1)	New	Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay greater than two years.	Undiscounted	2,100	3,000
1.17(m)(1)	New	Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay greater than two years.	Small	840	1,200
1.17(m)(1)	New	Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay greater than two years.	Micro	420	600
1.17(m)(2)	1453	Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay less than or equal to two years.	Undiscounted	2,100	2,200
1.17(m)(2)	2453	Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay less than or equal to two years.	Small	840	880
1.17(m)(2)	3453	Petition for revival of an abandoned application for a patent, for the delayed payment of the fee for issuing each patent, or for the delayed response by the patent owner in any reexamination proceeding, delay less than or equal to two years.	Micro	420	440
1.17(m)(1)	New	Petition for the delayed submission of a priority or benefit claim, delay greater than two years.	Undiscounted	2,100	3,000
1.17(m)(1)	New	Petition for the delayed submission of a priority or benefit claim, delay greater than two years.	Small	840	1,200

TABLE 19—SECTION 1.17 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.17(m)(1)	New	Petition for the delayed submission of a priority or benefit claim, delay greater than two years.	Micro	420	600
1.17(m)(2)	1454	Petition for the delayed submission of a priority or benefit claim, delay less than or equal to two years.	Undiscounted	2,100	2,200
1.17(m)(2)	2454	Petition for the delayed submission of a priority or benefit claim, delay less than or equal to two years.	Small	840	880
1.17(m)(2)	3454	Petition for the delayed submission of a priority or benefit claim, delay less than or equal to two years.	Micro	420	440
1.17(m)(1)	New	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years.	Undiscounted	2,100	3,000
1.17(m)(1)	New	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years.	Small	840	1,200
1.17(m)(1)	New	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years.	Micro	420	600
1.17(m)(2)	1784	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years.	Undiscounted	2,100	2,200
1.17(m)(2)	2784	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years.	Small	840	880
1.17(m)(2)	3784	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years.	Micro	420	440
1.17(m)(3)	1628	Petition for the extension of the twelve-month (six-month for designs) period for filing a subsequent application.	Undiscounted	2,100	2,200
1.17(m)(3)	2628	Petition for the extension of the twelve-month (six-month for designs) period for filing a subsequent application.	Small	840	880
1.17(m)(3)	3628	Petition for the extension of the twelve-month (six-month for designs) period for filing a subsequent application.	Micro	420	440
1.17(o)	1818	Document fee for third-party submissions (see 37 CFR 1.290(f))	Undiscounted	180	190
1.17(o)	2818	Document fee for third-party submissions (see 37 CFR 1.290(f))	Small	72	76
1.17(p)	1806	Submission of an Information Disclosure Statement	Undiscounted	260	275
1.17(p)	2806	Submission of an Information Disclosure Statement	Small	104	110
1.17(p)	3806	Submission of an Information Disclosure Statement	Micro	52	55
1.17(q)	1807	Processing fee for provisional applications	Undiscounted	50	53
1.17(q)	2807	Processing fee for provisional applications	Small	50	53
1.17(q)	3807	Processing fee for provisional applications	Micro	50	53
1.17(r)	1809	Filing a submission after final rejection (see 37 CFR 1.129(a))	Undiscounted	880	925
1.17(r)	2809	Filing a submission after final rejection (see 37 CFR 1.129(a))	Small	352	370
1.17(r)	3809	Filing a submission after final rejection (see 37 CFR 1.129(a))	Micro	176	185
1.17(s)	1810	For each additional invention to be examined (see 37 CFR 1.129(b)).	Undiscounted	880	925
1.17(s)	2810	For each additional invention to be examined (see 37 CFR 1.129(b)).	Small	352	370
1.17(s)	3810	For each additional invention to be examined (see 37 CFR 1.129(b)).	Micro	176	185
1.17(t)	1783	Petition to convert an international design application to a design application under 35 U.S.C. chapter 16.	Undiscounted	180	190
1.17(t)	2783	Petition to convert an international design application to a design application under 35 U.S.C. chapter 16.	Small	72	76
1.17(t)	3783	Petition to convert an international design application to a design application under 35 U.S.C. chapter 16.	Micro	36	38
1.17(u)(1)	New	Extension for response within first month, provisional application.	Undiscounted	220	50
1.17(u)(1)	New	Extension for response within first month, provisional application.	Small	88	20
1.17(u)(1)	New	Extension for response within first month, provisional application.	Micro	44	10
1.17(u)(2)	New	Extension for response within second month, provisional application.	Undiscounted	640	100
1.17(u)(2)	New	Extension for response within second month, provisional application.	Small	256	40
1.17(u)(2)	New	Extension for response within second month, provisional application.	Micro	128	20
1.17(u)(3)	New	Extension for response within third month, provisional application.	Undiscounted	1,480	200
1.17(u)(3)	New	Extension for response within third month, provisional application.	Small	592	80

TABLE 19—SECTION 1.17 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.17(u)(3)	New	Extension for response within third month, provisional application.	Micro	296	40
1.17(u)(4)	New	Extension for response within fourth month, provisional application.	Undiscounted	2,320	400
1.17(u)(4)	New	Extension for response within fourth month, provisional application.	Small	928	160
1.17(u)(4)	New	Extension for response within fourth month, provisional application.	Micro	464	80
1.17(u)(5)	New	Extension for response within fifth month, provisional application.	Undiscounted	3,160	800
1.17(u)(5)	New	Extension for response within fifth month, provisional application.	Small	1,264	320
1.17(u)(5)	New	Extension for response within fifth month, provisional application.	Micro	632	160
1.17(v)(1)	New	First time filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 50.	Undiscounted	n/a	200
1.17(v)(1)	New	First time filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 50.	Small	n/a	200
1.17(v)(1)	New	First time filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 50.	Micro	n/a	200
1.17(v)(2)	New	Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 100.	Undiscounted	n/a	300
1.17(v)(2)	New	Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 100.	Small	n/a	300
1.17(v)(2)	New	Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 100.	Micro	n/a	300
1.17(v)(3)	New	Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 200.	Undiscounted	n/a	300
1.17(v)(3)	New	Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 200.	Small	n/a	300
1.17(v)(3)	New	Filing an Information Disclosure Statement that causes the cumulative number of applicant-provided citations to exceed 200.	Micro	n/a	300
1.17(w)(1)	New	Filing an application or presentation of benefit claim more than five years after earliest benefit date.	Undiscounted	n/a	2,200
1.17(w)(1)	New	Filing an application or presentation of benefit claim more than five years after earliest benefit date.	Small	n/a	880
1.17(w)(1)	New	Filing an application or presentation of benefit claim more than five years after earliest benefit date.	Micro	n/a	440
1.17(w)(2)	New	Filing an application or presentation of benefit claim more than eight years after earliest benefit date.	Undiscounted	n/a	3,500
1.17(w)(2)	New	Filing an application or presentation of benefit claim more than eight years after earliest benefit date.	Small	n/a	1,400
1.17(w)(2)	New	Filing an application or presentation of benefit claim more than eight years after earliest benefit date.	Micro	n/a	700
1.17(x)	New	Consideration of AFCP 2.0 request	Undiscounted	n/a	500
1.17(x)	New	Consideration of AFCP 2.0 request	Small	n/a	200
1.17(x)	New	Consideration of AFCP 2.0 request	Micro	n/a	100

Section 1.18

Section 1.18 is proposed to be amended by revising paragraphs (a) through (f) to set forth patent issue fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.18 are shown in table 20.

TABLE 20—SECTION 1.18 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.18(a)	1511	Reissue issue fee	Undiscounted	$1,200	$1,260
1.18(a)	2511	Reissue issue fee	Small	480	504

TABLE 20—SECTION 1.18 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.18(a)	3511	Reissue issue fee	Micro	240	252
1.18(a)	1501	Utility issue fee	Undiscounted	1,200	1,260
1.18(a)	2501	Utility issue fee	Small	480	504
1.18(a)	3501	Utility issue fee	Micro	240	252
1.18(b)(1)	1502	Design issue fee	Undiscounted	740	1,300
1.18(b)(1)	2502	Design issue fee	Small	296	520
1.18(b)(1)	3502	Design issue fee	Micro	148	260
1.18(b)(1)	1509	Hague design issue fee	Undiscounted	740	1,300
1.18(b)(1)	2509	Hague design issue fee	Small	296	520
1.18(b)(1)	3509	Hague design issue fee	Micro	148	260
1.18(c)	1503	Plant issue fee	Undiscounted	840	880
1.18(c)	2503	Plant issue fee	Small	336	352
1.18(c)	3503	Plant issue fee	Micro	168	176
1.18(d)(3)	1505	Publication fee for republication	Undiscounted	320	336
1.18(d)(3)	2505	Publication fee for republication	Small	320	336
1.18(d)(3)	3505	Publication fee for republication	Micro	320	336
1.18(e)	1455	Filing an application for patent term adjustment	Undiscounted	210	300
1.18(e)	2455	Filing an application for patent term adjustment	Small	210	300
1.18(e)	3455	Filing an application for patent term adjustment	Micro	210	300
1.18(f)	1456	Request for reinstatement of term reduced	Undiscounted	420	440
1.18(f)	2456	Request for reinstatement of term reduced	Small	420	440
1.18(f)	3456	Request for reinstatement of term reduced	Micro	420	440

Section 1.19

Section 1.19 is proposed to be amended by revising paragraphs (a), (b), and (f) to set forth document supply fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.19 are shown in table 21.

TABLE 21—SECTION 1.19 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.19(a)(2)	8003	Printed copy of plant patent in color	Undiscounted	$15	$16
1.19(b)(1)(i)(A) and (ii)(A).	8007	Copy of patent application as filed	Undiscounted	35	37
1.19(b)(1)(i)(B)	8051	Copy patent file wrapper, paper medium, any number of sheets.	Undiscounted	290	305
1.19(b)(1)(i)(D)	8010	Individual application documents, other than application as filed, per document.	Undiscounted	25	26
1.19(b)(1)(ii)(B)	8052	Copy patent file wrapper, electronic medium, any size or provided electronically.	Undiscounted	60	63
1.19(b)(3)	8013	Copy of office records, except copies of applications as filed	Undiscounted	25	26
1.19(b)(4)	8014	For assignment records, abstract of title and certification, per patent.	Undiscounted	35	37
1.19(f)	8017	Copy of non-U.S. document	Undiscounted	25	26

Section 1.20

Section 1.20 is proposed to be amended by revising paragraphs (a) through (h), (j), and (k) to set forth post issuance fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.20 are shown in table 22.

The USPTO proposes to revise the introductory text to paragraph (d) and to add paragraphs (d)(1) and (d)(2)(i) through (v) to create separate tiered fees for terminal disclaimers under § 1.321.

The USPTO proposes to add paragraph (j)(4) to create a fee for requesting supplemental redetermination after Notice of Final Determination.

TABLE 22—SECTION 1.20 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.20(a)	1811	Certificate of correction	Undiscounted	$160	$168
1.20(a)	2811	Certificate of correction	Small	160	168
1.20(a)	3811	Certificate of correction	Micro	160	168
1.20(b)	1816	Processing fee for correcting inventorship in a patent	Undiscounted	160	168
1.20(b)	2816	Processing fee for correcting inventorship in a patent	Small	160	168
1.20(b)	3816	Processing fee for correcting inventorship in a patent	Micro	160	168
1.20(c)(1)(i)	1831	Ex parte reexamination (§ 1.510(a)) streamlined	Undiscounted	6,300	6,615

TABLE 22—SECTION 1.20 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.20(c)(1)(i)	2831	Ex parte reexamination (§ 1.510(a)) streamlined	Small	2,520	2,646
1.20(c)(1)(i)	3831	Ex parte reexamination (§ 1.510(a)) streamlined	Micro	1,260	1,323
1.20(c)(2)	1812	Ex parte reexamination (§ 1.510(a)) non-streamlined	Undiscounted	12,600	13,230
1.20(c)(2)	2812	Ex parte reexamination (§ 1.510(a)) non-streamlined	Small	5,040	5,292
1.20(c)(2)	3812	Ex parte reexamination (§ 1.510(a)) non-streamlined	Micro	2,520	2,646
1.20(c)(3)	1821	Each reexamination independent claim in excess of three and also in excess of the number of such claims in the patent under reexamination.	Undiscounted	480	600
1.20(c)(3)	2821	Each reexamination independent claim in excess of three and also in excess of the number of such claims in the patent under reexamination.	Small	192	240
1.20(c)(3)	3821	Each reexamination independent claim in excess of three and also in excess of the number of such claims in the patent under reexamination.	Micro	96	120
1.20(c)(4)	1822	Each reexamination claim in excess of 20 and also in excess of the number of claims in the patent under reexamination.	Undiscounted	100	200
1.20(c)(4)	2822	Each reexamination claim in excess of 20 and also in excess of the number of claims in the patent under reexamination.	Small	40	80
1.20(c)(4)	3822	Each reexamination claim in excess of 20 and also in excess of the number of claims in the patent under reexamination.	Micro	20	40
1.20(c)(6)	1824	Petitions in a reexamination proceeding, except for those specifically enumerated in 37 CFR 1.550(i) and 1.937(d).	Undiscounted	2,040	2,140
1.20(c)(6)	2824	Petitions in a reexamination proceeding, except for those specifically enumerated in 37 CFR 1.550(i) and 1.937(d).	Small	816	856
1.20(c)(6)	3824	Petitions in a reexamination proceeding, except for those specifically enumerated in 37 CFR 1.550(i) and 1.937(d).	Micro	408	428
1.20(d)(1)	1814	Statutory disclaimer, excluding terminal disclaimer	Undiscounted	170	179
1.20(d)(1)	2814	Statutory disclaimer, excluding terminal disclaimer	Small	170	179
1.20(d)(1)	3814	Statutory disclaimer, excluding terminal disclaimer	Micro	170	179
1.20(d)(2)(i)	New	Terminal disclaimer, filed prior to the first action on the merits	Undiscounted	170	200
1.20(d)(2)(i)	New	Terminal disclaimer, filed prior to the first action on the merits	Small	170	200
1.20(d)(2)(i)	New	Terminal disclaimer, filed prior to the first action on the merits	Micro	170	200
1.20(d)(2)(ii)	New	Terminal disclaimer, filed prior to a final action or allowance	Undiscounted	170	500
1.20(d)(2)(ii)	New	Terminal disclaimer, filed prior to a final action or allowance	Small	170	500
1.20(d)(2)(ii)	New	Terminal disclaimer, filed prior to a final action or allowance	Micro	170	500
1.20(d)(2)(iii)	New	Terminal disclaimer, filed after final or allowance	Undiscounted	170	800
1.20(d)(2)(iii)	New	Terminal disclaimer, filed after final or allowance	Small	170	800
1.20(d)(2)(iii)	New	Terminal disclaimer, filed after final or allowance	Micro	170	800
1.20(d)(2)(iv)	New	Terminal disclaimer, filed on or after a notice of appeal	Undiscounted	170	1,100
1.20(d)(2)(iv)	New	Terminal disclaimer, filed on or after a notice of appeal	Small	170	1,100
1.20(d)(2)(iv)	New	Terminal disclaimer, filed on or after a notice of appeal	Micro	170	1,100
1.20(d)(2)(v)	New	Terminal disclaimer, filed in a patented case or in an application for reissue.	Undiscounted	170	1,400
1.20(d)(2)(v)	New	Terminal disclaimer, filed in a patented case or in an application for reissue.	Small	170	1,400
1.20(d)(2)(v)	New	Terminal disclaimer, filed in a patented case or in an application for reissue.	Micro	170	1,400
1.20(e)	1551	For maintaining an original or any reissue patent, due at 3.5 years.	Undiscounted	2,000	2,100
1.20(e)	2551	For maintaining an original or any reissue patent, due at 3.5 years.	Small	800	840
1.20(e)	3551	For maintaining an original or any reissue patent, due at 3.5 years.	Micro	400	420
1.20(f)	1552	For maintaining an original or any reissue patent, due at 7.5 years.	Undiscounted	3,760	3,950
1.20(f)	2552	For maintaining an original or any reissue patent, due at 7.5 years.	Small	1,504	1,580
1.20(f)	3552	For maintaining an original or any reissue patent, due at 7.5 years.	Micro	752	790
1.20(g)	1553	For maintaining an original or any reissue patent, due at 11.5 years.	Undiscounted	7,700	8,085
1.20(g)	2553	For maintaining an original or any reissue patent, due at 11.5 years.	Small	3,080	3,234
1.20(g)	3553	For maintaining an original or any reissue patent, due at 11.5 years.	Micro	1,540	1,617
1.20(h)	1554	Surcharge—3.5 year—late payment within 6 months	Undiscounted	500	525
1.20(h)	2554	Surcharge—3.5 year—late payment within 6 months	Small	200	210
1.20(h)	3554	Surcharge—3.5 year—late payment within 6 months	Micro	100	105
1.20(h)	1555	Surcharge—7.5 year—late payment within 6 months	Undiscounted	500	525
1.20(h)	2555	Surcharge—7.5 year—late payment within 6 months	Small	200	210
1.20(h)	3555	Surcharge—7.5 year—late payment within 6 months	Micro	100	105

TABLE 22—SECTION 1.20 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.20(h)	1556	Surcharge—11.5 year—late payment within 6 months	Undiscounted	500	525
1.20(h)	2556	Surcharge—11.5 year—late payment within 6 months	Small	200	210
1.20(h)	3556	Surcharge—11.5 year—late payment within 6 months	Micro	100	105
1.20(j)(1)	1457	Application for extension of term of patent	Undiscounted	1,180	6,700
1.20(j)(1)	2457	Application for extension of term of patent	Small	1,180	6,700
1.20(j)(1)	3457	Application for extension of term of patent	Micro	1,180	6,700
1.20(j)(2)	1458	Initial application for interim extension (see 37 CFR 1.790)	Undiscounted	440	1,320
1.20(j)(2)	2458	Initial application for interim extension (see 37 CFR 1.790)	Small	440	1,320
1.20(j)(2)	3458	Initial application for interim extension (see 37 CFR 1.790)	Micro	440	1,320
1.20(j)(3)	1459	Subsequent application for interim extension (see 37 CFR 1.790).	Undiscounted	230	680
1.20(j)(3)	2459	Subsequent application for interim extension (see 37 CFR 1.790).	Small	230	680
1.20(j)(3)	3459	Subsequent application for interim extension (see 37 CFR 1.790).	Micro	230	680
1.20(j)(4)	New	Supplemental redetermination after notice of final determination	Undiscounted	n/a	1,440
1.20(j)(4)	New	Supplemental redetermination after notice of final determination	Small	n/a	1,440
1.20(j)(4)	New	Supplemental redetermination after notice of final determination	Micro	n/a	1,440
1.20(k)(1)	1826	Request for supplemental examination	Undiscounted	4,620	4,850
1.20(k)(1)	2826	Request for supplemental examination	Small	1,848	1,940
1.20(k)(1)	3826	Request for supplemental examination	Micro	924	970
1.20(k)(2)	1827	Reexamination ordered as a result of supplemental examination	Undiscounted	12,700	13,335
1.20(k)(2)	2827	Reexamination ordered as a result of supplemental examination	Small	5,080	5,334
1.20(k)(2)	3827	Reexamination ordered as a result of supplemental examination	Micro	2,540	2,667
1.20(k)(3)(i)	1828	Supplemental examination document size fee—for nonpatent document having between 21 and 50 sheets.	Undiscounted	180	190
1.20(k)(3)(i)	2828	Supplemental examination document size fee—for nonpatent document having between 21 and 50 sheets.	Small	72	76
1.20(k)(3)(i)	3828	Supplemental examination document size fee—for nonpatent document having between 21 and 50 sheets.	Micro	36	38
1.20(k)(3)(ii)	1829	Supplemental examination document size fee—for each additional 50 sheets or a fraction thereof in a nonpatent document.	Undiscounted	300	315
1.20(k)(3)(ii)	2829	Supplemental examination document size fee—for each additional 50 sheets or a fraction thereof in a nonpatent document.	Small	120	126
1.20(k)(3)(ii)	3829	Supplemental examination document size fee—for each additional 50 sheets or a fraction thereof in a nonpatent document.	Micro	60	63

Section 1.21

Section 1.21 is proposed to be amended by revising paragraphs (a), (e), (h), (i), and (n) through (q) to set forth miscellaneous fees and charges as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.21 are shown in table 23.

TABLE 23—SECTION 1.21 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.21(a)(1)(i)	9001	Application fee (non-refundable)	Undiscounted	$110	$116
1.21(a)(1)(ii)(A)	9010	For test administration by commercial entity	Undiscounted	210	221
1.21(a)(1)(iii)	9029	For USPTO-administered review of registration examination	Undiscounted	470	494
1.21(a)(1)(iv)	9030	Request for extension of time in which to schedule examination for registration to practice (non-refundable).	Undiscounted	115	121
1.21(a)(2)(i)	9003	On registration to practice under § 11.6	Undiscounted	210	221
1.21(a)(2)(ii)	9026	On grant of limited recognition under § 11.9(b)	Undiscounted	210	221
1.21(a)(4)(i)	9005	Certificate of good standing as an attorney or agent, standard	Undiscounted	40	42
1.21(a)(4)(ii)	9006	Certificate of good standing as an attorney or agent, suitable for framing.	Undiscounted	50	53
1.21(a)(5)(i)	9012	Review of decision by the Director of Enrollment and Discipline under § 11.2(c).	Undiscounted	420	440
1.21(a)(5)(ii)	9013	Review of decision of the Director of Enrollment and Discipline under § 11.2(d).	Undiscounted	420	440
1.21(a)(6)(ii)	9028	For USPTO-assisted change of address within the Office of Enrollment and Discipline Information System.	Undiscounted	70	74
1.21(a)(9)(i)	9020	Delinquency fee	Undiscounted	50	53
1.21(a)(9)(ii)	9004	Administrative reinstatement fee	Undiscounted	210	221

TABLE 23—SECTION 1.21 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.21(a)(10)	9014	On petition for reinstatement by a person excluded or suspended on ethical grounds, or excluded on consent from practice before the Office.	Undiscounted	1,680	1,764
1.21(e)	8020	International type search report	Undiscounted	40	42
1.21(h)(2)	8021	Recording each patent assignment, agreement or other paper, per property—if not submitted electronically.	Undiscounted	50	53
1.21(i)	8022	Publication in Official Gazette	Undiscounted	25	26
1.21(n)	8026	Handling fee for incomplete or improper application	Undiscounted	140	147
1.21(o)(1)	1091	Submission of sequence listings of 300MB to 800MB	Undiscounted	1,060	1,115
1.21(o)(1)	2091	Submission of sequence listings of 300MB to 800MB	Small	424	446
1.21(o)(1)	3091	Submission of sequence listings of 300MB to 800MB	Micro	212	223
1.21(o)(2)	1092	Submission of sequence listings of more than 800MB	Undiscounted	10,500	11,025
1.21(o)(2)	2092	Submission of sequence listings of more than 800MB	Small	4,200	4,410
1.21(o)(2)	3092	Submission of sequence listings of more than 800MB	Micro	2,100	2,205
1.21(p)	8053	Additional fee for overnight delivery	Undiscounted	40	42
1.21(q)	8054	Additional fee for expedited service	Undiscounted	170	179

Section 1.78

Section 1.78 is proposed to be amended by revising paragraph (d)(3)(i) to include the fee cited in § 1.17(w) as one of the requirements that must be submitted during the pendency of the later-filed application.

The USPTO proposes to revise paragraph (e)(2) to add the applicable fee in § 1.17(w) to the list of required items that must accompany a petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, 365(c), or 386(c) for the benefit of a prior-filed application.

Section 1.97

Section 1.97 is proposed to be amended by revising paragraph (a) to require the proposed information disclosure statement size fee under § 1.17(v) for an information disclosure statement in compliance with § 1.98 to be considered by the USPTO during the pendency of the application.

Section 1.98

Section 1.98 is proposed to be amended by revising the introductory text in paragraph (a) to include paragraph (a)(4) in the items that shall be included with any information disclosure statement.

The USPTO proposes to add paragraph (a)(4), which will require a clear written assertion that the information disclosure statement is accompanied by the applicable information disclosure statement size fee under § 1.17(v) or a clear written assertion that no information disclosure statement size fee under § 1.17(v) is required.

Section 1.136

Section 1.136 is proposed to be amended by revising paragraph (a)(1) to include the addition of the fee set in § 1.17(u) in extensions of time.

Section 1.138

Section 1.138 is proposed to be amended by revising paragraph (d) to expand the applicability of the express abandonment rule to permit such refunds in national stage applications filed under 35 U.S.C. 371. The current rule permits such refunds only in nonprovisional applications filed under 35 U.S.C. 111(a) and § 1.53(b). Paragraph (d) is also proposed to be amended to clarify that refunds of search and excess claim fee payments under these provisions are limited to the search and excess claim fees set forth in § 1.16 (which apply to applications filed under 35 U.S.C. 111(a) and § 1.53(b)) and search and excess claim fees set forth in § 1.492 (which apply to national stage applications filed under 35 U.S.C. 371). Paragraph (d) is also proposed to be amended to clarify that refunds of search and excess claim fee payments under these provisions are limited to the search and excess claim fees set forth in § 1.16 (which apply to applications filed under 35 U.S.C. 111(a) and § 1.53(b)) and search and excess claim fees set forth in § 1.492 (which apply to national stage applications filed under 35 U.S.C. 371).

Section 1.445

Section 1.445 is proposed to be amended by revising and republishing paragraph (a) to set forth international filing, processing, and search fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.445 are shown in table 24. The proposed fees are for or an international application having a receipt date that is on or after the effective date of the final rule. Fees previously provided for in paragraphs (a)(1)(i)(A), (a)(2)(i), and (a)(3)(i) for international applications having a receipt date that is on or after December 29, 2023 will be redesignated as (a)(1)(i)(B), (a)(2)(ii), and (a)(3)(ii) and will apply to international applications having a receipt date that is on or after December 29, 2022 and before the effective date of the final rule. Other paragraphs under paragraphs (a)(1) through (3) are proposed to be redesignated to accommodate these proposed changes.

TABLE 24—SECTION 1.445 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.445(a)(1)(i)(A)	1601	Transmittal fee	Undiscounted	$260	$285
1.445(a)(1)(i)(A)	2601	Transmittal fee	Small	104	114
1.445(a)(1)(i)(A)	3601	Transmittal fee	Micro	52	57
1.445(a)(2)(i)	1602	Search fee—regardless of whether there is a corresponding application (see 35 U.S.C. 361(d) and PCT Rule 16).	Undiscounted	2,180	2,400

TABLE 24—SECTION 1.445 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.445(a)(2)(i)	2602	Search fee—regardless of whether there is a corresponding application (see 35 U.S.C. 361(d) and PCT Rule 16).	Small	872	960
1.445(a)(2)(i)	3602	Search fee—regardless of whether there is a corresponding application (see 35 U.S.C. 361(d) and PCT Rule 16).	Micro	436	480
1.445(a)(3)(i)	1604	Supplemental search fee when required, per additional invention.	Undiscounted	2,180	2,400
1.445(a)(3)(i)	2604	Supplemental search fee when required, per additional invention.	Small	872	960
1.445(a)(3)(i)	3604	Supplemental search fee when required, per additional invention.	Micro	436	480
1.445(a)(4)	1621	Transmitting application to Intl. Bureau to act as receiving office.	Undiscounted	260	285
1.445(a)(4)	2621	Transmitting application to Intl. Bureau to act as receiving office.	Small	104	114
1.445(a)(4)	3621	Transmitting application to Intl. Bureau to act as receiving office.	Micro	52	57
1.445(a)(5)	1627	Late furnishing fee for providing a sequence listing in response to an invitation under PCT rule 13ter.	Undiscounted	320	335
1.445(a)(5)	2627	Late furnishing fee for providing a sequence listing in response to an invitation under PCT rule 13ter.	Small	128	134
1.445(a)(5)	3627	Late furnishing fee for providing a sequence listing in response to an invitation under PCT rule 13ter.	Micro	64	67

Section 1.482

Section 1.482 is proposed to be amended by revising paragraphs (a) and (c) to set forth international preliminary examination and processing fees for international patent applications entering the international stage as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.482 are shown in table 25.

TABLE 25—SECTION 1.482 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.482(a)(1)(i)	1605	Preliminary examination fee—U.S. was the ISA	Undiscounted	$640	$705
1.482(a)(1)(i)	2605	Preliminary examination fee—U.S. was the ISA	Small	256	282
1.482(a)(1)(i)	3605	Preliminary examination fee—U.S. was the ISA	Micro	128	141
1.482(a)(1)(ii)	1606	Preliminary examination fee—U.S. was not the ISA	Undiscounted	800	880
1.482(a)(1)(ii)	2606	Preliminary examination fee—U.S. was not the ISA	Small	320	352
1.482(a)(1)(ii)	3606	Preliminary examination fee—U.S. was not the ISA	Micro	160	176
1.482(a)(2)	1607	Supplemental examination fee per additional invention	Undiscounted	640	705
1.482(a)(2)	2607	Supplemental examination fee per additional invention	Small	256	282
1.482(a)(2)	3607	Supplemental examination fee per additional invention	Micro	128	141
1.482(c)	1627	Late furnishing fee for providing a sequence listing in response to an invitation under PCT rule 13ter.	Undiscounted	320	335
1.482(c)	2627	Late furnishing fee for providing a sequence listing in response to an invitation under PCT rule 13ter.	Small	128	134
1.482(c)	3627	Late furnishing fee for providing a sequence listing in response to an invitation under PCT rule 13ter.	Micro	64	67

Section 1.492

Section 1.492 is proposed to be amended by revising paragraphs (a) through (f) and (h) through (j) to set forth national stage fees for international patent applications as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.492 are shown in table 26.

TABLE 26—SECTION 1.492 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.492(a)	1631	Basic national stage fee	Undiscounted	$320	$350
1.492(a)	2631	Basic national stage fee	Small	128	140
1.492(a)	3631	Basic national stage fee	Micro	64	70
1.492(b)(2)	1641	National stage search fee—U.S. was the ISA	Undiscounted	140	145
1.492(b)(2)	2641	National stage search fee—U.S. was the ISA	Small	56	58
1.492(b)(2)	3641	National stage search fee—U.S. was the ISA	Micro	28	29
1.492(b)(3)	1642	National stage search fee—search report prepared and provided to USPTO.	Undiscounted	540	565

TABLE 26—SECTION 1.492 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.492(b)(3)	2642	National stage search fee—search report prepared and provided to USPTO.	Small	216	226
1.492(b)(3)	3642	National stage search fee—search report prepared and provided to USPTO.	Micro	108	113
1.492(b)(4)	1632	National stage search fee—all other situations	Undiscounted	700	770
1.492(b)(4)	2632	National stage search fee—all other situations	Small	280	308
1.492(b)(4)	3632	National stage search fee—all other situations	Micro	140	154
1.492(c)(2)	1633	National stage examination fee—all other situations	Undiscounted	800	880
1.492(c)(2)	2633	National stage examination fee—all other situations	Small	320	352
1.492(c)(2)	3633	National stage examination fee—all other situations	Micro	160	176
1.492(d)	1614	Each independent claim in excess of three	Undiscounted	480	600
1.492(d)	2614	Each independent claim in excess of three	Small	192	240
1.492(d)	3614	Each independent claim in excess of three	Micro	96	120
1.492(e)	1615	Each claim in excess of 20	Undiscounted	100	200
1.492(e)	2615	Each claim in excess of 20	Small	40	80
1.492(e)	3615	Each claim in excess of 20	Micro	20	40
1.492(f)	1616	Multiple dependent claim	Undiscounted	860	905
1.492(f)	2616	Multiple dependent claim	Small	344	362
1.492(f)	3616	Multiple dependent claim	Micro	172	181
1.492(h)	1617	Search fee, examination fee or oath or declaration after the date of commencement of the national stage.	Undiscounted	160	170
1.492(h)	2617	Search fee, examination fee or oath or declaration after the date of commencement of the national stage.	Small	64	68
1.492(h)	3617	Search fee, examination fee or oath or declaration after the date of commencement of the national stage.	Micro	32	34
1.492(i)	1618	English translation after thirty months from priority date	Undiscounted	140	145
1.492(i)	2618	English translation after thirty months from priority date	Small	56	58
1.492(i)	3618	English translation after thirty months from priority date	Micro	28	29
1.492(j)	1681	National stage application size fee—for each additional 50 sheets that exceeds 100 sheets.	Undiscounted	420	440
1.492(j)	2681	National stage application size fee—for each additional 50 sheets that exceeds 100 sheets.	Small	168	176
1.492(j)	3681	National stage application size fee—for each additional 50 sheets that exceeds 100 sheets.	Micro	84	88

Section 1.555

Section 1.555 is proposed to be amended by revising paragraph (a) to require the proposed information disclosure statement size fee under § 1.17(v) for an information disclosure statement in compliance with § 1.98 to be considered by the USPTO during the pendency of the reexamination proceeding.

Section 1.1031

Section 1.1031 is proposed to be amended by revising paragraph (a) to set forth international design application fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 1.1031 are shown in table 27.

TABLE 27—SECTION 1.1031 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
1.1031(a)	1781	Hague international design application—transmittal fee	Undiscounted	$120	$125
1.1031(a)	2781	Hague international design application—transmittal fee	Small	48	50
1.1031(a)	3781	Hague international design application—transmittal fee	Micro	24	25

Section 41.20

Section 41.20 is proposed to be amended by revising paragraphs (a) and (b) to set forth petition and appeal fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 41.20 are shown in table 28.

TABLE 28—SECTION 41.20 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
41.20(a)	1405	Petitions to the Chief Administrative Patent Judge under 37 CFR 41.3.	Undiscounted	$420	$440
41.20(a)	2405	Petitions to the Chief Administrative Patent Judge under 37 CFR 41.3.	Small	420	440

TABLE 28—SECTION 41.20 FEE CHANGES—Continued

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
41.20(a)	3405	Petitions to the Chief Administrative Patent Judge under 37 CFR 41.3.	Micro	420	440
41.20(b)(1)	1401	Notice of appeal	Undiscounted	840	880
41.20(b)(1)	2401	Notice of appeal	Small	336	352
41.20(b)(1)	3401	Notice of appeal	Micro	168	176
41.20(b)(2)(ii)	1404	Filing a brief in support of an appeal in an inter partes reexamination proceeding.	Undiscounted	2,100	2,200
41.20(b)(2)(ii)	2404	Filing a brief in support of an appeal in an inter partes reexamination proceeding.	Small	840	880
41.20(b)(2)(ii)	3404	Filing a brief in support of an appeal in an inter partes reexamination proceeding.	Micro	420	440
41.20(b)(3)	1403	Request for oral hearing	Undiscounted	1,360	1,430
41.20(b)(3)	2403	Request for oral hearing	Small	544	572
41.20(b)(3)	3403	Request for oral hearing	Micro	272	286
41.20(b)(4)	1413	Forwarding an appeal in an application or ex parte reexamination proceeding to the Board.	Undiscounted	2,360	2,480
41.20(b)(4)	2413	Forwarding an appeal in an application or ex parte reexamination proceeding to the Board.	Small	944	992
41.20(b)(4)	3413	Forwarding an appeal in an application or ex parte reexamination proceeding to the Board.	Micro	472	496

Section 42.15

Section 42.15 is proposed to be amended by revising paragraphs (a) through (e) and adding paragraph (f) to set forth inter partes review and post-grant review or covered business method patent review of a patent fees as authorized under section 10 of the AIA. The changes to the fee amounts indicated in § 42.15 are shown in table 29.

TABLE 29—SECTION 42.15 FEE CHANGES

CFR section	Fee code	Description	Entity type	Current fee	Proposed fee
42.15(a)(1)	1406	Inter partes review request fee—Up to 20 claims	Undiscounted	$19,000	$23,750
42.15(a)(2)	1414	Inter partes review post-institution fee—Up to 20 claims	Undiscounted	22,500	28,125
42.15(a)(3)	1407	Inter partes review request of each claim in excess of 20	Undiscounted	375	470
42.15(a)(4)	1415	Inter partes post-institution request of each claim in excess of 20.	Undiscounted	750	940
42.15(b)(1)	1408	Post-grant or covered business method review request fee—Up to 20 claims.	Undiscounted	20,000	25,000
42.15(b)(2)	1416	Post-grant or covered business method review post-institution fee—Up to 20 claims.	Undiscounted	27,500	34,375
42.15(b)(3)	1409	Post-grant or covered business method review request of each claim in excess of 20.	Undiscounted	475	595
42.15(b)(4)	1417	Post-grant or covered business method review post-institution request of each claim in excess of 20.	Undiscounted	1,050	1,315
42.15(c)(1)	1412	Petition for a derivation proceeding	Undiscounted	420	440
42.15(d)	1411	Request to make a settlement agreement available and other requests filed in a patent trial proceeding.	Undiscounted	420	440
42.15(e)	1418	Pro hac vice admission fee	Undiscounted	250	263
42.15(f)	New	Request for review of a PTAB decision by the Director	Undiscounted	n/a	440

VII. Rulemaking Considerations

A. America Invents Act

This proposed rule seeks to set or adjust fees under section 10(a) of the AIA as amended by the SUCCESS Act, Public Law 115–273, 132 Stat. 4158. Section 10(a) of the AIA authorizes the Director of the USPTO to set or adjust by rule any patent fee established, authorized, or charged under 35 U.S.C. for any services performed, or materials furnished, by the USPTO. The SUCCESS Act extends the USPTO fee setting authority until September 2026. Section 10 prescribes that fees may be set or adjusted only to recover the aggregate estimated cost to the USPTO for processing, activities, services, and materials relating to patents, including administrative costs of the agency with respect to such patent fees. Section 10 authority includes flexibility to set individual fees in a way that furthers key policy factors, while taking into account the cost of the respective services. Section 10(e) of the AIA sets forth the general requirements for rulemakings that set or adjust fees under this authority. In particular, section 10(e)(1) requires the Director to publish in the **Federal Register** any proposed fee change under section 10 and include in such publication the specific rationale and purpose for the proposal, including the possible expectations or benefits resulting from the proposed change. For such rulemakings, the AIA requires that the USPTO provide a public comment period of not less than 45 days.

PPAC advises the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on the management, policies, goals, performance, budget, and user fees of

patent operations. When proposing fees under section 10 of the AIA, the Director must provide PPAC with the proposed fees at least 45 days prior to publishing the proposed fees in the **Federal Register**. PPAC then has at least 30 days within which to deliberate, consider, and comment on the proposal, as well as hold public hearing(s) on the proposed fees. PPAC must provide a written report to the public detailing the committee's comments, advice, and recommendations regarding the proposed fees before the USPTO issues a final rule. The USPTO must consider and analyze any comments, advice, or recommendations received from PPAC before setting or adjusting fees.

Consistent with this framework, on April 20, 2023, the Director notified PPAC of the USPTO's intent to set or adjust patent fees and submitted a preliminary patent fee proposal with supporting materials. The preliminary patent fee proposal and associated materials are available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.* PPAC held a public hearing at the USPTO's headquarters in Alexandria, Virginia, on May 18, 2023, where members of the public were given the opportunity to provide oral testimony. Transcripts of the hearing are available for review on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/PPAC_Hearing_Transcript-20230518.pdf.* Members of the public were also given the opportunity to submit written comments for PPAC to consider and these comments are available on *Regulations.gov* at *https://www.regulations.gov/document/PTO-P-2023-0017-0001.* On August 14, 2023, PPAC released a written report setting forth in detail their comments, advice, and recommendations regarding the preliminary proposed fees. The PPAC Report is available on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/PPAC-Report-on-2023-Fee-Proposal.docx.* The USPTO considered and analyzed all comments, advice, and recommendations received from PPAC before publishing this NPRM.

B. Regulatory Flexibility Act (RFA)

The USPTO publishes this Initial Regulatory Flexibility Analysis (IRFA) as required by the RFA (5 U.S.C. 601 *et seq.*) to examine the impact of this proposed rule on small entities. Under the RFA, whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish an NPRM, the agency must prepare and make available for public comment an IRFA, unless the agency certifies under 5 U.S.C. 605(b) that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. Given that this proposed fee schedule is projected to result in $2,050 million in additional aggregate revenue over the current fee schedule (baseline) for the period including FY 2025 to FY 2029, the USPTO acknowledges that the fee adjustments proposed will impact all entities seeking patent protection and could have a significant impact on small and micro entities. The $2,050 million in additional aggregate revenue results from an additional $301 million in FY 2025, $434 million in FY 2026, $437 million in FY 2027, $437 million in FY 2028, and $441 million in FY 2029.

While the USPTO welcomes all comments on this IRFA, it particularly seeks comments describing the type and extent of the impact of the proposed patent fees on commenters' specific businesses. In describing the impact, the USPTO requests biographic detail about the impacted businesses or concerns, including the size, average annual revenue, past patent activity (*e.g.,* applications submitted, contested cases pursued, maintenance fees paid, patents abandoned, etc.), and planned patent activity of the impacted business or concern, where feasible. The USPTO will use this information to further assess the impact of this proposed rule on small entities. Where possible, comments should also describe any recommended alternative methods of setting and adjusting patent fees that would further reduce the impact on small entities.

Items 1–5 below discuss the five items specified in 5 U.S.C. 603(b)(1)–(5) to be addressed in an IRFA. Item 6 below discusses the alternatives to this proposal that were considered.

1. A description of the reasons why the action by the agency is being considered.

Section 10 of the AIA authorizes the Director of the USPTO to set or adjust by rule any patent fee established, authorized, or charged under 35 U.S.C, for any services performed, or materials furnished, by the USPTO. Section 10 prescribes that patent fees may be set or adjusted only to recover the aggregate estimated costs for processing, activities, services, and materials relating to patents, including USPTO administrative costs with respect to such patent fees. This proposed fee schedule will recover the aggregate costs of patent operations while enabling the USPTO to predictably finance the agency's daily operations and mitigate financial risks.

2. *The objectives of, and legal basis for, the proposed rule.*

Since its inception, the AIA strengthened the patent system by affording the USPTO the ''resources it requires to clear the still sizeable backlog of patent applications and move forward to deliver to all American inventors the first rate service they deserve.'' H.R. Rep. No. 112–98(I), at 163 (2011). The objective of this proposed rule is to set or adjust patent fees under section 10 of the AIA to recover the aggregate costs of patent operations and secure sufficient revenue to deliver efficient and reliable services to the USPTO's stakeholders. The fee revenue would help to promote clear, enforceable patents that are essential to economic growth, global competitiveness, and promoting innovation. Additional information on the USPTO's goals and operating requirements may be found in the ''USPTO FY 2025 President's Budget Request,'' available on the USPTO website at *https://www.uspto.gov/about-us/performance-and-planning/budget-and-financial-information.*

3. *A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.*

a. SBA Size Standard

The Small Business Act (SBA) size standards applicable to most analyses conducted to comply with the RFA are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with less than a specified maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. As provided by the RFA, and after consulting with the Small Business Administration, the USPTO formally adopted an alternate size standard for the purpose of conducting an analysis or making a certification under the RFA for patent-related regulations. See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR 67109, 67109 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office 37, 60 (Dec. 12, 2006). The USPTO's alternate small business size standard consists of the SBA's previously established size standard for entities entitled to pay reduced patent fees. See 13 CFR 121.802.

Unlike the SBA's generally applicable small business size standards, the size standard for the USPTO is not industry-specific. The USPTO's definition of a small business concern for RFA

purposes is a business or other concern that: (1) meets the SBA's definition of a ''business concern or concern'' set forth in § 121.105, and (2) meets the size standards set forth in § 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) whose number of employees, including affiliates, does not exceed 500 persons, and (b) that has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern that would not qualify as a nonprofit organization or a small business concern under this definition. See 71 FR at 67109, 1313 Off. Gaz. Pat. Office 60.

A patent applicant can self-identify on a patent application as qualifying as a small entity or may provide certification of micro entity status for reduced patent fees under the USPTO's alternative size standard. The data is captured and tracked for each patent application submitted.

b. Small Entity Defined

The AIA, as amended by the UAIA, provides that fees set or adjusted under section 10(a) ''for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents shall be reduced by 60 percent'' with respect to the application of such fees to any ''small entity'' (as defined in § 1.27) that qualifies for reduced fees under 35 U.S.C. 41(h)(1). In turn, 125 Stat. at 316–17. 35 U.S.C. 41(h)(1) provides that certain patent fees ''shall be reduced by 60 percent'' for a small business concern as defined by section 3 of the SBA, and to any independent inventor or nonprofit organization as defined in regulations described by the Director.

c. Micro Entity Defined

Section 10(g) of the AIA created a new category of entity called a ''micro entity.'' 35 U.S.C. 123; see also 125 Stat. at 318–19. Section 10(b) of the AIA, as amended by the UAIA, provides that the fees set or adjusted under section 10(a) ''for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents shall be reduced by 80 percent with respect to the application of such fees to any micro entity as defined by 35 U.S. Code 123.'' 125 Stat. at 315–17. 35 U.S.C. 123(a) defines a ''micro entity'' as an applicant who makes a certification that the applicant: (1) qualifies as a small entity as defined in § 1.27; (2) has not been named as an inventor on more than four previously filed patent applications, other than applications filed in another country, provisional applications under 35 U.S.C. 111(b), 35 U.S.C. 111(b), or Patent Cooperation Treaty (PCT) applications for which the basic national fee under 35 U.S.C. 41(a) was not paid; (3) did not, in the calendar year preceding the calendar year in which the applicable fee is being paid, have a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986 (26 U.S.C. 61(a)), exceeding three times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census; and (4) has not assigned, granted, or conveyed, and is not under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in the application concerned to an entity exceeding the income limit set forth in (3) above. See 125 Stat. at 318; see also *https://www.uspto.gov/PatentMicroEntity.* 35 U.S.C. 123(d) also defines a ''micro'' as an applicant who certifies that: (1) The applicant's employer, from which the applicant obtains the majority of the applicant's income, is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or (2) the applicant has assigned, granted, conveyed, or is under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in the particular applications to such an institution of higher education.

d. Estimate of Number of Small Entities Affected

The changes in this proposed rule will apply to any entity, including small and micro entities, that pays any patent fee set forth in the NPRM. The reduced fee rates (60% for small entities and 80% for micro entities) will continue to apply to any small entity asserting small entity status and to any micro entity certifying micro entity status for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents.

The USPTO reviews historical data to estimate the percentages of application filings asserting small entity status. Table 30 presents a summary of such small entity filings by type of application (utility, reissue, plant, design) over the last five years.

TABLE 30—NUMBER OF PATENT APPLICATIONS FILED IN THE LAST FIVE YEARS *

	FY2020	FY2021	FY2022	FY2023 **	Average
Utility:					
All	607,496	594,078	590,086	594,858	596,630
Small	139,064	142,488	140,131	142,646	141,082
% Small	22.9%	24.0%	23.7%	24.0%	23.6%
Micro	19,408	19,927	18,467	17,559	18,840
% Micro	3.2%	3.4%	3.1%	3.0%	3.2%
Reissue:					
All	1,204	1,195	1,245	1,115	1,190
Small	363	381	394	381	380
% Small	30.1%	31.9%	31.6%	34.2%	31.9%
Micro	31	19	33	14	24
% Micro	2.6%	1.6%	2.7%	1.3%	2.0%
Plant:					
All	1,043	945	933	865	947
Small	504	424	444	415	447
% Small	48.3%	44.9%	47.6%	48.0%	47.2%
Micro	7	6	10	5	7
% Micro	0.7%	0.6%	1.1%	0.6%	0.7%
Design:					
All	50,002	56,086	55,670	54,659	54,104
Small	19,035	19,892	18,935	20,354	19,554
% Small	38.1%	35.5%	34.0%	37.2%	36.1%
Micro	9,042	15,154	14,466	14,239	13,225

TABLE 30—NUMBER OF PATENT APPLICATIONS FILED IN THE LAST FIVE YEARS *—Continued

	FY2020	FY2021	FY2022	FY2023 **	Average
% Micro	18.1%	27.0%	26.0%	26.1%	24.4%

* The patent application filing data in this table includes RCEs.
** FY 2023 application filing data are preliminary and will be finalized in the FY 2024 Annual Financial Report (AFR) and Annual Performance Plan and Annual Performance Report (APPR).

Because the percentage of small entity filings varies widely between application types, the USPTO has averaged the small entity filing rates over the past five years for those application types to estimate future filing rates by small and micro entities. Those average rates appear in the last column of table 30. The USPTO estimates that small entity filing rates will continue for the next five years at these average historic rates.

The USPTO forecasts the number of projected patent applications (*i.e.,* workload) for the next five years using a combination of historical data, economic analysis, and subject matter expertise. The USPTO estimates that UPR patent application filings will grow by 0.4% in FY 2024 and about 1.5% per year on average from FY 2025 through FY 2029. Design patent applications are forecast independently of UPR applications because they exhibit different filing behaviors.

Using the estimated filings for the next five years, and the average historic rates of small entity filings, table 31 presents the USPTO's estimates of the number of patent application filings by all applicants, including small and micro entities, over the next five fiscal years by application type.

The USPTO has previously undertaken an elasticity analysis to examine if fee adjustments may impact small entities and whether increases in fees would result in some such entities not submitting applications. Elasticity measures how sensitive demand for services by patent applicants and patentees is to fee changes. If elasticity is low enough (demand is *inelastic*), then fee increases will not reduce patenting activity enough to negatively impact overall revenues. If elasticity is high enough (demand is *elastic*), then increasing fees will decrease patenting activity enough to decrease revenue. The USPTO analyzed elasticity at the overall filing level across all patent applicants with regard to entity size and estimated the potential impact to patent application filings across entities. Additional information about how the USPTO estimates elasticity is provided in ''Setting and Adjusting Patent Fees during Fiscal Year 2020—Description of Elasticity Estimates,'' available on the USPTO website at *https://www.uspto.gov/sites/default/files/documents/Elasticity_Appendix.docx.*

TABLE 31—ESTIMATED NUMBERS OF PATENT APPLICATIONS, FY 2024–2029

	FY 2024 (current)	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Utility—All	595,315	607,897	613,902	622,038	628,036	641,784
Reissue—All	640	660	680	700	700	700
Plant—All	860	860	860	860	860	860
Design—All	54,986	57,185	59,472	62,446	65,568	68,847
Total—All	651,801	666,602	674,914	686,044	695,164	712,191

4. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and type of professional skills necessary for preparation of the report or record.

If implemented, this proposed rule will not change the burden of existing reporting and recordkeeping requirements for payment of fees. The current requirements for small and micro entities will continue to apply. Therefore, the professional skills necessary to file and prosecute an application through issue and maintenance remain unchanged under this proposal. This action proposes only to adjust patent fees and not to set procedures for asserting small entity status or certifying micro entity status, as previously discussed.

The full proposed fee schedule (see Part VI: Discussion of Specific Rules) is set forth in the NPRM. The proposed fee schedule sets or adjusts 455 patent fees in total. This includes 73 new fees.

5. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rules.

The USPTO is the sole agency of the U.S. Government responsible for administering the provisions of 35 U.S.C. pertaining to examining and granting patents. It is solely responsible for issuing rules to comply with section 10 of the AIA. No other Federal, State, or local entity has jurisdiction over the examination and granting of patents.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, this cannot be avoided except by treaty (such as the Paris Convention for the Protection of Industrial Property, or the PCT). Nevertheless, the USPTO believes that there are no other duplicative or overlapping rules.

6. A description of any significant alternatives to the proposed rules which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rules on small entities.

The USPTO considered several alternative approaches to this proposed rule, discussed below, including full cost recovery for individual services, an across-the-board adjustment to fees, and a baseline (current fee rates). The discussion here begins with a description of the fee schedule adopted for this proposed rule.

a. Alternative 1: Proposed Alternative—Set and Adjust Patent Fees

The alternative proposed herein secures the USPTO's required revenue to facilitate the effective administration of the U.S. patent system, including implementing the Strategic Plan. The revenue will allow the USPTO to

continue to balance timely examination—to help innovators bring their ideas and products to impact more quickly and efficiently—with improvements in patent quality—particularly, the robustness and reliability of issued patents—and ensure the USPTO can resource mission success. This will benefit all applicants, including small and micro entities, without undue burden to patent applicants and holders, barriers to entry, or reduced incentives to innovate. This alternative maintains small and micro entity discounts. Compared to the current fee schedule, there are no new small or micro entity fee codes being extended to existing undiscounted fee rates and none are being eliminated.

As discussed throughout this document, the fee changes proposed in this alternative are moderate compared to other alternatives. Given that the proposed fee schedule will result in increased aggregate revenue under this alternative, small and micro entities would pay higher fees when compared to the current fee schedule (Alternative 4).

In summary, the fees to obtain a patent will increase. All fees are subject to the 5% across-the-board increase. In addition to the across-the-board increase, some fees will be subject to a larger increase. For example, the fee rate for a first RCE will increase by 10%, the second RCE by 25%, and third and subsequent RCEs by 80%, respectively. Also, AIA trial fees will increase 25% to better align the fee rates charged with the actual costs borne by the USPTO to provide these proceedings and so PTAB can continue to maintain the appropriate level of judicial and administrative resources to continue to provide high-quality and timely decisions for AIA trials.

Adjusting the patent fee schedule as proposed in this NPRM allows the USPTO to implement the patent-related strategic goals and objectives documented in the Strategic Plan and to carry out requirements as described in the FY 2025 Budget. Specifically, the revenue from this alternative is sufficient to recover the aggregate costs of patent operations and to support the strategic objectives to issue and maintain robust and reliable patents; improve patent application pendency; optimize the patent application process to enable efficiencies for applicants and other stakeholders; and enhance internal processes to prevent fraudulent and abusive behaviors that do not embody the USPTO's mission. Alternative 1 focuses on building resiliency against financial shocks by maintaining the minimum operating reserve balance (approximately one month of operating expenses) while building the operating reserve balance to the optimal reserve target (approximately three months of operating expenses). While the other alternatives discussed facilitate progress toward some of the USPTO's goals, the proposed alternative is the only one that does so in a way that does not impose undue costs on patent applicants and holders.

The fee schedule for Alternative 1: Proposed Alternative–Set and Adjust Patent Fees is available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting,* in the document titled ''Setting and Adjusting Patent Fees During Fiscal Year 2025—IRFA Tables.'' For the comparison between proposed fees under Alternative 1 and current fees, the ''current fees'' column displays the fees that are in effect as of the publication of this NPRM. This column is used to calculate dollar and percent fee change compared to proposed fees.

b. Other Alternatives Considered

In addition to the proposed fee schedule set forth in Alternative 1 above, several other alternative approaches were considered. For each alternative considered, the USPTO calculated proposed fees and the resulting revenue derived by each alternative scenario. The proposed fees and their corresponding revenue tables are available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.* Please note, only the fees outlined in Alternative 1 are proposed in this NPRM; other scenarios are shown only to demonstrate the analysis of other options.

Alternative 2: Unit Cost Recovery

It is common practice in the Federal Government to set individual fees at a level sufficient to recover the cost of that single service. In fact, official guidance on user fees, as cited in OMB Circular A–25, ''User Charges,'' states that user charges (fees) should be sufficient to recover the full cost to the Federal Government of providing the particular service, resource, or good, when the government is acting in its capacity as sovereign.

As such, the USPTO considered setting most individual undiscounted fees at the historical cost of performing the activities related to the particular service in FY 2022. The USPTO recognizes that using FY 2022 costs to set fee rates beginning in FY 2025 does not account for inflationary factors that would likely increase costs and necessitate higher fees in the out-years. However, the USPTO contends that the FY 2022 data is the best unit cost data available to inform this analysis.

There are several complexities in achieving individual fee unit cost recovery for the patent fee schedule. The most significant is the AIA requirement to provide a 60% discount on fees to small entities and an 80% discount on fees to micro entities. To account for this requirement, this alternative retains existing small and micro entity discounts where eligible under AIA authority. To provide these discounts and still generate sufficient revenue to recover the anticipated budgetary requirements over the five-year period, maintenance fees must be set significantly above unit cost under this alternative. Note that the USPTO no longer collects activity-based information for maintenance fees, and previous year unit costs were negligible.

Except for maintenance fees, this alternative sets fees for which there is no FY 2022 cost data at current rates. For the small number of services that have a variable fee, the aggregate revenue table does not list a fee. Instead, for those services with an estimated workload, the workload is listed in dollars rather than units to develop revenue estimates. Fees without either a fixed fee rate or a workload estimate are assumed to provide zero revenue.

Alternative 2 does not align well with the strategic and policy goals of this proposed rule. Front-end services (*i.e.,* filing, search, and examination) are costlier for the USPTO to perform than back-end services (*i.e.,* issuance and maintenance), but both the current (the Baseline) and proposed fee schedule (Alternative 1) are structured to collect fees at filing below the cost and more fees further along in the process, when the patent owner has better information about a patent's value, rather than at the time of filing, when applicants are less certain about the value of their invention. Setting fees at the cost of the service under Alternative 2 would reverse the long-established policy to set front-end fees below cost to foster innovation and would create a barrier for entry into the patent system.

The USPTO has estimated the potential quantitative elasticity impacts for application filings (*e.g.,* filing, search, and examination fees), maintenance renewals (all three stages), and other major fee categories. Results of this analysis indicate that a high cost of entry into the patent system could lead to a significant decrease in the incentives to invest in innovative

activities among all entities, especially for small and micro entities. Under the current fee schedule, maintenance fees subsidize all applications. By setting fees to recover the cost of each service at each point in the application process, the USPTO is effectively charging high fees for every patent application, meaning those applicants who have less information about the patentability of their claims or the market value of their invention may be less likely to pursue patent prosecution. The ultimate effect of these changes in behavior is likely to stifle innovation. While the loss of the front-end subsidy designed to promote innovation strategies is the most obvious cost of this alternative, the impacts of much costlier patent processing options (*e.g.,* RCEs and appeals) are also noticeable.

Similarly, the USPTO suspects that patent renewal rates could change as well, given fee reductions for maintenance fees at each of the three stages. While some innovators and firms may choose to file fewer applications given the higher front-end costs, others, whose claims are allowed or upheld, may seek to fully maximize the benefits of obtaining a patent by keeping those patents in force for longer than they would have previously (*i.e.,* under the baseline). In the aggregate, patents that are maintained beyond their useful life weaken the IP system by slowing the rate of public accessibility and follow-on inventions, which is contrary to the USPTO's policy factor of promoting innovation strategies. In sum, this alternative is inadequate to accomplish the goals as stated in Part IV: Rulemaking Goals and Strategies.

The fee schedule for Alternative 2: Unit Cost Recovery is available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSetting AndAdjusting,* in the document titled ''Setting and Adjusting Patent Fees During Fiscal Year 2025—IRFA Tables.'' For the comparison between proposed (unit cost recovery) fees and current fees, the ''current fees'' column displays the fees that are in effect as of the publication of this NPRM. This column is used to calculate dollar and percent fee change compared to proposed fees.

Alternative 3: Across-the-Board Adjustment

In years past, the USPTO used its authority to adjust statutory fees annually according to increases in the consumer price index (CPI), which is a commonly used measure of inflation. Building on this prior approach and incorporating the additional authority under the AIA to set small and micro entity fees, Alternative 3 would set fees by applying a one-time 12.5%, across-the-board inflationary increase to the baseline (current fees) beginning in FY 2025. A 12.5% increase represents the change in revenue needed to achieve the aggregate revenue necessary to recover the aggregate costs laid out in the FY 2025 Budget.

Under this alternative, nearly every existing fee would be increased, no new fees would be introduced, and no fees would be discontinued or reduced. This alternative maintains the status quo ratio of front-end and back-end fees, given that all fees would be adjusted by the same escalation factor, thereby promoting innovation strategies and allowing applicants to gain access to the patent system through fees set below cost while patent holders pay issue and maintenance fees above cost to subsidize the below-cost front-end fees. Alternative 3 nevertheless fails to implement policy factors and deliver benefits beyond what exists in the Baseline fee schedule (*e.g.,* no fee adjustments to offer new patent prosecution options or facilitate more effective administration of the patent system).

The fee schedule for Alternative 3: Across-the-Board Adjustment is available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSetting AndAdjusting,* in the document titled ''Setting and Adjusting Patent Fees During Fiscal Year 2025—IRFA Tables.'' For the comparison between proposed (across-the-board adjustment) fees and current fees, the ''current fees'' column displays the fees that are in effect as of the publication of this NPRM. This column is used to calculate dollar and percent fee change compared to proposed fees.

Alternative 4: Baseline (Current Fee Schedule)

The USPTO considered a no-action alternative. This alternative would retain the status quo, meaning that the USPTO would continue the small and micro entity discounts that the Congress provided in section 10 of the AIA, as amended by the UAIA, and maintain the fees that became effective on December 29, 2022.

Alternative 4 would not secure aggregate revenue to recover the aggregate costs laid out in the FY 2025 Budget. Under this alternative, the USPTO only expects to collect sufficient revenue to continue executing some, not all, of the patent priorities. For example, the USPTO plans to hire approximately 800 to 850 patent examiners in FY 2024 through FY 2025, and between 700 and 900 patent examiners in FY 2026 through FY 2029 (averaging 350 over estimated attrition levels) during the five-year planning horizon. This additional examination capacity will allow the agency to improve patent reliability and maintain patent term adjustment (PTA) compliance rates. Alternative 4 provides neither sufficient resources to hire the same number of examiners nor sufficient resources to continue building the patent operating reserve to its optimal level in the five-year planning horizon. In fact, current estimates project that under the Baseline fee schedule, the USPTO would withdraw funds from the patent operating reserve in every year, until the reserve is exhausted during FY 2027. This approach would not provide sufficient aggregate revenue to accomplish the USPTO's rulemaking goals as stated in Part IV: Rulemaking Goals and Strategies. IT improvements, progress on timely processing and quality, and other improvement activities would continue, but at a significantly slower rate as increases in core patent examination costs crowd out funding for other improvements. Likewise, without a fee increase, the USPTO would deplete its operating reserves, leaving the USPTO vulnerable to fiscal and economic events. This would expose core operations to unacceptable levels of financial risk and would position the USPTO to have to return to making inefficient, short-term funding decisions.

Alternatives Specified by the RFA

The RFA provides that an agency also consider four specified ''alternatives'' or approaches, namely: (i) establishing different compliance or reporting requirements or timetables that take into account the resources available to small entities; (ii) clarifying, consolidating, or simplifying compliance and reporting requirements under the rule for small entities; (iii) using performance rather than design standards; and (iv) exempting small entities from coverage of the rule, or any part thereof. 5 U.S.C. 604(c). The USPTO discusses each of these specified alternatives or approaches below and describes how this NPRM is adopting these approaches.

i. Differing Requirements

As discussed above, the changes proposed in this proposed rule would continue existing fee discounts for small and micro entities that take into account the reduced resources available to them as well as offer new discounts when applicable under AIA authority. Specifically, micro entities would continue to receive an 80% reduction in

most patent fees under this proposal and small entities that do not qualify as micro entities would continue to receive a 60% reduction in most patent fees.

This proposed rule sets fee levels but does not set or alter procedural requirements for asserting small or micro entity status. To pay reduced patent fees, small entities must merely assert small entity status to pay reduced patent fees. The small entity may make this assertion by either checking a box on the transmittal form, ''Applicant claims small entity status,'' or by paying the basic filing or basic national small entity fee exactly. The process to claim micro entity status is similar in that eligible entities need only submit a written certification of their status prior to or at the time a reduced fee is paid. This proposed rule does not change any reporting requirements for any small or micro entity. For both small and micro entities, the burden to establish their status is nominal (making an assertion or submitting a certification) and the benefit of the fee reductions (60% for small entities and 80% for micro entities) is significant.

This proposed rule makes the best use of differing requirements for small and micro entities. It also makes the best use of the redesigned fee structure, as discussed further below.

ii. Clarification, Consolidation, or Simplification of Requirements

This proposed rule pertains to setting or adjusting patent fees. Any compliance or reporting requirements proposed in this rule are de minimis and necessary to implement lower proposed fees. Therefore, any clarifications, consolidations, or simplifications to compliance and reporting requirements for small entities are not applicable or would not achieve the objectives of this rulemaking.

iii. Performance Standards

Performance standards do not apply to the current proposed rule.

iv. Exemption for Small and Micro Entities

The proposed changes here maintain a 60% reduction in fees for small entities and an 80% reduction in fees for micro entities. The USPTO considered exempting small and micro entities from paying increased patent fees but determined that the USPTO would lack statutory authority for this approach. Section 10(b) of the AIA, as amended by the UAIA, provides that ''fees set or adjusted under subsection (a) for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents *shall* be reduced by 60 percent [for small entities] and *shall* be reduced by 80 percent [for micro entities]'' (emphasis added). Neither the AIA, UAIA, nor any other statute authorizes the USPTO simply to exempt small or micro entities, as a class of applicants, from paying increased patent fees.

C. Executive Order 12866 (Regulatory Planning and Review)

This proposed rule has been determined to be economically significant for purposes of Executive Order (E.O.) 12866 (Sept. 30, 1993), as amended by E.O. 14094 (April 6, 2023), Modernizing Regulatory Review. The USPTO has developed an RIA as required for rulemakings deemed to be economically significant. The complete RIA is available on the fee setting section of the USPTO website at *https://www.uspto.gov/FeeSettingAndAdjusting.*

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The USPTO has complied with E.O. 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the proposed rule; (2) tailored the proposed rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism)

This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under E.O. 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under E.O. 13211 because this proposed rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under E.O. 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of E.O. 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under E.O. 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property)

This rulemaking will not affect a taking of private property or otherwise have taking implications under E.O. 12630 (Mar. 15, 1988).

K. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this proposed rule are expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this proposed rule is a ''major rule'' as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995

The proposed changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act

This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. This proposed rule involves information collection requirements which are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). The collection of information involved in this proposed rule has been reviewed and previously approved by OMB under control numbers 0651–0012, 0651–0016, 0651–0017, 0651–0020, 0651–0021, 0651–0022, 0651–0024, 0651–0027, 0651–0031, 0651–0032, 0651–0033, 0651–0034, 0651–0035, 0651–0059, 0651–0062, 0651–0063, 0651–0064, 0651–0069, 0651–0073, and 0651–0075.

Notwithstanding any other provision of law, no person is required to respond to nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

P. E-Government Act Compliance

The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to government information and services, and for other purposes.

List of Subjects

37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

37 CFR Part 41

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements.

37 CFR Part 42

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, 37 CFR parts 1, 41, and 42 are proposed to be amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Section 1.16 is amended by revising the tables in paragraphs (a) through (s) and (u) to read as follows:

§ 1.16 National application filing, search, and examination fees.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

By a micro entity (§ 1.29)	$70.00
By a small entity (§ 1.27(a))	140.00
By a small entity (§ 1.27(a)) if the application is submitted in compliance with the USPTO electronic filing system (§ 1.27(b)(2))	70.00
By other than a small or micro entity	350.00

(b) * * *

TABLE 2 TO PARAGRAPH (b)

By a micro entity (§ 1.29)	$60.00
By a small entity (§ 1.27(a))	120.00
By other than a small or micro entity	300.00

(c) * * *

TABLE 3 TO PARAGRAPH (c)

By a micro entity (§ 1.29)	$48.00
By a small entity (§ 1.27(a))	96.00
By other than a small or micro entity	240.00

(d) * * *

TABLE 4 TO PARAGRAPH (d)

By a micro entity (§ 1.29)	$63.00
By a small entity (§ 1.27(a))	126.00
By other than a small or micro entity	315.00

(e) * * *

TABLE 5 TO PARAGRAPH (e)

By a micro entity (§ 1.29)	$70.00
By a small entity (§ 1.27(a))	140.00
By other than a small or micro entity	350.00

(f) * * *

TABLE 6 TO PARAGRAPH (f)

By a micro entity (§ 1.29)	$34.00
By a small entity (§ 1.27(a))	68.00
By other than a small or micro entity	170.00

(g) * * *

TABLE 7 TO PARAGRAPH (g)

By a micro entity (§ 1.29)	$13.00
By a small entity (§ 1.27(a))	26.00
By other than a small or micro entity	65.00

(h) * * *

TABLE 8 TO PARAGRAPH (h)

By a micro entity (§ 1.29)	$120.00
By a small entity (§ 1.27(a))	240.00
By other than a small or micro entity	600.00

(i) * * *

TABLE 9 TO PARAGRAPH (i)

By a micro entity (§ 1.29)	$40.00
By a small entity (§ 1.27(a))	80.00
By other than a small or micro entity	200.00

(j) * * *

TABLE 10 TO PARAGRAPH (j)

By a micro entity (§ 1.29)	$181.00
By a small entity (§ 1.27(a))	362.00
By other than a small or micro entity	905.00

(k) * * *

TABLE 11 TO PARAGRAPH (k)

By a micro entity (§ 1.29)	$154.00
By a small entity (§ 1.27(a))	308.00

TABLE 11 TO PARAGRAPH (k)—Continued

By other than a small or micro entity	770.00

(l) * * *

TABLE 12 TO PARAGRAPH (l)

By a micro entity (§ 1.29)	$60.00
By a small entity (§ 1.27(a))	120.00
By other than a small or micro entity	300.00

(m) * * *

TABLE 13 TO PARAGRAPH (m)

By a micro entity (§ 1.29)	$97.00
By a small entity (§ 1.27(a))	194.00
By other than a small or micro entity	485.00

(n) * * *

TABLE 14 TO PARAGRAPH (n)

By a micro entity (§ 1.29)	$154.00
By a small entity (§ 1.27(a))	308.00
By other than a small or micro entity	770.00

(o) * * *

TABLE 15 TO PARAGRAPH (o)

By a micro entity (§ 1.29)	$176.00
By a small entity (§ 1.27(a))	352.00
By other than a small or micro entity	880.00

(p) * * *

TABLE 16 TO PARAGRAPH (p)

By a micro entity (§ 1.29)	$140.00
By a small entity (§ 1.27(a))	280.00
By other than a small or micro entity	700.00

(q) * * *

TABLE 17 TO PARAGRAPH (q)

By a micro entity (§ 1.29)	$145.00
By a small entity (§ 1.27(a))	290.00
By other than a small or micro entity	725.00

(r) * * *

TABLE 18 TO PARAGRAPH (r)

By a micro entity (§ 1.29)	$510.00
By a small entity (§ 1.27(a))	1,020.00
By other than a small or micro entity	2,550.00

(s) * * *

TABLE 19 TO PARAGRAPH (s)

By a micro entity (§ 1.29)	$88.00
By a small entity (§ 1.27(a))	176.00
By other than a small or micro entity	440.00

* * * * *

(u) * * *

TABLE 21 TO PARAGRAPH (u)

By a micro entity (§ 1.29)	$84.00
By a small entity (§ 1.27(a))	168.00
By other than a small or micro entity	420.00

■ 3. Section 1.17 is amended by:
■ a. Revising paragraph (a) introductory text;
■ b. Revising the tables in paragraphs (a)(1) through (5), (c), (d), (e)(1);
■ c. Revising paragraph (e)(2);
■ d. Adding paragraph (e)(3);
■ e. Revising the table in paragraph (f);
■ f. Revising paragraph (g);
■ g. Revising the tables in paragraphs (h), (i)(1) and (2), and (k);
■ h. Revising paragraph (m);
■ i. Revising the tables in paragraphs (o) and (p);
■ j. Revising paragraph (q);
■ k. Revising the tables in paragraphs (r) through (t); and
■ l. Adding paragraphs (u) through (x).

The revisions and additions read as follows:

§ 1.17 Patent application and reexamination processing fees.

(a) Extension fees pursuant to § 1.136(a), except in provisional applications filed under § 1.53(c):

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

By a micro entity (§ 1.29)	$46.00
By a small entity (§ 1.27(a))	92.00
By other than a small or micro entity	230.00

(2) * * *

TABLE 2 TO PARAGRAPH (a)(2)

By a micro entity (§ 1.29)	$134.00
By a small entity (§ 1.27(a))	268.00
By other than a small or micro entity	670.00

(3) * * *

TABLE 3 TO PARAGRAPH (a)(3)

By a micro entity (§ 1.29)	$311.00
By a small entity (§ 1.27(a))	622.00
By other than a small or micro entity	1,555.00

(4) * * *

TABLE 4 TO PARAGRAPH (a)(4)

By a micro entity (§ 1.29)	$487.00
By a small entity (§ 1.27(a))	974.00
By other than a small or micro entity	2,435.00

(5) * * *

TABLE 5 TO PARAGRAPH (a)(5)

By a micro entity (§ 1.29)	$664.00
By a small entity (§ 1.27(a))	1,328.00
By other than a small or micro entity	3,320.00

* * * * *

(c) * * *

TABLE 6 TO PARAGRAPH (c)

By a micro entity (§ 1.29)	$882.00
By a small entity (§ 1.27(a))	1,764.00
By other than a small or micro entity	4,410.00

(d) * * *

TABLE 7 TO PARAGRAPH (d)

By a micro entity (§ 1.29)	$134.00
By a small entity (§ 1.27(a))	268.00
By other than a small or micro entity	670.00

(e) * * *

(1) * * *

TABLE 8 TO PARAGRAPH (e)(1)

By a micro entity (§ 1.29)	$300.00
By a small entity (§ 1.27(a))	600.00
By other than a small or micro entity	1,500.00

(2) For filing a second request for continued examination pursuant to § 1.114 in an application:

TABLE 9 TO PARAGRAPH (e)(2)

By a micro entity (§ 1.29)	$500.00
By a small entity (§ 1.27(a))	1,000.00
By other than a small or micro entity	2,500.00

(3) For filing a third or subsequent request for continued examination pursuant to § 1.114 in an application:

TABLE 10 TO PARAGRAPH (e)(3)

By a micro entity (§ 1.29)	$720.00
By a small entity (§ 1.27(a))	1,440.00
By other than a small or micro entity	3,600.00

(f) * * *

TABLE 11 TO PARAGRAPH (f)

By a micro entity (§ 1.29)	$88.00
By a small entity (§ 1.27(a))	176.00
By other than a small or micro entity	440.00

Note 1 to table 11 to paragraph (f):
§ 1.36(a)—for revocation of a power of attorney by fewer than all of the applicants.
§ 1.53(e)—to accord a filing date.
§ 1.182—for decision on a question not specifically provided for in an application for patent.

§ 1.183—to suspend the rules in an application for patent.
§ 1.741(b)—to accord a filing date to an application under § 1.740 for extension of a patent term.
§ 1.1023—to review the filing date of an international design application.

(g)(1) For filing a petition under one of the following sections which refers to this paragraph (g):

TABLE 12 TO PARAGRAPH (g)(1)

By a micro entity (§ 1.29)	$46.00
By a small entity (§ 1.27(a))	92.00
By other than a small or micro entity	230.00

Note 2 to table 12 to paragraph (g)(1):
§ 1.12—for access to an assignment record.
§ 1.14—for access to an application.
§ 1.46—for filing an application on behalf of an inventor by a person who otherwise shows sufficient proprietary interest in the matter.
§ 1.55(f)—for filing a belated certified copy of a foreign application.
§ 1.55(g)—for filing a belated certified copy of a foreign application.
§ 1.57(a)—for filing a belated certified copy of a foreign application.
§ 1.59—for expungement of information.
§ 1.136(b)—for review of a request for extension of time when the provisions of § 1.136(a) are not available.
§ 1.377—for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
§ 1.550(c)—for patent owner requests for extension of time in *ex parte* reexamination proceedings.
§ 1.956—for patent owner requests for extension of time in *inter partes* reexamination proceedings.
§ 5.12 of this chapter—for expedited handling of a foreign filing license.
§ 5.15 of this chapter—for changing the scope of a license.
§ 5.25 of this chapter—for retroactive license.

(2) For filing a petition to suspend action in an application under § 1.103(a):

(i) For filing a first request for suspension pursuant to § 1.103(a) in an application:

TABLE 13 TO PARAGRAPH (g)(2)(i)

By a micro entity (§ 1.29)	$60.00
By a small entity (§ 1.27(a))	120.00
By other than a small or micro entity	300.00

(ii) For filing a second or subsequent request for suspension pursuant to § 1.103(a) in an application:

TABLE 14 TO PARAGRAPH (g)(2)(ii)

By a micro entity (§ 1.29)	$90.00
By a small entity (§ 1.27(a))	180.00
By other than a small or micro entity	450.00

(h) * * *

TABLE 15 TO PARAGRAPH (h)

By a micro entity (§ 1.29)	$29.00
By a small entity (§ 1.27(a))	58.00
By other than a small or micro entity	145.00

Note 3 to table 15 to paragraph (h):
§ 1.84—for accepting color drawings or photographs.
§ 1.91—for entry of a model or exhibit.
§ 1.102(d)—to make an application special.
§ 1.138(c)—to expressly abandon an application to avoid publication.
§ 1.313—to withdraw an application from issue.
§ 1.314—to defer issuance of a patent.

(i) * * *

(1) * * *

TABLE 16 TO PARAGRAPH (i)(1)

By a micro entity (§ 1.29)	$29.00
By a small entity (§ 1.27(a))	58.00
By other than a small or micro entity	145.00

Note 4 to table 16 to paragraph (i)(1):
§ 1.28(c)(3)—for processing a non-itemized fee deficiency based on an error in small entity status.
§ 1.29(k)(3)—for processing a non-itemized fee deficiency based on an error in micro entity status.
§ 1.41—for supplying the name or names of the inventor or joint inventors in an application without either an application data sheet or the inventor's oath or declaration, except in provisional applications.
§ 1.48—for correcting inventorship, except in provisional applications.
§ 1.52(d)—for processing a nonprovisional application filed with a specification in a language other than English.
§ 1.53(c)(3)—to convert a provisional application filed under § 1.53(c) into a nonprovisional application under § 1.53(b).
§ 1.71(g)(2)—for processing a belated amendment under § 1.71(g).
§ 1.102(e)—for requesting prioritized examination of an application.
§ 1.103(b)—for requesting limited suspension of action, continued prosecution application for a design patent (§ 1.53(d)).
§ 1.103(c)—for requesting limited suspension of action, request for continued examination (§ 1.114).
§ 1.103(d)—for requesting deferred examination of an application.
§ 1.291(c)(5)—for processing a second or subsequent protest by the same real party in interest.
§ 3.81of this chapter—for a patent to issue to assignee, assignment submitted after payment of the issue fee.

(2) * * *

TABLE 17 TO PARAGRAPH (i)(2)

By a micro entity (§ 1.29)	$147.00
By a small entity (§ 1.27(a))	147.00
By other than a small or micro entity	147.00

Note 5 to table 17 to paragraph (i)(2):
§ 1.217—for processing a redacted copy of a paper submitted in the file of an application in which a redacted copy was submitted for the patent application publication.
§ 1.221—for requesting voluntary publication or republication of an application.

* * * * *

(k) * * *

TABLE 18 TO PARAGRAPH (k)

By a micro entity (§ 1.29)	$336.00
By a small entity (§ 1.27(a))	672.00
By other than a small or micro entity	1,680.00

* * * * *

(m)(1) For filing a petition under one of the following sections which refers to this paragraph (m), when the petition is filed more than two years after the date when the required action was due:

TABLE 19 TO PARAGRAPH (m)(1)

By a micro entity (§ 1.29)	$600.00
By a small entity (§ 1.27(a))	1,200.00
By other than a small or micro entity	3,000.00

Note 6 to table 19 to paragraph (m)(1):
§ 1.55(e)—for the delayed submission of a priority claim, when the petition is filed more than two years after the date when the priority claim was due.
§ 1.78(c) or (e)—for the delayed submission of a benefit claim, when the petition is filed more than two years after the date when the benefit claim was due.
§ 1.137—for filing a petition for the revival of an abandoned application for a patent, or for the delayed payment of the fee for issuing each patent, when the petition is filed more than two years after the abandonment of the application.
§ 1.137—for filing a petition for the revival of a reexamination proceeding that was terminated or limited due to a delayed response by the patent owner, when the petition is filed more than two years after the termination or limitation of the reexamination proceeding.
§ 1.378—for filing a petition to accept a delayed payment of the fee for maintaining a patent in force, when the petition is filed more than two years after the patent expiration date.
§ 1.1051—for filing a petition to excuse an applicant's failure to act within prescribed time limits in an international design application, when the petition is filed more than two years after the abandonment of the application.

(2) For filing a petition under § 1.55(e), § 1.78(c), § 1.78(e), § 1.137, § 1.1051, or § 1.378, when the petition is filed before the time period specified in paragraph (m)(1) of this section:

TABLE 20 TO PARAGRAPH (m)(2)

By a micro entity (§ 1.29)	$440.00
By a small entity (§ 1.27(a))	880.00
By other than a small or micro entity	2,200.00

(3) For filing a petition under § 1.55(c), § 1.78(b), or § 1.452 for the extension of the 12-month (six-month for designs) period for filing a subsequent application:

TABLE 21 TO PARAGRAPH (m)(3)

By a micro entity (§ 1.29)	$440.00
By a small entity (§ 1.27(a))	880.00
By other than a small or micro entity	2,200.00

* * * * *

(o) * * *

TABLE 22 TO PARAGRAPH (o)

By a small entity (§ 1.27(a)) or micro entity (§ 1.29)	$76.00
By other than a small or micro entity	190.00

(p) * * *

TABLE 23 TO PARAGRAPH (p)

By a micro entity (§ 1.29)	$55.00
By a small entity (§ 1.27(a))	110.00
By other than a small or micro entity	275.00

(q) Processing fee for taking action under one of the following sections which refers to this paragraph (q): $53.00.

(1) Section 1.41—to supply the name or names of the inventor or inventors after the filing date without a cover sheet as prescribed by § 1.51(c)(1) in a provisional application.

(2) Section 1.48—for correction of inventorship in a provisional application.

(3) Section 1.53(c)(2)—to convert a nonprovisional application filed under § 1.53(b) to a provisional application under § 1.53(c).

(r) * * *

TABLE 24 TO PARAGRAPH (r)

By a micro entity (§ 1.29)	$185.00
By a small entity (§ 1.27(a))	370.00
By other than a small or micro entity	925.00

(s) * * *

TABLE 25 TO PARAGRAPH (s)

By a micro entity (§ 1.29)	$185.00
By a small entity (§ 1.27(a))	370.00
By other than a small or micro entity	925.00

(t) * * *

TABLE 26 TO PARAGRAPH (t)

By a micro entity (§ 1.29)	$38.00
By a small entity (§ 1.27(a))	76.00
By other than a small or micro entity	190.00

(u) Extension fees pursuant to § 1.136(a) in provisional applications filed under § 1.53(c):

(1) For reply within first month:

TABLE 27 TO PARAGRAPH (u)(1)

By a micro entity (§ 1.29)	$10.00
By a small entity (§ 1.27(a))	20.00
By other than a small or micro entity	50.00

(2) For reply within second month:

TABLE 28 TO PARAGRAPH (u)(2)

By a micro entity (§ 1.29)	$20.00
By a small entity (§ 1.27(a))	40.00
By other than a small or micro entity	100.00

(3) For reply within third month:

TABLE 29 TO PARAGRAPH (u)(3)

By a micro entity (§ 1.29)	$40.00
By a small entity (§ 1.27(a))	80.00
By other than a small or micro entity	200.00

(4) For reply within fourth month:

TABLE 30 TO PARAGRAPH (u)(4)

By a micro entity (§ 1.29)	$80.00
By a small entity (§ 1.27(a))	160.00
By other than a small or micro entity	400.00

(5) For reply within fifth month:

TABLE 31 TO PARAGRAPH (u)(5)

By a micro entity (§ 1.29)	$160.00
By a small entity (§ 1.27(a))	320.00
By other than a small or micro entity	800.00

(v) Information disclosure statement size fee for an information disclosure statement filed under § 1.97 that, inclusive of the number of applicant-provided or patent owner-provided items of information listed under § 1.98(a)(1) on the information disclosure statement, causes the cumulative number of applicant-provided or patent owner-provided items of information under § 1.98(a)(1) during the pendency of the application or reexamination proceeding to:

(1) Exceed 50 but not exceed 100. . . . . .$200;

(2) Exceed 100 but not exceed 200. . . . . .$500, less any amount previously paid under paragraph (v)(1) of this section; and

(3) Exceed 200. . . . . .$800, less any amounts previously paid under paragraphs (v)(1) and/or (2) of this section.

(w) Additional fee for presenting a benefit claim in a nonprovisional application under 35 U.S.C. 120, 121, 365(c), or 386(c) and § 1.78(d):

(1) When the actual filing date of the nonprovisional application in which the benefit claim is presented is more than 5 years and no more than 8 years from the earliest filing date for which benefit is claimed under 35 U.S.C. 120, 121, 365(c), or 386(c) and § 1.78(d):

TABLE 32 TO PARAGRAPH (w)(1)

By a micro entity (§ 1.29)	$440.00
By a small entity (§ 1.27(a))	880.00
By other than a small or micro entity	2,200.00

(2) When the actual filing date of the nonprovisional application in which the benefit claim is presented is more than 8 years from the earliest filing date for which benefit is claimed under 35 U.S.C. 120, 121, 365(c), or 386(c) and

§ 1.78(d), the amount shown in this paragraph is due, less any amount previously paid under paragraph (w)(1) of this section:

TABLE 33 TO PARAGRAPH (w)(2)

By a micro entity (§ 1.29)	$700.00
By a small entity (§ 1.27(a))	1,400.00
By other than a small or micro entity	3,500.00

(x) For submission of a request for consideration under the After Final Consideration Pilot Program 2.0:

TABLE 34 TO PARAGRAPH (x)

By a micro entity (§ 1.29)	$100.00
By a small entity (§ 1.27(a))	200.00
By other than a small or micro entity	500.00

■ 4. Section 1.18 is amended by:
■ a. Revising the tables in paragraphs (a), (b)(1), and (c); and
■ b. Revising paragraphs (d)(2) and (3), (e), and (f).

The revisions read as follows:

§ 1.18 Patent post allowance (including issue) fees.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

By a micro entity (§ 1.29)	$252.00
By a small entity (§ 1.27(a))	504.00
By other than a small or micro entity	1,260.00

(b)(1) * * *

TABLE 2 TO PARAGRAPH (b)(1)

By a micro entity (§ 1.29)	260.00
By a small entity (§ 1.27(a))	520.00
By other than a small or micro entity	1,300.00

* * * * *

(c) * * *

TABLE 3 TO PARAGRAPH (c)

By a micro entity (§ 1.29)	$176.00
By a small entity (§ 1.27(a))	352.00
By other than a small or micro entity	880.00

(d)(1) * * *

(2) Publication fee before January 1, 2014: $320.00

(3) Republication fee (§ 1.221(a)): $336.00

(e) For filing an application for patent term adjustment under § 1.705: $300.00

(f) For filing a request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) in an application for patent term adjustment under § 1.705: $440.00

■ 5. Section 1.19 is amended by revising paragraphs (a)(2), (b)(1)(i)(A), (B), and (D), (b)(1)(ii)(A) and (B), (b)(3) and (4), and (f) to read as follows:

§ 1.19 Document supply fees.

* * * * *

(a) * * *

(2) Printed copy of a plant patent in color: $16.00

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) Application as filed: $37.00

(B) Copy Patent File Wrapper, Paper Medium, Any Number of Sheets: $305.00.

* * * * *

(D) Individual application documents, other than application as filed, per document: $26.00

(ii) * * *

(A) Application as filed: $37.00

(B) Copy Patent File Wrapper, Electronic, Any Medium, Any Size: $63.00

* * * * *

(3) Copy of Office records, except copies available under paragraph (b)(1) or (2) of this section: $26.00

(4) For assignment records, abstract of title and certification, per patent: $37.00

* * * * *

(f) Uncertified copy of a non-United States patent document, per document: $26.00

* * * * *

■ 6. Section 1.20 is amended by:
■ a. Revising paragraphs (a) and (b);
■ b. Revising the tables in (c)(1)(i) through (c)(4) and (c)(6);

■ c. Revising paragraph (d);
■ d. Revising the tables in paragraphs (e) through (h);
■ e. Revising paragraph (j); and
■ f. Revising the tables in (k)(1) and (2) and (k)(3)(i) and (ii).

The revisions read as follows:

§ 1.20 Post-issuance fees.

(a) For providing a certificate of correction for an applicant's mistake (§ 1.323): $168.00.

(b) Processing fee for correcting inventorship in a patent (§ 1.324): $168.00.

(c) * * *

(1)(i) * * *

TABLE 1 TO PARAGRAPH (c)(1)(i)

By a micro entity (§ 1.29)	$1,323.00
By a small entity (§ 1.27(a))	2,646.00
By other than a small or micro entity	6,615.00

* * * * *

(2) * * *

TABLE 2 TO PARAGRAPH (c)(2)

By a micro entity (§ 1.29)	$2,646.00
By a small entity (§ 1.27(a))	5,292.00
By other than a small or micro entity	13,320.00

(3) * * *

TABLE 3 TO PARAGRAPH (c)(3)

By a micro entity (§ 1.29)	$120.00
By a small entity (§ 1.27(a))	240.00
By other than a small or micro entity	600.00

(4) * * *

TABLE 4 TO PARAGRAPH (c)(4)

By a micro entity (§ 1.29)	$40.00
By a small entity (§ 1.27(a))	80.00
By other than a small or micro entity	200.00

* * * * *

(6) * * *

TABLE 5 TO PARAGRAPH (c)(6)

By a micro entity (§ 1.29)	$428.00
By a small entity (§ 1.27(a))	856.00
By other than a small or micro entity	2,140.00

* * * * *

(d) For filing statutory and terminal disclaimers.

(1) For filing each statutory disclaimer under § 1.321(a), other than a terminal disclaimer: $179.00.

(2) For filing each terminal disclaimer under § 1.321:

(i) In a non-reissue application before the mailing of a first Office action on the merits $200.00;

(ii) In a non-reissue application after the period specified in paragraph (d)(2)(i) of this section and before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application $500.00;

(iii) In a non-reissue application after the period specified in paragraph (d)(2)(ii) of this section, and before any submission of a notice of appeal under § 41.31 $800.00;

(iv) In a non-reissue application on or after the submission of a notice of appeal under § 41.31 $1,100.00; and

(v) In a patent or application for reissue $1,400.00.

(e) * * *

TABLE 7 TO PARAGRAPH (e)

By a micro entity (§ 1.29)	$420.00
By a small entity (§ 1.27(a))	840.00
By other than a small or micro entity	2,100.00

(f) * * *

TABLE 8 TO PARAGRAPH (f)

By a micro entity (§ 1.29)	$790.00
By a small entity (§ 1.27(a))	1,580.00
By other than a small or micro entity	3,950.00

(g) * * *

TABLE 9 TO PARAGRAPH (g)

By a micro entity (§ 1.29)	$1,617.00
By a small entity (§ 1.27(a))	3,234.00
By other than a small or micro entity	8,805.00

(h) * * *

TABLE 10 TO PARAGRAPH (h)

By a micro entity (§ 1.29)	$105.00
By a small entity (§ 1.27(a))	210.00
By other than a small or micro entity	525.00

* * * * *

(j) For filing an application for extension of the term of a patent:

(1) Application for extension under § 1.740: $6,700.00

(2) Initial application for interim extension under § 1.790: $1,320.00

(3) Subsequent application for interim extension under § 1.790: $680.00

(4) Requesting supplemental redetermination after notice of final determination: $1,440.00

(k) * * *

(1) * * *

TABLE 11 TO PARAGRAPH (k)(1)

By a micro entity (§ 1.29)	$970.00
By a small entity (§ 1.27(a))	1,940.00
By other than a small or micro entity	4,850.00

(2) * * *

TABLE 12 TO PARAGRAPH (k)(2)

By a micro entity (§ 1.29)	$2,667.00
By a small entity (§ 1.27(a))	5,334.00
By other than a small or micro entity	13,335.00

(3) * * *

(i) * * *

TABLE 13 TO PARAGRAPH (k)(3)(i)

By a micro entity (§ 1.29)	$38.00
By a small entity (§ 1.27(a))	76.00
By other than a small or micro entity	190.00

(ii) * * *

TABLE 15 TO PARAGRAPH (k)(3)(ii)

By a micro entity (§ 1.29)	$63.00
By a small entity (§ 1.27(a))	126.00
By other than a small or micro entity	315.00

■ 7. Section 1.21 is amended by:

■ a. Revising paragraphs (a)(1)(i), (a)(1)(ii)(A), (a)(1)(iii) and (iv), (a)(2)(i) and (ii), (a)(4)(i) and (ii), (a)(5)(i) and

(ii), (a)(6)(ii), (a)(9)(i) and (ii), (a)(10), (e), (h)(2), (i), and (n);

■ b. Revising the tables in paragraphs (o)(1) and (2); and

■ c. Revising paragraphs (p) and (q).

The revisions read as follows:

§ 1.21 Miscellaneous fees and charges.

* * * * *

(a) * * *

(l) * * *

(i) Application Fee (non-refundable): $116.00.

(ii) * * *

(A) For test administration by commercial entity: $221.00.

* * * * *

(iii) For USPTO-administered review of registration examination: $494.00.

(iv) Request for extension of time in which to schedule examination for registration to practice (non-refundable): $121.00

(2) * * *

(i) On registration to practice under § 11.6 of this chapter: $221.00.

(ii) On grant of limited recognition under § 11.9(b) of this chapter: $221.00.

* * * * *

(4) * * *

(i) Standard: $42.00

(ii) Suitable for framing: $53.00

(5) * * *

(i) By the Director of Enrollment and Discipline under § 11.2(c) of this chapter: $440.00

(ii) Of the Director of Enrollment and Discipline under § 11.2(d) of this chapter: $440.00

(6) * * *

(i) * * *

(ii) For USPTO-assisted change of address: $74.00

* * * * *

(9) * * *

(i) Delinquency fee: $53.00

(ii) Administrative reinstatement fee: $221.00

(10) On application by a person for recognition or registration after disbarment or suspension on ethical grounds, or resignation pending disciplinary proceedings in any other jurisdiction; on application by a person for recognition or registration who is asserting rehabilitation from prior conduct that resulted in an adverse decision in the Office regarding the person's moral character; on application by a person for recognition or registration after being convicted of a felony or crime involving moral turpitude or breach of fiduciary duty; and on petition for reinstatement by a person excluded or suspended on ethical grounds, or excluded on consent from practice before the Office: $1,764.00

* * * * *

(e) International type search reports: For preparing an international type search report of an international type search made at the time of the first action on the merits in a national patent application: $42.00

* * * * *

(h) * * *

(1) * * *

(2) If not submitted electronically: $53.00

(i) Publication in Official Gazette: For publication in the Official Gazette of a notice of the availability of an application or a patent for licensing or sale: Each application or patent: $26.00

* * * * *

(n) For handling an application in which proceedings are terminated pursuant to § 1.53(e): $147.00

(o) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (o)(1)

By a micro entity (§ 1.29)	$223.00
By a small entity (§ 1.27(a))	446.00
By other than a small or micro entity	1,115.00

(2) * * *

TABLE 2 TO PARAGRAPH (o)(2)

By a micro entity (§ 1.29)	$2,205.00
By a small entity (§ 1.27(a))	4,410.00
By other than a small or micro entity	11,025.00

(p) Additional Fee for Overnight Delivery: $42.00

(q) Additional fee for expedited service: $179.00

■ 8. Section 1.78 is amended by revising paragraphs (d)(3)(i) and (e)(2) to read as follows:

§ 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

* * * * *

(d) * * *

(3)(i) The reference required by 35 U.S.C. 120 and paragraph (d)(2) of this section, and the applicable fee set forth in § 1.17(w), must be submitted during the pendency of the later-filed application.

* * * * *

(e) * * *

(2) The petition fee as set forth in § 1.17(m), and the applicable fee set forth in § 1.17(w); and

* * * * *

■ 9. Section 1.97 is amended by revising paragraph (a) to read as follows:

§ 1.97 Filing of information disclosure statement.

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section and be accompanied by any applicable information disclosure statement size fee under § 1.17(v).

* * * * *

■ 10. Section 1.98 is amended by revising paragraph (a) introductory text and adding paragraph (a)(4) to read as follows:

§ 1.98 Content of information disclosure statement.

(a) Any information disclosure statement filed under § 1.97 shall include the items listed in paragraphs (a)(1) through (4) of this section.

* * * * *

(4) A clear written assertion that the information disclosure statement is accompanied by the applicable information disclosure statement size fee under § 1.17(v) or a clear written assertion that no information disclosure statement size fee under § 1.17(v) is required.

* * * * *

■ 11. Section 1.136 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 1.136 Extensions of time.

(a)(1) If an applicant is required to reply within a nonstatutory or shortened statutory time period, applicant may extend the time period for reply up to the earlier of the expiration of any maximum period set by statute or five months after the time period set for reply, if a petition for an extension of time and the fee set in § 1.17(a) or (u) are filed, unless:

* * * * *

■ 12. Section 1.138 is amended by revising paragraph (d) to read as follows:

§ 1.138 Express abandonment.

* * * * *

(d) An applicant seeking to abandon an application filed under 35 U.S.C. 111(a) and § 1.53(b) on or after December 8, 2004, or a national stage application under 35 U.S.C. 371 in which the basic national fee was paid on or after December 8, 2004 to obtain a refund of the search fee and excess claims fee paid in the application, must submit a declaration of express abandonment by way of a petition under this paragraph before an examination has been made of the application. The date indicated on any certificate of mailing or transmission under § 1.8 will not be taken into account in determining whether a petition under § 1.138(d) was filed before an examination has been made of the application. Refunds under this paragraph are limited to the search fees and excess claim fees set forth in §§ 1.16 and 1.492. If a request for refund of the search fee and excess claims fee paid in the application is not filed with the declaration of express abandonment under this paragraph or within two months from the date on which the declaration of express abandonment under this paragraph was filed, the Office may retain the entire search fee and excess claims fee paid in the application. This two-month period is not extendable. If a petition and declaration of express abandonment under this paragraph are not filed before an examination has been made of the application, the Office will not refund any part of the search fee and excess claims fee paid in the application except as provided in § 1.26.

■ 13. Section 1.445 is amended by revising and republishing paragraph (a) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) The following fees and charges for international applications are established by law or by the director under the authority of 35 U.S.C. 376:

(1) A transmittal fee (see 35 U.S.C. 361(d) and PCT Rule 14) consisting of:

(i) A basic portion:

(A) For an international application having a receipt date that is on or after [EFFECTIVE DATE OF FINAL RULE]:

TABLE 1 TO PARAGRAPH (a)(1)(i)(A)

By a micro entity (§ 1.29)	$57.00
By a small entity (§ 1.27(a))	114.00
By other than a small or micro entity	285.00

(B) For an international application having a receipt date that is on or after December 29, 2022, and before [EFFECTIVE DATE OF FINAL RULE]:

TABLE 2 TO PARAGRAPH (a)(1)(i)(B)

By a micro entity (§ 1.29)	$52.00
By a small entity (§ 1.27(a))	104.00
By other than a small or micro entity	260.00

(C) For an international application having a receipt date that is on or after October 2, 2020, and before December 29, 2022:

TABLE 3 TO PARAGRAPH (a)(1)(i)(C)

By a micro entity (§ 1.29)	$65.00
By a small entity (§ 1.27(a))	130.00
By other than a small or micro entity	260.00

(D) For an international application having a receipt date that is on or after January 1, 2014, and before October 2, 2020:

TABLE 4 TO PARAGRAPH (a)(1)(i)(D)

By a micro entity (§ 1.29)	$60.00
By a small entity (§ 1.27(a))	120.00
By other than a small or micro entity	240.00

(E) For an international application having a receipt date that is before January 1, 2014: $240.00

(ii) A non-electronic filing fee portion for any international application designating the United States of America that is filed on or after November 15, 2011, other than by the USPTO patent electronic filing system, except for a plant application:

TABLE 5 TO PARAGRAPH (a)(1)(ii)

By a small entity (§ 1.27(a))	200.00
By other than a small or micro entity	400.00

(2) A search fee (see 35 U.S.C. 361(d) and PCT Rule 16):

(i) For an international application having a receipt date that is on or after [EFFECTIVE DATE OF FINAL RULE]:

TABLE 6 TO PARAGRAPH (a)(2)(i)

By a micro entity (§ 1.29)	$480.00
By a small entity (§ 1.27(a))	960.00
By other than a small or micro entity	2,400.00

(ii) For an international application having a receipt date that is on or after April 1, 2023, and before [EFFECTIVE DATE OF FINAL RULE]:

TABLE 7 TO PARAGRAPH (a)(2)(ii)

By a micro entity (§ 1.29)	$436.00
By a small entity (§ 1.27(a))	872.00
By other than a small or micro entity	2,180.00

(iii) For an international application having a receipt date that is on or after October 2, 2020, and before April 1, 2023:

TABLE 8 TO PARAGRAPH (a)(2)(iii)

By a micro entity (§ 1.29)	$545.00
By a small entity (§ 1.27(a))	1,090.00
By other than a small or micro entity	2,180.00

(iv) For an international application having a receipt date that is on or after January 1, 2014, and before October 2, 2020:

TABLE 9 TO PARAGRAPH (a)(2)(iv)

By a micro entity (§ 1.29)	$520.00
By a small entity (§ 1.27(a))	1,040.00
By other than a small or micro entity	2,080.00

(v) For an international application having a receipt date that is before January 1, 2014: $2,080.00

(3) A supplemental search fee when required, per additional invention:

(i) For an international application having a receipt date that is on or after [EFFECTIVE DATE OF FINAL RULE]:

TABLE 10 TO PARAGRAPH (a)(3)(i)

By a micro entity (§ 1.29)	$480.00
By a small entity (§ 1.27(a))	960.00
By other than a small or micro entity	2,400.00

(ii) For an international application having a receipt date that is on or after April 1, 2023, and before [EFFECTIVE DATE OF FINAL RULE]:

TABLE 11 TO PARAGRAPH (a)(3)(ii)

By a micro entity (§ 1.29)	$436.00
By a small entity (§ 1.27(a))	872.00
By other than a small or micro entity	2,180.00

(iii) For an international application having a receipt date that is on or after October 2, 2020, and before April 1, 2023:

TABLE 12 TO PARAGRAPH (a)(3)(iii)

By a micro entity (§ 1.29)	$545.00
By a small entity (§ 1.27(a))	1,090.00
By other than a small or micro entity	2,180.00

(iv) For an international application having a receipt date that is on or after January 1, 2014, and before October 2, 2020:

TABLE 13 TO PARAGRAPH (a)(3)(iv)

By a micro entity (§ 1.29)	$520.00
By a small entity (§ 1.27(a))	1,040.00
By other than a small or micro entity	2,080.00

(v) For an international application having a receipt date that is before January 1, 2014: $2,080.00

(4) A fee equivalent to the transmittal fee in paragraph (a)(1) of this section that would apply if the USPTO was the Receiving Office for transmittal of an international application to the International Bureau for processing in its capacity as a Receiving Office (PCT Rule 19.4).

(5) Late furnishing fee for providing a sequence listing in response to an invitation under PCT Rule 13*ter:*

TABLE 14 TO PARAGRAPH (a)(5)

By a micro entity (§ 1.29)	$67.00
By a small entity (§ 1.27(a))	134.00
By other than a small or micro entity	335.00

(6) Late payment fee pursuant to PCT Rule 16*bis*.2.

* * * * *

■ 14. Section 1.482 is amended by revising the tables in paragraphs (a)(1)(i) and (ii), (a)(2), and (c) to read as follows:

§ 1.482 International preliminary examination and processing fees.

(a) * * *

(1) * * *

(i) * * *

TABLE 1 TO PARAGRAPH (a)(1)(i)

By a micro entity (§ 1.29)	$141.00
By a small entity (§ 1.27(a))	282.00
By other than a small or micro entity	705.00

(ii) * * *

TABLE 2 TO PARAGRAPH (a)(1)(ii)

By a micro entity (§ 1.29)	$176.00
By a small entity (§ 1.27(a))	352.00
By other than a small or micro entity	880.00

(2) * * *

TABLE 3 TO PARAGRAPH (a)(2)

By a micro entity (§ 1.29)	$141.00
By a small entity (§ 1.27(a))	282.00
By other than a small or micro entity	705.00

* * * * *

(c) * * *

TABLE 4 TO PARAGRAPH (c)

By a micro entity (§ 1.29)	$67.00

TABLE 4 TO PARAGRAPH (c)—Continued

By a small entity (§ 1.27(a))	134.00
By other than a small or micro entity	335.00

■ 15. Section 1.492 is amended by revising the tables in paragraphs (a), (b)(2) through (4), (c)(2), (d) through (f), and (h) through (j) to read as follows.

§ 1.492 National stage fees.

* * * * *

(a) * * *

TABLE 1 TO PARAGRAPH (a)

By a micro entity (§ 1.29)	$70.00
By a small entity (§ 1.27(a))	140.00
By other than a small or micro entity	350.00

(b) * * *

(2) * * *

TABLE 3 TO PARAGRAPH (b)(2)

By a micro entity (§ 1.29)	$29.00
By a small entity (§ 1.27(a))	58.00
By other than a small or micro entity	145.00

(3) * * *

TABLE 4 TO PARAGRAPH (b)(3)

By a micro entity (§ 1.29)	$113.00
By a small entity (§ 1.27(a))	226.00
By other than a small or micro entity	565.00

(4) * * *

TABLE 5 TO PARAGRAPH (b)(4)

By a micro entity (§ 1.29)	$154.00
By a small entity (§ 1.27(a))	308.00
By other than a small or micro entity	770.00

(c) * * *

(2) * * *

TABLE 7 TO PARAGRAPH (c)(2)

By a micro entity (§ 1.29)	$176.00
By a small entity (§ 1.27(a))	352.00
By other than a small or micro entity	880.00

(d) * * *

TABLE 8 TO PARAGRAPH (d)

By a micro entity (§ 1.29)	$120.00
By a small entity (§ 1.27(a))	240.00
By other than a small or micro entity	600.00

(e) * * *

TABLE 9 TO PARAGRAPH (e)

By a micro entity (§ 1.29)	$40.00
By a small entity (§ 1.27(a))	80.00

TABLE 9 TO PARAGRAPH (e)—Continued

By other than a small or micro entity	200.00

(f) * * *

TABLE 10 TO PARAGRAPH (f)

By a micro entity (§ 1.29)	$181.00
By a small entity (§ 1.27(a))	362.00
By other than a small or micro entity	905.00

* * * * *

(h) * * *

TABLE 11 TO PARAGRAPH (h)

By a micro entity (§ 1.29)	$34.00
By a small entity (§ 1.27(a))	68.00
By other than a small or micro entity	170.00

(i) * * *

TABLE 12 TO PARAGRAPH (i)

By a micro entity (§ 1.29)	$29.00
By a small entity (§ 1.27(a))	58.00
By other than a small or micro entity	145.00

(j) * * *

TABLE 13 TO PARAGRAPH (j)

By a micro entity (§ 1.29)	$88.00
By a small entity (§ 1.27(a))	176.00
By other than a small or micro entity	440.00

■ 16. Section 1.555 is amended by revising paragraph (a) to read as follows:

§ 1.555 Information material to patentability in *ex parte* reexamination and *inter partes* reexamination proceedings.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective reexamination occurs when, at the time a reexamination proceeding is being conducted, the Office is aware of and evaluates the teachings of all information material to patentability in a reexamination proceeding. Each individual associated with the patent owner in a reexamination proceeding has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability in a reexamination proceeding. The individuals who have a duty to disclose to the Office all information known to them to be material to patentability in a reexamination proceeding are the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding. The duty to disclose the information exists with respect to each claim pending in the reexamination proceeding until the claim is cancelled. Information material to the patentability of a cancelled claim need not be submitted if the information is not material to patentability of any claim remaining under consideration in the reexamination proceeding. The duty to disclose all information known to be material to patentability in a reexamination proceeding is deemed to be satisfied if all information known to be material to patentability of any claim in the patent after issuance of the reexamination certificate was cited by the Office or submitted to the Office in an information disclosure statement. However, the duties of candor, good faith, and disclosure have not been complied with if any fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct by, or on behalf of, the patent owner in the reexamination proceeding. Any information disclosure statement must be filed with the items listed in § 1.98(a) as applied to individuals associated with the patent owner in a reexamination proceeding, should be filed within two months of the date of the order for reexamination, or as soon thereafter as possible, and be accompanied by any applicable information disclosure statement size fee under § 1.17(v).

* * * * *

■ 16. Section 1.1031 is amended by revising the table in paragraph (a) to read as follows:

§ 1.1031 International design application fees.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

By a micro entity (§ 1.29)	$25.00
By a small entity (§ 1.27(a))	50.00
By other than a small or micro entity	125.00

* * * * *

PART 41—PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 17. The authority citation for part 41 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 41, 134, 135, and Public Law 112–29.

■ 18. Section 41.20 is amended by:
■ a. Revising paragraph (a); and
■ b. Revising the tables in paragraphs (b)(1), (b)(2)(ii), and (b)(3) and (4).

The revisions read as follows:

§ 41.20 Fees.

(a) *Petition fee.* The fee for filing petitions to the Chief Administrative Patent Judge under § 41.3 is: $440.00

(b) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (b)(1)

By a micro entity (§ 1.29)	$176.00
By a small entity (§ 1.27(a))	352.00
By other than a small or micro entity	880.00

(2) * * *

(ii) * * *

TABLE 2 TO PARAGRAPH (b)(2)(ii)

By a micro entity (§ 1.29)	$440.00
By a small entity (§ 1.27(a))	880.00
By other than a small or micro entity	2,200.00

(3) * * *

TABLE 3 TO PARAGRAPH (b)(3)

By a micro entity (§ 1.29)	$286.00
By a small entity (§ 1.27(a))	572.00
By other than a small or micro entity	1,430.00

(4) * * *

TABLE 4 TO PARAGRAPH (b)(4)

By a micro entity (§ 1.29)	$496.00
By a small entity (§ 1.27(a))	992.00
By other than a small or micro entity	2,480.00

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 19. The authority citation for part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 6, 21, 23, 41, 135, 311, 312, 316, 321–326; Pub. L. 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

■ 20. Section 42.15 is amended by:
■ a. Revising paragraphs (a)(1) through (4), (b)(1) through (4), (c)(1), (d), and (e); and
■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 42.15 Fees.

(a) * * *

(1) *Inter Partes* Review request fee—up to 20 claims: $23,750.00

(2) *Inter Partes* Review Post-Institution fee—up to 20 claims: $28,125.00

(3) In addition to the *Inter Partes* Review request fee, for requesting a review of each claim in excess of 20: $470.00

(4) In addition to the *Inter Partes* Post-Institution request fee, for requesting a review of each claim in excess of 20: $940.00

(b) * * *

(1) Post-Grant or Covered Business Method Patent Review request fee—up to 20 claims: $25,000.00

(2) Post-Grant or Covered Business Method Patent Review Post-Institution fee—up to 20 claims: $34,375.00

(3) In addition to the Post-Grant or Covered Business Method Patent Review request fee, for requesting a review of each claim in excess of 20: $595.00

(4) In addition to the Post-Grant or Covered Business Method Patent Review Post-Institution fee, for requesting a review of each claim in excess of 20: $1,315.00

(c) * * *

(1) Derivation petition fee: $440.00

* * * * *

(d) Any request requiring payment of a fee under this part, including a written request to make a settlement agreement available: $440.00

(e) Fee for non-registered practitioners to appear *pro hac vice* before the Patent Trial and Appeal Board: $263.00

(f) Fee for requesting a review of a Patent Trial and Appeal Board decision by the Director: $440.

Katherine Kelly Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2024–06250 Filed 4–2–24; 8:45 am]

BILLING CODE 3510–16–P

FEDERAL REGISTER

Vol. 89 Wednesday,
No. 65 April 3, 2024

Part V

Environmental Protection Agency

40 CFR Part 63
National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0083; FRL–5919.1–02–OAR]

RIN 2060–AV82

National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA or the Agency) is finalizing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Integrated Iron and Steel Manufacturing Facilities to regulate hazardous air pollutant (HAP) emissions. The amendments include: HAP from unmeasured fugitive and intermittent particulate (UFIP) sources previously not regulated by the NESHAP; previously unregulated HAP for sinter plants:; previously unregulated pollutants for blast furnace (BF) stoves and basic oxygen process furnaces (BOPFs) primary control devices; and previously unregulated pollutants for BF primary control devices. We are also finalizing an update to the technology review for this source category.

DATES: This final rule is effective June 3, 2024. The incorporation by reference (IBR) of material publications listed in the rule is approved by the Director of the Federal Register (FR) beginning June 3, 2024. The incorporation by reference (IBR) of certain other material listed in the rule was approved by the Director of the Federal Register (FR) as of July 13, 2020.

ADDRESSES: The EPA established a docket for this action under Docket ID No. EPA–HQ–OAR–2002–0083. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and is publicly available only in hard copy. With the exception of such materials, publicly available docket materials are available electronically in *https://www.regulations.gov/* or in hard copy at the EPA Docket Center, Room 3334, WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Katie Boaggio, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2223; email address: *boaggio.katie@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. Throughout this document the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ACI activated carbon injection
BF blast furnace
BOPF basic oxygen process furnace
BTF Beyond-the-Floor
CAA Clean Air Act
CBI Confidential Business Information
COS Carbonyl Sulfide
CFR Code of Federal Regulations
D/F dioxins and furans
EAV equivalent annualized value
EJ environmental justice
EPA Environmental Protection Agency
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HF hydrogen fluoride
HMTDS hot metal transfer, desulfurization, and skimming
ICR Information Collection Request
II&S Integrated Iron and Steel
km kilometer
MACT maximum achievable control technology
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PAH polycyclic aromatic hydrocarbons
PM particulate matter
PBT persistent, bioaccumulative, and toxic
PRA Paperwork Reduction Act
PV present value
RFA Regulatory Flexibility Act
RTR residual risk and technology review
SSM startup, shutdown, and malfunction
THC total hydrocarbons
TEQ toxic equivalency
tpy tons per year
UFIP unmeasured fugitive and intermittent particulate
UMRA Unfunded Mandates Reform Act
UPL upper prediction limit
VCS voluntary consensus standards
VE visible emissions
VOC volatile organic compound
WP work practice

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

The EPA set maximum achievable control technology (MACT) standards for the Integrated Iron and Steel Manufacturing Facilities major source category in 2003 (68 FR 27645) under 40 CFR part 63, subpart FFFFF and completed a residual risk and technology review final rule in July 2020 (85 FR 42074). The purpose of this rule is to (1) fulfill the EPA's statutory obligations pursuant to CAA section 112(d)(6); *see Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020) (''*LEAN*''), and (2) improve the emissions standards for this source category based on new information regarding developments in practices, processes, and control technologies.

2. Summary of the Major Provisions of the Regulatory Action

To comply with CAA section 112, we are finalizing: (1) new emissions limits based on MACT for five currently unregulated HAP (COS, CS_2, Hg, HCl, and HF) from the sinter plants located at integrated iron and steel manufacturing facilities; and (2) new MACT standards, in the form of opacity limits and work practice (WP) standards, for five unregulated sources of UFIP emissions: Unplanned Bleeder Valve Openings, Planned Bleeder Valve Openings, Slag Pits, Beaching, and Bell Leaks. In this context, opacity is a measure of the amount of light that is blocked or absorbed by an air pollution plume. The components of air pollution that block or absorb light are primarily particulate matter (PM). An opacity level of 0 percent means that plumes of air pollution do not block or absorb light and are fully transparent (*i.e.,* no visible emissions), while an opacity of 100 percent means that plumes are dense and block all light (*i.e.,* the trained observer or special camera cannot see any background behind the plume). Observers are trained and certified using smoke generators which produce known opacity levels, and periodic recertification is required every six months. More details regarding the EPA approved method for opacity readings by a trained observer are available at the following website: *https://www.epa.gov/emc/method-9-visual-opacity.* Alternatively, opacity can be observed with special cameras following a specific method (known as the digital camera opacity technique (DCOT), 40 CFR 63.7823), and those images interpreted by trained individuals. For the Integrated Iron and Steel Manufacturing sector (and a number of other metals processing and production sectors), a significant portion of the emitted PM is composed of HAP metals (such as arsenic, lead, manganese, and chromium) that are primarily emitted in particulate form as demonstrated in the emissions tests available in the docket for this action. Therefore, for the Integrated Iron and Steel Manufacturing sector, as well as several other industry sectors, PM and opacity serve as surrogates for particulate HAP metals.

We are also finalizing new emissions limits for three unregulated pollutants for BF stoves and BOPFs: THC (as a surrogate for non-dioxin and non-furan organic HAP), HCl, and D/F; and for two unregulated pollutants for BFs: THC (as a surrogate for non-dioxin and non-furan organic HAP) and HCl. In this action, pursuant to CAA section 112(d)(6), we are also finalizing: (1) work practice standards for the basic oxygen process furnace (BOPF) shops; (2) a requirement that facilities conduct Method 9 readings two times per month at the BOPF Shop and BF casthouse; (3) a fenceline monitoring requirement for chromium to help ensure the work practices and opacity limits are achieving the anticipated reductions; and (4) revised standards for D/F and PAHs from sinter plants to reflect the installation and operation of activated carbon injection (ACI) technology. At this time, we are not finalizing the proposed revised opacity limits for the BOPF or the BF casthouse, as explained later in this preamble.

3. Costs and Benefits

To meet the requirements of E.O. 12866, the EPA projected the emissions reductions, costs, and benefits that may result from the final rule. These results are presented in detail in the regulatory impact analysis (RIA) accompanying this final rule developed in response to E.O. 12866. The final rule is significant under E.O. 12866 Section 3(f)(1), as amended by E.O. 14094, due to the monetized benefits of fine particulate matter ($PM_{2.5}$) reductions likely to result from the UFIP emissions standards included in the final rule. The RIA, which is available in the docket for this action, focuses on the elements of the final rule that are likely to result in quantifiable cost or emissions changes compared to a baseline without these regulatory requirements. We estimated the cost, emissions, and benefit impacts for the 2026 to 2035 period, discounted to 2024. We show the present value (PV) and equivalent annualized value (EAV) of costs, benefits, and net benefits of this action in 2022 dollars. The EAV represents a flow of constant annual values that would yield a sum equivalent to the PV. The EAV represents the value of a typical cost or benefit for each year of the analysis, consistent with the estimate of the PV, in contrast to year-specific estimates.

The initial analysis year in the RIA is 2026 because we assume that will be the first year of full implementation of the rule. We are finalizing that facilities will have 1 year to demonstrate compliance with the relevant standards following promulgation. This analysis assumes that full compliance with the standards will occur in early 2025. Therefore, the first full year of impacts will occur in 2026. The final analysis year is 2035, which allows us to provide ten years of projected impacts after the rule takes effect.

The cost analysis presented in the RIA reflects a nationwide engineering analysis of compliance cost and emissions reductions. Impacts are calculated by setting parameters on how and when affected facilities are assumed to respond to a particular regulatory regime, calculating estimated cost and emissions impact estimates for each facility, differencing from the baseline scenario, and then summing to the desired level of aggregation.

The EPA expects health benefits due to the emissions reductions projected from the rule. We expect that HAP emission reductions will improve health and welfare associated with reduced exposure for those affected by these emissions. In addition, the EPA expects that $PM_{2.5}$ emission reductions that will occur concurrent with the reductions in HAP emissions will improve air quality and are likely to improve health and welfare associated with exposure to $PM_{2.5}$ and HAP. For the RIA, the EPA monetized benefits associated with premature mortality and morbidity from reduced exposure to $PM_{2.5}$. Discussion of both the monetized and non-monetized benefits can be found in Chapter 4 of the RIA.

Table 1 presents the emission changes and the PV and EAV of the projected monetized benefits, compliance costs, and net benefits over the 2026 to 2035 period under the rule. All discounting

of impacts presented uses social discount rates of 3 and 7 percent.

TABLE 1—MONETIZED BENEFITS, COSTS, NET BENEFITS, AND EMISSIONS REDUCTIONS OF THE FINAL NESHAP SUBPART FFFFF AMENDMENTS, 2026 THROUGH 2035 [a]

[Dollar estimates in millions of 2022 dollars, discounted to 2024]

	3 Percent discount rate		7 Percent discount rate	
	PV	EAV	PV	EAV
Benefits [b]	$1,800 and $3,700	$200 and $420	$1,200 and $2,600	$170 and $340.
Compliance Costs	$45	$5.3	$36	$5.1.
Net Benefits	$1,800 and $3,700	$190 and $410	$1,200 and $2,600	$160 and $330.
Emissions Reductions (short tons)	2026–2035 Total			
HAP	640			
PM	18,000			
$PM_{2.5}$	4,700			
Non-monetized Benefits in this Table	HAP benefits from reducing 640 short tons of HAP from 2026–2035. Non-health benefits from reducing 18,000 tons of PM, of which 4,700 tons is $PM_{2.5}$, from 2026–2035. Benefits from reducing HCl, HF, Hg, D/F TEQ, COS, and CS2. Visibility benefits. Reduced vegetation effects.			

[a] Totals may not sum due to independent rounding. Numbers rounded to two significant digits unless otherwise noted.

[b] Monetized benefits include health benefits associated with reductions in $PM_{2.5}$ emissions. The monetized health benefits are quantified using two alternative concentration-response relationships from the Di et al. (2016) and Turner et al. (2017) studies and presented at real discount rates of 3 and 7 percent. The two benefits estimates are separated by the word ''and'' to signify that they are two separate estimates. Benefits from HAP reductions remain unmonetized and are thus not reflected in the table.

B. Does this action apply to me?

Table 2 of this preamble lists the NESHAP and associated regulated industrial source category that is the subject of this final rule. Table 2 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this final action is likely to affect. The final standards are directly applicable to the affected sources. Federal, state, local, and Tribal government entities are not affected by this final action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576; July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA–450/3–91–030; July 1992), the Integrated Iron and Steel Manufacturing Facilities source category is any facility engaged in producing steel from iron ore. Integrated iron and steel manufacturing includes the following processes: sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BFs by the reduction of iron-bearing materials with a hot gas. The steel production process occurs in the BOPFs where hot liquid iron from the BF is loaded (*i.e.,* charged) into the BOPF along with coke, lime, alloys, and steel scrap, and includes blowing oxygen into the furnace through a lance resulting in oxidation reactions to produce steel.

TABLE 2—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

Source category	NESHAP	NAICS code [1]
Integrated Iron and Steel Manufacturing Facilities	40 CFR part 63, subpart FFFFF	331110

[1] North American Industry Classification System.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website.

D. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) by June 3, 2024. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for

public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

This action finalizes amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Integrated Iron and Steel Manufacturing Facilities source category. The statutory authority for this action is provided by section 112 of the CAA, as amended (42 U.S.C. 7401, *et seq.*). In the first stage of the CAA section 112 standard-setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.''

For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable after considering cost, energy requirements, and non-air quality health and environmental impacts. These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' In certain instances, as provided in CAA section 112(h), if it is the judgment of the Administrator that it is not feasible to prescribe or enforce an emission standard, the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor, commonly referred to as ''beyond-the-floor'' (BTF) standards.

CAA section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every eight years. While conducting this review, which we call the ''technology review,'' the EPA is not required to recalculate the MACT floors that were established during earlier rulemakings. *Nat. Resources Def. Council, et al.* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008); *Ass'n of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). However, costs may not be considered when setting the MACT floor and may only be considered when determining whether beyond-the-floor standards are appropriate. *See* CAA section 112(d)(3).

CAA section 112(f) requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. This review is known as the ''residual risk review,'' and it must occur within eight years after promulgation of the standards. When the EPA conducts the ''technology review'' together with the ''residual risk review,'' the combined review is known as a ''risk and technology review'' or ''RTR.''

The EPA initially promulgated the Integrated Iron and Steel Manufacturing Facilities NESHAP on May 20, 2003 (68 FR 27645), codified at title 40, part 63, subpart FFFFF (the NESHAP). The rule was amended on July 13, 2006 (71 FR 39579). The amendments added a new compliance option, revised emission limitations, reduced the frequency of repeat performance tests for certain emission units, added corrective action requirements, and clarified monitoring, recordkeeping, and reporting requirements.

In 2015, a coalition of environmental advocacy groups filed a lawsuit to compel the EPA to fulfill its statutory duty to conduct the CAA sections 112(d) and 112(f)(2) reviews of 21 NESHAPs, including Integrated Iron and Steel Manufacturing Facilities. As a result of that litigation, the EPA was required by court order to complete the RTR for the Integrated Iron and Steel Manufacturing Facilities source category by May 5, 2020. *California Communities Against Toxics* v. *Wheeler,* No. 1:15–00512, Order (D.D.C. March 13, 2017, as modified Feb. 20, 2020). The resulting RTR conducted for the Integrated Iron and Steel Manufacturing Facilities NESHAP was signed on May 4, 2020. 85 FR 42074 (July 13, 2020).

In an April 2020 decision by the U.S. Court of Appeals for the District of Columbia Circuit, on a petition for review of the EPA's NESHAP rulemaking for a different source category (pulp mill combustion sources), the court held that the EPA has an obligation to address all unregulated HAP emissions from a source category when the Agency conducts the eight-year technology review required by CAA section 112(d)(6). *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088, 1098–99 (''*LEAN*''). The parties in *California Communities Against Toxics* thereafter filed a joint motion to extend those deadlines to allow the EPA to revise the rules in accordance with the *LEAN* opinion. The court granted the motion, setting a new deadline for this rule of October 26, 2023. Order, *California Communities Against Toxics,* No. 15–512 (D.D.C. April 14, 2021). Based on further negotiation between the parties, the deadline for this final rule was changed to March 11, 2024. Minute Order, *California Communities Against Toxics,* No. 15–512 (D.D.C. Sept. 20, 2023).

In September 2021, industry and environmental advocacy groups filed petitions for review of the 2020 Integrated Iron and Steel Manufacturing Facilities final rule, and these petitions have been consolidated. *American Iron and Steel Inst., et al.* v. *EPA,* No. 20–1354 (D.C. Cir.); *Clean Air Council, et al.* v. *EPA,* No. 20–1355 (D.C. Cir.). The consolidated case is being held in abeyance pending the promulgation of this final rule. *See EPA's Unopposed Mot. to Hold Cases in Abeyance,* No. 20–1354 (consol.) (D.C. Cir.), Dkt. No. 2028131 (reporting to the D.C. Circuit the March 11, 2024 final rule deadline); Order, *American Iron and Steel Inst.,* No. 20–1354 (consol.) (D.C. Cir. Dec. 7, 2022).

In light of this litigation history, this final rule addresses multiple issues, including: (1) new standards to address previously unregulated emissions of HAP from the Integrated Iron and Steel Manufacturing Facilities source category pursuant to the *LEAN* decision and CAA sections 112(d)(2) and (3) and 112(h) and, (2) revised standards for a few currently regulated HAP, as well as fenceline monitoring requirements, pursuant to the CAA section 112(d)(6) technology review.

B. What is the source category and how does the current NESHAP regulate its HAP emissions?

As described above, the Integrated Iron and Steel Manufacturing Facilities source category includes any facility engaged in producing steel from refined iron ore (also known as taconite pellets). These facilities first produce iron from iron ore taconite pellets, sinter, coke, and other raw materials using blast furnaces (BFs), then produce steel from the hot liquid iron produced from the blast furnaces, along with coke, lime, alloys, steel scrap, and other raw materials using basic oxygen process furnaces (BOPFs). Integrated iron and steel manufacturing includes the following processes: sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BFs by the reduction of iron-bearing materials with a very hot gas. The steel production process includes BOPFs and ladle metallurgy operations. Currently there are eight operating facilities in this source category.

The main sources of HAP emissions from integrated iron and steel manufacturing are the BF; BF stove; BOPF; hot metal transfer, desulfurization, and skimming (HMTDS) operations; ladle metallurgy operations; sinter plant windbox; sinter plant discharge end; and sinter cooler. All eight facilities have BFs, BF stoves, BOPFs, HMTDS operations, and ladle metallurgy operations. However, only three facilities have sinter plants and only two facilities with currently operating sinter plants.

The following are descriptions of the BF, BOPF, and sinter plants:

- The BF is a key integrated iron and steel process unit where molten iron is produced from raw materials such as iron ore, lime, sinter, coal and coke.
- The BOPF is a key integrated iron and steel process unit where steel is made from molten iron, scrap steel, lime, dolomite, coal, coke, and alloys.
- Sinter is derived from material formed in the bottom of the blast furnace, composed of oily scale, blast furnace sludge, and coke breeze, along with tarry material and oil absorbed from the sump in which the sinter is recovered. The sinter plant processes the waste that would otherwise be landfilled so that iron and other valuable materials can be re-used in the blast furnace. Only three sources covered by the Integrated Iron and Steel Manufacturing Facility category have sinter plants, down from nine facilities with sinter plants in 2003.

In addition to point sources, the EPA identified seven UFIP emission sources for this source category, including BF bleeder valve unplanned openings, BF bleeder valve planned openings, BF bell leaks, BF casthouse fugitives, BF iron beaching, BF and BOPF slag handling and storage operations, and BOPF shop fugitives. These UFIP emission sources were identified by observation of visible plumes by EPA regional staff during onsite source inspections and were subsequently investigated to determine the causes and any possible methods for reductions. These inspections are documented in numerous reports and photographs between 2008 and the present.[1] The NESHAP regulates two of these sources—BF casthouse fugitives and BOPF shop fugitives—with opacity limits.

The following are descriptions of the main process units and the seven UFIP sources:

- The BF is a key integrated iron and steel process unit where molten iron is produced from raw materials such as iron ore, lime, sinter, coal and coke.
- The BOPF is a key integrated iron and steel process unit where steel is made from molten iron, scrap steel, lime, dolomite, coal, coke, and alloys.
- Sinter is derived from material formed in the bottom of the blast furnace, composed of oily scale, blast furnace sludge, and coke breeze, along with tarry material and oil absorbed from the sump in which the sinter is recovered. The sinter plant processes the waste that would otherwise be landfilled so that iron and other valuable materials can be re-used in the blast furnace. Only three sources covered by the Integrated Iron and Steel Manufacturing Facility category have sinter plants, down from nine facilities with sinter plants in 2003.
- The BOPF shop is the structure that houses the entire BOPF and auxiliary activities, such as hot iron transfer, skimming, and desulfurization of the iron and ladle metallurgy operations, which generate fugitive emissions.
- The BF casthouse is the structure that houses the lower portion of the BF and encloses the tapping operation and the iron and slag transport operations, which generate fugitive emissions.
- The bleeder valve is a device at the top of the BF that, when open, relieves BF internal pressure to the ambient air. The valve can operate as both a self-actuating safety device to relieve excess pressure and as an operator-initiated instrument for process control. A bleeder valve opening means any opening of the BF bleeder valve, which allows gas and/or PM to flow past the sealing seat. Multiple openings and closings of a bleeder valve that occur within a 30-minute period could be considered a single bleeder valve opening. There are two types of openings, planned and unplanned.
- A planned bleeder valve opening means an opening that is initiated by an operator as part of a furnace startup, shutdown, or temporary idling for maintenance action. Operators can prepare the furnace for planned openings to minimize or eliminate emissions from the bleeder valves.
- An unplanned bleeder valve opening means an opening that is not planned and is caused by excess pressure within the furnace. The pressure buildup can occur when raw materials do not descend smoothly after being charged at the top of the BF and accumulate in large masses within the furnace. When the large masses finally dislodge (slip) due to their weight, a pressure surge results.
- Slag is a by-product containing impurities that is released from the BF or BOPF along with molten iron when the BF or BOPF is tapped from the bottom of the furnace. The slag is less dense than iron and, therefore, floats on top of the iron. Slag is removed by skimmers and then transported to open pits to cool to enable later removal. Usually there is one slag pit for every BF or BOPF.
- Iron beaching occurs when iron from a BF cannot be charged to the BOPF because of problems in steelmaking units; the hot molten iron from the BF is placed onto the ground, in some cases within a three-sided structure.
- The BF bells are part of the charging system on top of the furnace that allows for materials to be loaded into the furnace or next bell (as in the case of small bells) without letting BF gas escape. It is a two-bell system, where a smaller bell is above a larger bell. These bells must be tightly sealed to the blast furnace when not in use for charging, so that BF gas and uncontrolled emissions do not escape to the atmosphere. Over time, the surfaces that seal the bells wear down and need to be repaired or replaced. If these seals are not repaired or replaced in a timely manner, emissions of HAP and PM can increase significantly.

In the 2020 final rule, the Agency found that risks due to emissions of air toxics from this source category were

[1] *See, e.g.,* communications between B. Dickens and P. Miller, U.S. EPA Region V, Chicago, IL, with D.L. Jones, U.S. EPA, Office of Air Quality Planning and Standards, Office of Air and Radiation, 2015–2018. See also *Ample Margin of Safety for Nonpoint Sources in the II&S Industry.* Both documents are available in the docket to this rule.

acceptable and concluded that the NESHAP provided an ample margin of safety to protect public health. Although the 2020 NESHAP found the risks acceptable and no new requirements should be imposed, new data was collected via a CAA section 114 request to industry after re-opening the rule, due to the *LEAN* court decision. These new data necessitated technology review updates, in addition to establishing new MACT standards for unregulated HAPs pursuant to the *LEAN* court decision. Under the technology review in the 2020 RTR, the EPA found no developments in practices, processes, or control technologies that necessitated revision of the standards at that time. However, in response to a 2004 administrative petition for reconsideration of the 2003 NESHAP, the 2020 final rule promulgated a new MACT emissions limit for mercury (0.00026 lbs mercury/ton scrap metal) with two compliance options: (1) conduct annual compliance tests (to demonstrate compliance with the MACT limit); or (2) confirm that the facility obtains their auto scrap from suppliers that participate in the National Vehicle Mercury Switch Recovery Program (NVMRP) or another approved mercury switch removal program or that the facility only uses scrap that does not contain mercury switches. We also removed exemptions for periods of startup, shutdown, and malfunction (SSM) consistent with *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008); clarified that the emissions standards apply at all times; added electronic reporting of performance test results and compliance reports; and made minor corrections and clarifications for a few other rule provisions. All documents used to develop the previous 2003, 2006, and 2020 final rules can be found in either the legacy docket, A–2000–44, or the electronic docket, EPA–HQ–OAR–2002–0083.

The NESHAP includes emissions limits for PM and opacity standards—both of which are surrogates for non-mercury PM HAP metals—for furnaces and sinter plants. To support the continued use of PM as a surrogate for certain non-mercury HAP metals, we considered the holding in *National Lime Ass'n* v. *EPA,* 233 F.3d 625 (D.C. Cir. 2000). In considering whether the EPA may use PM, a criteria pollutant, as a surrogate for metal HAP, the D.C. Circuit stated that the EPA ''may use a surrogate to regulate hazardous pollutants if it is 'reasonable' to do so,'' *id.* at 637, establishing criteria for determining whether the use of PM as a surrogate for non-mercury metal HAP was reasonable. The court found that PM is a reasonable surrogate for HAP if: (1) ''HAP metals are invariably present'' in the source's PM,'' *id.*; (2) the ''source's PM control technology indiscriminately captures HAP metals along with other particulates,'' *id.* at 639; and (3) ''PM control is the only means by which facilities 'achieve' reductions in HAP metal emissions,'' *id.* If these criteria are satisfied and the PM emission standards reflect what the best sources achieve in compliance with CAA section 112(d)(3), then ''EPA is under no obligation to achieve a particular numerical reduction in HAP metal emissions.'' *Id.* The EPA has established and promulgated PM limits as a surrogate for particulate HAP metals successfully in several NESHAP regulations, including Ferroalloys Production (80 FR 37366, June 30, 2015), Taconite Iron Ore Processing (68 FR 61868), and Primary Copper Smelting (67 FR 40478, June 12, 2002).

The NESHAP also includes an operating limit for the oil content of the sinter plant feedstock or, as an alternative, an emissions limit for volatile organic compounds (VOC) for the sinter plant windbox exhaust stream. The oil limit, and the alternative VOC limit, serve as surrogates for all organic HAP. Moreover, the NESHAP includes an emissions limit for mercury emissions from the BOPF Group, which is the collection of BOPF shop steelmaking operating units and their control devices including the BOPF primary emission control system, BOPF secondary control system, ladle metallurgy units, and hot metal transfer, desulfurization and slag skimming units.

C. What changes did we propose for the Integrated Iron and Steel Manufacturing Facilities source category?

On July 31, 2023, the EPA published a proposal in the **Federal Register** to set standards to regulate HAP emissions from five UFIP sources that were not previously regulated by the NESHAP: Bell Leaks, Unplanned Bleeder Valve Openings, Planned Bleeder Valve Openings, Slag Pits, and Beaching. For sinter plants, we proposed standards for five previously unregulated HAP: COS, CS_2, Hg, HCl, and HF. For BF stoves and BOPFs, we proposed standards for three previously unregulated pollutants: THC (as a surrogate for non-dioxin and non-furan organic HAP), HCl, and D/F. And for BFs, we proposed standards for two previously unregulated pollutants: THC (as a surrogate for non-dioxin and non-furan organic HAP) and HCl.

As an update to the technology review, we proposed to revise the previous BOPF shop fugitive 20 percent opacity limit to a 5 percent opacity limit and require specific work practices; revise the current BF casthouse fugitive 20 percent opacity limit to a 5 percent opacity limit; and revise the current standards for D/F and PAH for sinter plants to reflect current control performance of sinter plants for these HAP. We also proposed a fenceline monitoring requirement for Cr, including a requirement that if a monitor exceeds the proposed Cr action level, the facility would need to conduct a root cause analysis and take corrective action to lower emissions.

III. What is the rationale for our final decisions and amendments for the Integrated Iron and Steel Manufacturing Facilities source category?

For each issue, this section provides a description of what we proposed and what we are finalizing, a summary of key comments and responses, and the EPA's rationale for the final decisions and amendments. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the document, *Summary of Public Comments and Responses for Proposed Amendments to the National Emission Standards for Hazardous Air Pollutants for Integrated Iron and Steel Manufacturing Facilities,* which is available in the docket for this action. This document is also referred to as the Response to Comments (RTC) in subsequent sections of this preamble.

A. Standards To Address Five Unregulated UFIP Sources for Both New and Existing Sources

1. What did we propose for the five previously unregulated UFIP sources?

a. BF Unplanned Bleeder Valve Openings

Based on the data we received through the CAA section 114 requests, the average number of unplanned openings of the best performing five furnaces in the source category is 5 unplanned openings per year. Therefore, we proposed an operational limit of five unplanned openings per year per furnace for existing sources, which was an estimate of the MACT floor level of performance for existing sources. For new sources, we proposed an operational limit of zero unplanned openings per year because the best performing single source in our database reported zero unplanned openings for the most recent representative year.

Additionally, we proposed work practice standards that would require facilities to do the following: (1) install and operate devices (*e.g.,* stockline monitors) to continuously measure/monitor material levels in the furnace, at a minimum of three locations, using alarms to inform operators of static conditions that indicate a slip may occur and alert them that there is a need to take action to prevent the slips and unplanned openings from occurring; (2) install and operate instruments such as a thermocouple and transducer on the furnace to monitor temperature and pressure to help determine when a slip may occur; (3) install a screen to remove fine particulates from raw materials to ensure only properly-sized raw materials are charged into the BF; and (4) develop, and submit to the EPA for approval, a plan that explains how the facility will implement these requirements. Additionally, we proposed that facilities would need to report the unplanned openings (including the date, time, duration, and any corrective actions taken) in their semiannual compliance reports.

b. BF Planned Bleeder Valve Openings

Based on our evaluation of available information and pursuant to CAA section 112(d)(2) and (3), for existing sources we proposed a MACT floor limit of 8 percent opacity for any 6-minute averaging period for the BF planned bleeder valve openings. We did not propose the BTF option of 5 percent opacity for existing sources because we determined that 5 percent opacity may not be feasible for some sources on a consistent basis. For new sources, we proposed an opacity of 0 percent because based on the available data, the best performing single source had opacity of 0 percent during the planned opening. We expect that new sources will be able to configure their furnace design and operations similarly to the best performing single source which, in combination with utilizing the suggested work practices described in the document *Unmeasurable Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* should allow them to achieve an opacity of 0 percent. We did not propose any work practices under CAA section 112(h) for the BF planned bleeder valve openings; facilities will have the flexibility to choose an appropriate approach to meet the opacity limit.

c. BF and BOPF Slag Processing, Handling, and Storage

Based on our analyses and pursuant to CAA section 112(d)(2) and (3), for existing sources we proposed a BTF opacity limit of 5 percent based on 6-minute averages for visible emissions from slag pits and during slag handling, storage, and processing. Regarding new sources, we proposed a MACT floor opacity limit of 2.5 percent based on 6-minute averages for visible emissions from slag pits and during slag handling, storage, and processing.

d. BF Bell Leaks

Based on our evaluation and pursuant to CAA section 112(d)(2) and (3), we proposed 10 percent opacity as an action level, as described below in this paragraph, for large bell leaks (not a MACT emissions limit). Along with this action level, we also proposed that the BF top will need to be observed monthly for visible emissions (VE) with EPA Method 22, 40 CFR part 60, appendix A–7, which determines the presence or absence of a visible plume, to identify leaks, and if VE are detected out of the interbell relief valve (indicating leaks from the large bell), we proposed that the facility would then need to perform EPA Method 9, 40 CFR part 60, appendix A–4, tests which determines the opacity (*i.e.,* degree to which a plume obscures the background), monthly and if opacity is greater than 10 percent (based on a 3-minute average), the large bell seals will need to be repaired or replaced within 4 months. For the small bell, we proposed that facilities will need to replace or repair seals prior to a metal throughput limit, specified by the facility, that has been proven and documented to produce no opacity from the small bells.

e. Beaching of Iron From BFs

Pursuant to CAA section 112(d)(2) and (3) and CAA section 112(h), we proposed a MACT standard that would require facilities to: (1) have full or partial enclosures for the beaching process or use CO_2 to suppress fumes; and (2) minimize the height, slope, and speed of beaching.

2. What comments did we receive on the proposed standards and, what are our responses?

a. BF Unplanned Bleeder Valve Openings

Comment: Commenters stated that in developing the proposed limit on the number of unplanned pressure release device (PRD) openings that could occur within a year, the EPA treated all BFs alike by placing them in a single category. Commenters stated that because larger BFs are able to accommodate higher internal pressures before the need for an unplanned opening, the EPA should create two separate subcategories of blast furnaces. Commenters stated that in reviewing data for unplanned PRD openings, they believed that subcategorization is appropriate and necessary if an action level or limit of any type is to be established for the number of events. In particular, commenters noted that large BFs have significantly fewer unplanned openings, where ''Large BF'' is defined as a BF with a working volume greater than 2,500 cubic meters (m^3). Commenters also stated that the EPA did not account for variability across sources and asked EPA to apply an upper prediction limit (UPL) if it were to finalize a limit on unplanned openings. Commenters stated that a 99 percent UPL analysis of the data supports limits of 52 unplanned openings for large BFs and 112 unplanned openings for small BFs.

Response: We agree with the commenter that larger BFs are able to accommodate higher internal pressure and that subcategorization based on BF size is appropriate. In this final rule, we define ''large BF'' as a BF with a working volume greater than 2,500 m^3 and are establishing separate limits on unplanned openings for large and small BF.

EPA also agrees with commenters that it is important to account for variability in the incidence of unplanned openings. Accordingly, in the final rule the EPA has decided to base the limit on the highest number of unplanned openings reported within the top five sources to ensure that we adequately account for variability, rather than the proposed approach of basing the limit on the average number of unplanned openings within the top five sources.

EPA disagrees with commenters' suggestion that it should apply a 99 percent UPL to determine the limit on unplanned openings. The EPA commonly uses the 99 percent UPL to calculate numerical emissions limits based on stack test data (*e.g.,* grams of HAP per cubic meter of stack exhaust gases). The UPL method is not appropriate to evaluate a count of unplanned openings because these are discrete events and are therefore not analogous to emissions data or test runs. In the context of this final rule, application of the UPL would therefore not appropriately reflect variability and would lead to an exceedingly high limit on unplanned openings that does not reflect the performance achieved at top-

performing sources. As noted above, the EPA has instead accounted for variability in this final rule by basing the limit on the highest number of unplanned openings observed among the five top-performing sources.

b. BF Planned Bleeder Valve Openings

Comment: Commenters agreed that these opacity limits will result in HAP reductions. Accordingly, commenters supported these revisions and additions and encouraged the EPA to not weaken any of the proposed limits.

Response: EPA appreciates the support and agrees that these opacity limits for planned bleeder valve openings will result in HAP reductions.

Comment: EPA should not adopt the proposed 8% opacity limit and weekly Method 9 testing for planned openings in addition to the new work practice standards. PRD openings by operators are routinely necessary and appropriate for proper BF operation. Emissions from planned openings are exceedingly low, ranging from 1.6 tpy to 0.3 tpy, with reductions projected between 0.4 and 0.08 tpy across the entire industry. The work practice standards are expensive, with estimated cost-effectiveness based upon the proposed rule having rates ranging from $134,000/ton to $672,000/ton. No regulation of these small contributors should occur. If EPA nonetheless moves forward, there should be an action level at 15% (based on a more robust UPL analysis).

Response: Based on our evaluation of public comments and available information, pursuant to CAA section 112(d)(2) and (3) and the *LEAN* court decision, for existing sources we are promulgating a MACT Floor limit of 8 percent opacity for any 6-minute averaging period for the BF planned bleeder valve openings. The MACT floor is the least stringent standard allowed by section 112 of the Clean Air Act. For new sources, we are promulgating an opacity of 0 percent because based on the available data, the best performing single source had opacity of 0 percent during the planned opening, which we consider the MACT Floor level for new sources pursuant to CAA section 112. As we explained in the proposed rule, we determined based on evaluation of available information that emissions can be minimized from bleeder valve planned openings cost effectively by implementing various actions before the valves are opened such as: (1) tapping as much liquid (iron and slag) out of the furnace as possible; (2) removing fuel and/or stopping fuel injection into the furnace; and (3) lowering bottom pressure. However, as explained in the proposed rule preamble, we did not propose any specific work practices for the BF planned bleeder valve openings and we are maintaining the decision to not require any specific work practices for the final rule. Facilities will have the flexibility to choose an appropriate approach to meet the opacity limit.

We estimate that this standard will result in about 0.41 tpy reduction in HAP metal emissions. The estimated cost is $54,600/yr for the entire category and $6,800/yr per facility. The estimated cost effectiveness is $134,000 per ton of HAP metals.

c. BF and BOPF Slag Processing, Handling, and Storage

Comment: Commenters stated that the proposed 5 percent opacity limit for slag handling operations should not be adopted. They contend that it is virtually impossible to enclose the extremely hot slag material or to universally apply water at all times to help suppress emissions because of the volatile nature of the material and the potential for a life-threatening hazardous explosion when the water violently expands in the form of steam. Commenters stated that the EPA had ignored these important safety concerns in proposing the 5 percent opacity limit, and that the control measures the EPA had identified to meet this limit could not be reasonably utilized. Commenters also argued that even if EPA's suggested control measures were applied, a UPL analysis would result in an opacity limit of 20 percent, far exceeding the proposed 5 percent level. Commenters noted that the EPA had improperly failed to account for variability in the performance of sources by declining to apply a UPL or other statistical analysis.

Response: After considering these comments, we agree that a limit of 5 percent opacity could result in higher cost impacts than we estimated at proposal for some facilities. As described in the proposed rule **Federal Register** notice published on July 31, 2023 (88 FR 49402), the proposed 5 percent opacity limit was a beyond-the-floor limit based on the EPA's understanding at that time that emissions could be cost effectively minimized from slag pits with the application of water spray or fogging and/or other work practices such as installing wind screens, dust suppression misters, and maintaining a high moisture content of the slag during handling, storage, and processing. However, at proposal we did not account for variability and certain other factors such as weather conditions and possible safety issues. Although we still conclude that these measures can help minimize emissions, these measures might not be sufficient to consistently maintain opacity below 5 percent.

In the proposed rule FR notice, we also described a potential MACT floor opacity limit of 9 percent for existing sources which was based on the straight average of the top five performing facilities. Based on the comments submitted, the EPA is finalizing an opacity limit of 10 percent based on a MACT floor analysis for existing sources. This final limit is based on the average opacity of 9 percent reported by the five top performing facilities, but rounding up slightly to 10 percent to account for variability. The EPA has historically used the UPL approach to develop MACT limits for stack emissions of individual pollutants, but has not historically determined opacity limits using a UPL approach. The UPL calculation introduces a predictive element to the statistics in order to account for variability. However, unlike typical emissions testing, EPA Method 9 tests frequently result in values of zero, which cannot be used in the UPL calculation so this approach for accounting for variability was not used. The EPA determined that rounding the opacity from 9 percent to 10 percent sufficiently accounts for variability in this process. Therefore, in this final rule we are promulgating a 10 percent opacity limit (based on six-minute averages) for slag processing, handling, and storage. Because this 10 percent opacity limit has been achieved in practice by top performing facilities, we expect that all facilities will be able to achieve this 10 percent opacity limit by application of some or all of the work practices described above and in the proposed rule **Federal Register** notice (88 FR 49402). Other comments and responses on this issue are provided in the RTC.

d. BF Bell Leaks

Comment: Commenters expressed concerns that the proposed triggers for action for large bells are too low and that the repair and replacement time should consider lead time and operational concerns. Commenters suggested that with this in mind, the EPA could establish a 20 percent opacity action level (6-minute average) with quarterly EPA Method 9 observation requirements. Under this approach, if a facility observes opacity in excess of 20 percent, the facility should be required to investigate, make operational changes, and conduct a repair, followed by repeat testing using EPA Method 9 to confirm the efficacy of the repair. If repairs are not successful, only then would replacement obligations be triggered. Other

commenters stated that if the EPA moves forward with work practice standards, the EPA should consider an alternative under which a facility would need to initiate operational or other corrective actions within five business days if an EPA Method 9 test identifies opacity of 20 percent or more. If the facility does not reduce opacity to less than 20 percent with those actions, the facility would have another five business days to initiate further operational or other corrective actions to reduce opacity to less than 20 percent. Only if the second attempt does not result in opacity of 20 percent or less would the test result be deemed a deviation requiring reporting and corrective actions, such as moving to the repair step or, if necessary, replacement of the large bell.

Response: We agree with the commenter who suggested the two-step approach for large bells is appropriate as well as the suggestion of 20% opacity instead of 10% opacity as a trigger. As discussed by the commenter, the replacement of bells is costly and there are numerous more cost-effective repair options available that can be achieved in a shorter time period to avoid full repair and replacement. This would help keep the bell repairs on a more organized schedule. Therefore, we decided to finalize a 20 percent opacity action level (instead of the proposed 10 percent opacity action level) and provide two five-business day periods to investigate the opacity trigger, as suggested by the commenter. Specifically, we changed the requirement to the following: if EPA Method 9 identifies opacity greater than 20 percent, the facility shall initiate corrective actions within five business days. If the first attempt to correct fails and EPA Method 9 again identifies that opacity is not reduced to 20 percent or lower, the facility would have another five business days to initiate further corrective actions to reduce opacity to 20 percent or lower. Only if the second attempt does not result in an opacity of 20 percent or less would it become a deviation, requiring reporting and corrective actions that we included in the proposed rule, such as moving to the repair step or, if unsuccessful, replacement of the large bell.

e. Beaching of Iron From BF's

Comment: Commenters supported the proposal to require facilities to: (1) have full or partial enclosures for the beaching process or use CO_2 to suppress fumes; and (2) minimize the height, slope, and speed of beaching. Commenters supported the addition of monitoring of vents from the partial enclosures to allow for additional information and accountability for these sources.

Response: EPA appreciates the support for the beaching requirements in the proposed rule.

Comment: Industry commenters stated that the proposed work practice standards to address already low emissions from beaching events, which the industry consistently works to minimize, would not provide meaningful reductions and would be extremely costly. Industry commenters estimated about 4 pounds per year of reduction from these proposed measures, lower than the estimates EPA provided in the final rule. Commenters also pointed out that EPA's estimated cost per ton of removal would be $15.8 million/ton and argued that this amount is unreasonable notwithstanding EPA's explanation that it must adhere to the floor provisions of the statute. Commenters stated that if EPA were to use the more accurate emissions and cost information provided by industry, the cost-effectiveness rate estimate based upon the proposed rule would be multiple times higher at $311 million/ton. Commenters also argued that EPA could reasonably interpret Section 112(d) to avoid this result.

Response: As EPA explained in the proposal preamble, as mandated by the *LEAN* court decision and CAA sections 112(d)(2), 112(d)(3), and 112(h), we proposed a MACT floor standard (which is the least stringent standard allowed by section 112 of the Clean Air Act) that would require facilities to: (1) have full or partial enclosures for the beaching process or use CO_2 to suppress fumes; and (2) minimize the height, slope, and speed of beaching. We expect this will result in a small amount of unquantified emission reductions since baseline emissions are already low (less than 1 tpy of HAP) and because most facilities are already following some or all of these work practices. Regarding costs, when EPA determines the MACT floor level of control, per the section 112 of the CAA, the EPA is obligated to determine the MACT floor level regardless of costs. It is only the potential beyond-the-floor standards for which costs become an important consideration. Nevertheless, as we mentioned in the proposal preamble, the estimated costs are only $55,000 per year for the entire category and an average annual cost of $6,800 per facility. More information regarding the standards for unregulated UFIP sources is available in the following document: *Unmeasurable Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is available in the docket for this action.

After considering public comments and available information, pursuant to CAA sections 112(d)(2) and (3) and 112(h) and the *LEAN* court decision, we are promulgating the same MACT Floor standard as proposed.

3. What are the final MACT standards and how will compliance be demonstrated?

a. BF Unplanned Bleeder Valve Openings

In certain instances, as provided in CAA section 112(h), if it is the judgment of the Administrator that it is not feasible to prescribe or enforce an emission standard under CAA section 112(d)(2) and (3), the EPA may set work practice standards under CAA section 112(h) in lieu of numerical emission standards. For BF unplanned bleeder valve openings, the Administrator has determined that since there is no direct measurement of emissions, we are finalizing a work practice standard. We are finalizing an operational limit for two subcategories of blast furnaces: large furnaces with a working volume of equal to or greater than 2,500 m^3; and small furnaces with a working volume of less than 2,500 m^3. This is to account for variability in unplanned opening occurrences between furnace size due to design elements that allow higher operating pressure near the valve openings, which leads to less openings per year for large furnaces. For the large blast furnaces, we are finalizing an operational limit of four unplanned openings per rolling year per furnace. For small blast furnaces, we are finalizing an operational limit of 15 unplanned openings per rolling year per furnace. Both are based on a qualitative approach of using the highest number of unplanned openings from the top five performing furnaces (top four for large furnaces as there are only four operating large furnaces). For most MACT floor standards in NESHAP rules, we typically have actual emissions test data for each of the top five sources. To calculate the MACT floor limit we use all the data (all the runs) from all 5 sources to calculate the 99th UPL to account for variability. And, we conclude that this 99th value (which is higher than the true average) represents the average performance of the top 5 sources with an adjustment to account for variability.

With unplanned openings, we do not have a UPL type tool. So, as an alternative to a UPL, we considered all the data from the top five performers,

and to ensure we account for variability among those top five performers, in this particular situation, we conclude that using the highest value (*i.e.,* highest number of unplanned openings) from any one source within the top five reflects our best estimate of an appropriate limit that would reflect performance of the top five sources with an adjustment to ensure we adequately account for the variability among those top five sources.

This approach is appropriate because it accounts for variability among the top five blast furnaces. For new sources, we are finalizing our proposed operational limit of zero unplanned openings per rolling year for both large and small furnaces because the best performing single source large and small blast furnace in our database reported zero unplanned openings for the most recent typical year.

Additionally, we are finalizing the work practice standards proposed for both furnace subcategories that require facilities to do the following: (1) install and operate devices (*e.g.,* stockline monitors) to continuously measure/monitor material levels in the furnace, at a minimum of three locations, using alarms to inform operators of static conditions that indicate a slip may occur, and alert them that there is a need to take action to prevent the slips and unplanned openings from occurring; (2) install and operate instruments such as a thermocouple and transducer on the furnace to monitor temperature and pressure to help determine when a slip may occur; (3) install a screen to remove fine particulates from raw materials to ensure only properly-sized raw materials are charged into the BF; and (4) develop, and submit to the EPA for approval, a plan that explains how the facility will implement these requirements. Additionally, facilities shall report the unplanned openings (including the date, time, duration, and any corrective actions taken) in their semiannual compliance reports.

b. BF Planned Bleeder Valve Openings

We are finalizing what we proposed for planned bleeder valve openings: a MACT floor limit of 8 percent opacity based on 6-minute averages. For new sources, we are finalizing an opacity of 0 percent. Facilities will have the flexibility to choose an appropriate approach to meet these opacity limits.

c. BF and BOPF Slag Processing, Handling, and Storage

As discussed above, we are finalizing an opacity limit of 10 percent based on 6-minute averages for BF and BOPF slag processing, handling, and storage, and slag pits. Regarding new sources, we are finalizing an opacity limit of 3 percent based on 6-minute averages for visible emissions from slag pits, and during slag handling, storage, and processing.

d. BF Bell Leaks

For bell leaks, we are finalizing a 20 percent opacity action level for large bell leaks as described below for new and existing large bells. This is not a numerical MACT emissions standard; because the Administrator has determined that it is not feasible to prescribe or enforce an emission standard in this instance, pursuant to CAA section 112(h), the EPA is setting work practice standards in lieu of numerical emission standards. We are also finalizing that the BF top must be observed monthly for visible emissions (VE) with EPA Method 22, 40 CFR part 60, appendix A–7, which determines the presence or absence of a visible plume, to identify leaks from the interbell relief valve (indicating leaks from the large bell). If VE are detected out of the interbell relief valve (indicating leaks from the large bell), the facility must perform EPA Method 9, 40 CFR part 60, appendix A–4, tests which determines the opacity (*i.e.,* degree to which a plume obscures the background) monthly, and if opacity is greater than 20 percent based on an average of three instantaneous and consecutive interbell relief valve openings, the facility must initiate operational or other corrective actions within five business days. After those five business days, the facility must perform EPA Method 9 tests again and, if opacity is greater than 20 percent, the facility will have another five business days to initiate further operational or corrective actions to reduce opacity to 20 percent or lower. After five additional business days (10 business days in total), the facility must perform EPA Method 9 tests again and, if opacity is still greater than 20 percent, the large bell seals must be repaired or replaced within four months. For the new and existing small bells, we are finalizing what we proposed, a requirement that facilities shall replace or repair seals prior to a metal throughput limit, specified by the facility, that has been proven and documented to produce no opacity from the small bells. Additionally, the facility must conduct monthly visible emissions testing for 15 minutes and amend the metal throughput limit in their operation and maintenance (O&M) plan as needed.

e. Beaching of Iron From BFs

As provided in CAA section 112(h), it is the judgment of the Administrator that it is not feasible to prescribe or enforce an emission standard for emissions from the beaching process, therefore the EPA is finalizing the proposed work practice standards in lieu of numerical emission standards. This work practice standard requires facilities to: (1) have full or partial enclosures for the beaching process or use CO_2 to suppress fumes; and (2) minimize the height, slope, and speed of beaching. This standard applies to both existing and new sources.

B. Reconsideration of BF Casthouse and BOPF Shop Standards for Currently Regulated Fugitive Sources Under CAA Section 112(d)(6) Technology Review

1. What did we propose for the BF casthouse and BOPF shop?

a. BF Casthouse

We proposed a 5 percent opacity limit based on 6-minute averages as an update to the CAA section 112(d)(6) technology review and proposed that facilities will need to measure opacity during the tapping operations (at least two times per month). We did not propose specific work practices for the BF casthouse, except that we proposed that the facilities will need to keep all openings, except roof monitors, closed during tapping and material transfer events (the only openings allowed during these events are those that were present in the original design of the casthouse).

b. BOPF Shop

Based on our review and analyses of the CAA section 114 information request responses we received in 2022 and 2023, and further review of the data the EPA assembled to support the 2020 RTR, we proposed that a standard composed of a 5 percent opacity limit with several specific work practices would be feasible and cost-effective for the BOPF shop. For example, based on the data we received, in the proposal we found that the maximum 3-minute opacity readings for the BOPF shops at four facilities were less than 5 percent. Furthermore, the use of work practices (described below) by the best performing facilities in the industry led us to conclude for the proposal that these work practices were feasible and, accordingly, we proposed a 5 percent opacity limit based on 3-minute average and work practices.

Specifically, we proposed that facilities will need to do the following: (1) keep all openings, except roof monitors (vents) and other openings that

are part of the designed ventilation of the facility, closed during tapping and material transfer events (the only openings that would be allowed during these events are the roof vents and other openings or vents that are part of the designed ventilation of the facility) to allow for more representative opacity observations from a single opening; (2) have operators conduct regular inspections of BOPF shop structure for unintended openings and leaks; (3) optimize positioning of hot metal ladles with respect to hood face and furnace mouth; (4) monitor opacity twice per month from all openings, or from the one opening known to have the highest opacity, for a full steel cycle, which must include a tapping event; and (5) develop and operate according to an Operating Plan to minimize fugitives and detect openings and leaks. We proposed that the BOPF Shop Operating Plan shall include:

- An explanation regarding how the facility will address and implement the four specific work practices listed above;
- A maximum hot iron pour/charge rate (pounds/second) for the first 20 seconds of hot metal charge (*i.e.,* the process of adding hot iron from the BF into the basic oxygen process furnace);
- A description of operational conditions of the furnace and secondary emission capture system that must be met prior to hot metal charge, including:
- A minimum flowrate of the secondary emission capture system during hot metal charge;
- A minimum number of times, but at least once, the furnace should be rocked between scrap charge and hot metal charge;
- A maximum furnace tilt angle during hot metal charging: and;
- An outline of procedures to attempt to reduce slopping.

2. What comments did we receive on the proposed revised BF casthouse and BOPF shop standards, and what are our responses?

a. BF Casthouse

Comment: Commenters noted that the EPA did not apply UPL calculations to the opacity data, even though the EPA's practice has been to do so for other numerical standards established on limited data sets. Commenters claim that the EPA's proposed opacity limit of 5 percent, without any adjustment for variability, lacked justification or explanation and is therefore arbitrary and capricious. These commenters argued that, when utilizing limited datasets, it is appropriate for the EPA to account for variability, and there is no technical basis for suggesting that some statistical methods should not be applied to this data set. When the EPA set the 20 percent opacity limits in 2003, the preamble included the EPA's statistical basis supporting that the limits were achievable. Commenters also stated the EPA should also include a one-time alternative limit per furnace cycle similar to the new source standards in the 2003 NESHAP.

Response: The EPA disagrees with the specific approach of using UPL calculations to develop opacity limits in the same manner that the UPL is used to calculate emissions limits. The EPA has historically used the UPL approach to develop MACT limits for stack emissions of individual pollutants but has not historically determined opacity limits using a UPL approach. The UPL calculation introduces a predictive element to the statistics in order to account for variability. However, as noted by the commenter, unlike typical emissions testing, EPA Method 9 may result in values of zero, which cannot be used in the UPL calculation. While the EPA has used the UPL approach for floor determinations when setting MACT emissions limits, the proposed changes to the BOPF Shop and BF casthouse opacity standards were based on a proposed updating of the CAA section 112(d)(6) technology review. Additionally, in the case of opacity measured according to EPA Method 9, the data EPA reviewed to develop the proposed standards were the maximum 6-minute (or 3-minute as applicable) averages evaluated over the entire test period. Likewise, compliance determinations are also based on the same approach. Utilizing the maximum short-term average during each test period to determine an appropriate standard, and to determine compliance, inherently accounts for some variation in the data used to set the standard.

However, with regard to the comments on variability, we acknowledge that there are many opacity readings that occurred over the past 2 to 6 years at the Integrated Iron and Steel (II&S) manufacturing facilities that show that there is a substantial amount of variability in opacity measurements across time and across furnaces. For example, many opacity tests for BOPF and BF furnace cycles that were completed over these 2–6 years reported maximum 3-minute and 6-minute opacity readings below 5 percent for a substantial amount of the cycles. In fact, for many furnace cycles the maximum opacity was 0 percent. On the other hand, the data show that during some BOPF or BF cycles, opacity is above 5 percent and sometimes well above 20 percent. The EPA has additionally continued to receive opacity data and analyses since the close of the public comment period on this rulemaking.

The EPA was not able to adequately analyze all the available data before the deadline for this final rule ordered by the court in *California Communities Against Toxics.* Also, for most of the opacity tests that had maximum opacity readings above 5 and 10 percent, the EPA does not have any information that explains why the opacity readings were higher than 5 percent on those particular days. In most cases, the EPA is unable to determine the cause of the higher values based on the data and information currently available. Until further revision, the opacity limits in the NESHAP for existing BOPF Shops and existing BF casthouses will remain at 20 percent based on 3-minute averages for the BOPF Shop and 6-minute averages for the BF casthouse.

The opacity data and further explanation of the opacity data and related information can be found in the technical memo titled: *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is in docket for this final rule.

b. BOPF Shop

Comment: Some commenters conducted their own assessment of what measures would be needed to comply with the proposed opacity limit and work practice standards, which is of course facility-specific, because every BOPF shop is unique. Based on their assessments, these commenters asserted that each BOPF shop—after applying all ''required'' work practice standards and even other work practices that the EPA suggested—would likely need to install full-shop controls to meet a 5 percent opacity limit at all times. The commenters represented that the cost to apply this type of control would be high and would involve the addition of at least one large fabric filter device to properly capture fugitive emissions and allow for proper ventilation for the building. The commenters asked EPA to take into account the significant changes BOPF shops would have to make to meet a 5 percent opacity standard that even the best performers cannot currently achieve on a regular basis. They suggested that because of the exorbitantly and unreasonably expensive measures that would need to be undertaken by this industry sector, and the significant possibility that even facilities installing such measures would not be able to consistently meet

the 5 percent opacity standard, the EPA should not move forward with the proposed opacity limit, at least until the Agency undertakes a robust engineering analysis to determine the technical and economic feasibility of controls that would be needed for BOPF shops to meet this lower standard.

Response: After considering public comments, the EPA now recognizes some operations may need to make more significant changes than we anticipated at proposal to meet the 5 percent opacity standard at all times. We acknowledge that there are many opacity readings that occurred over the past 2 to 6 years that indicate that there is a substantial amount of variability across time and across furnaces. For example, many opacity tests for BOPF cycles (*i.e.,* steel cycles) that were completed over these 2–6 years reported maximum 3-minute opacity readings below 5 percent for a substantial amount of the cycles. On the other hand, the data show that during some BOPF cycles, opacity is above 5 percent and sometimes above 20 percent.

The EPA was not able to adequately analyze all the available data before the court-ordered deadline for this final rule. Also, for those tests that had maximum opacity readings above 10 or 20 percent, in most cases, the EPA does not have any information that explains why the opacity readings were high on those particular days. In most cases, the EPA is unable to determine the cause of the higher values based on the data and information we have. Therefore, the EPA is not finalizing any changes to the opacity limits for the BOPF Shop in this final action. Instead, the EPA intends to continue reviewing and analyzing the opacity data from both the BF casthouse and the BOPF shop that we have and also collect additional data in the near future so that the EPA can gain a better understanding of the achievability of various opacity levels and the reasons why opacity levels are sometimes elevated. After EPA completes this additional data gathering and analyses, the EPA intends to consider potential revisions to the opacity limits in a separate future action. Until further revision, the opacity limit in the NESHAP for BOPF Shops will remain at 20 percent based on 3-minute averages, and the opacity limit in the NESHAP for BF casthouses will remain at 20 percent based on 6-minute averages, consistent with the current regulation.

The EPA is still finalizing opacity testing requirements for BF casthouse and BOPF shop fugitives as well as the proposed work practice standards for BOPF shop fugitives which are expected to reduce HAP emissions by 25 tpy. This accounts for 39% of the estimated emission reductions from UFIP sources with this promulgation.

Comment: One commenter stated that the EPA's reliance on the limited 2022 CAA section 114 testing results to determine that a 5 percent opacity standard would be achievable by BOPF shops for relatively modest capital and annual operating costs was inappropriate and has led the EPA to propose a standard that is technically and economically infeasible to meet. In an appendix to their comments, the commenters put forward alternative emission factors and cost estimates that, in their view, indicate the proposed standards would cost $88 million per ton to reduce just 2.6 tpy of HAP emissions industrywide. This conclusion is very different from the EPA's own analysis of its proposed rule, which was based on an assumption that no capital expenditures would be needed, and that for less than $500,000 per year industry-wide, all 11 existing BOPF shops should be able to meet a 5 percent opacity standard and comply with the numerous proposed work practice standards. Commenters also said that BOPF shops would not be able to meet a 5 percent opacity standard based on 3-minute averages from every opening at all times without significant capital expenditures, and remain concerned that even with this level of spending, there may be times when the shops would not be able to meet that standard. Commenters stated that until the EPA can demonstrate through a robust engineering study that the proposed opacity limit would be achievable at a certain spending level and with certain technology in place that is reasonable and cost-effective, the EPA should not move forward to finalize the proposed standards.

Response: As stated in previous responses to comments in this preamble, the EPA is not finalizing any changes to the opacity limits for the BOPF Shop in this final action. See previous responses to comments in this preamble for further explanation.

Comment: Commenters stated that because the proposal establishing an absolute 5 percent limit did not take into account the range of operations or impacts resulting in variability, it is clear that some periods of operation above 5 percent opacity will occur even with proper operation. They believe that any proposal that includes an opacity standard lower than 20 percent must provide that compliance is achieved provided there are no more than a set number of excursions above the revised limit in order to capture normal fluctuation events that occur during normal operation. Specifically, the EPA should follow the form of the current ''new source'' BOPF shop MACT opacity standard: maintain the opacity (for any set of 6-minute averages) of secondary emissions that exit any opening in the BOPF shop or other building housing a BOPF or shop operation at or below 15 percent, except that 6-minute averages greater than 15 percent but no more than 20 percent may occur twice per steel production cycle. A steel production cycle is defined in 40 CFR 63.7822.

Response: As stated in previous responses to comments in this preamble, the EPA is not finalizing any changes to the opacity limits for the BOPF Shop in this final action. The opacity limit for existing BOPF Shops will remain at 20 percent based on 3-minute averages. See previous responses to comments in this preamble for further explanation.

3. What are the revised standards for the BF casthouse and BOPF shop standards and how will compliance be demonstrated?

a. BF Casthouse

As stated in previous responses to comments in this preamble, the EPA is not finalizing any changes to the opacity limits for the BF casthouse in this final action. Facilities will need to comply with the 20 percent opacity limits that are already in the NESHAP. However, the EPA is requiring more frequent Method 9 tests as explained elsewhere in this preamble. See previous responses to comments in this preamble for further explanation.

b. BOPF Shop

For the reasons discussed in the responses to comments above, we are finalizing work practice standards for the BOPF. Specifically, in this final rule, we are requiring facilities to do the following: (1) keep all openings, except roof monitors (vents) and other openings that are part of the designed ventilation of the facility, closed during tapping and material transfer events (the only openings allowed during these events are the roof vents and other openings or vents that are part of the designed ventilation of the facility) to allow for more representative opacity observations from a single opening; (2) have operators conduct regular inspections of BOPF shop structure for unintended openings and leaks; (3) optimize positioning of hot metal ladles with respect to hood face and furnace mouth; (4) monitor opacity twice per month from all openings, or from the one opening known to have the highest

opacity, for a full steel cycle, which must include a tapping event; and (5) develop and operate according to an Operating Plan to minimize fugitives and detect openings and leaks.

The purpose of the Operating Plan is to address variability in unit design and operations by creating an individualized strategy for implementing work practice standards at each source. Owners and operators can develop specific work practices that make sense for each unit and that maximize emission reduction efficiency for each unit. We require that the BOPF Shop Operating Plan include:

- An explanation regarding how the facility will address and implement the four specific work practices listed above;
- A maximum hot iron pour/charge rate (pounds/second) for the first 20 seconds of hot metal charge (*i.e.,* the process of adding hot iron from the BF into the basic oxygen process furnace);
- A description of operational conditions of the furnace and secondary emission capture system that must be met prior to hot metal charge, including:
- A minimum flowrate of the secondary emission capture system during hot metal charge;
- A minimum number of times, but at least once, the furnace should be rocked between scrap charge and hot metal charge;
- A maximum furnace tilt angle during hot metal charging: and;
- An outline of procedures to attempt to reduce slopping.

The BOPF shop work practice standards and Operating Plan are expected to result in the same HAP emission reductions as the Proposed Rule at 25 tpy. This accounts for 39% of the estimated emission reductions from UFIP sources with this promulgation.

C. What are the decisions for fenceline monitoring?

1. What did we propose for fenceline monitoring?

Pursuant to CAA section 112(d)(6), we proposed adding fenceline monitoring for chromium. Fenceline monitoring refers to the placement of monitors along the perimeter of a facility to measure pollutant concentrations. Coupled with requirements for root cause analysis and corrective action upon triggering an actionable level, this work practice standard is a development in practices considered under CAA section 112(d)(6) for the purposes of managing fugitive emissions. The measurement of these pollutant concentrations and comparison to concentrations estimated from mass emissions via dispersion modeling can be used to ground-truth emission estimates from a facility's emissions inventory. If concentrations at the fenceline are greater than expected, the likely cause is that there are underreported or unknown emission sources affecting the monitors. In addition to the direct indication that emissions may be higher than inventories would suggest, fenceline monitoring provides information on the location of potential emissions sources. Further, when used with a mitigation strategy, such as root cause analysis and corrective action upon exceedance of an action level, fenceline monitoring can be effective in reducing emissions and reducing the uncertainty associated with emissions estimation and characterization. Finally, public reporting of fenceline monitoring data provides public transparency and greater visibility, leading to more focus and effort in reducing emissions.

Specifically, we proposed that facilities must install four ambient air monitors at or near the fenceline at appropriate locations around the perimeter of the facility, regardless of facility size, based on a site-specific plan approved by the EPA to collect and analyze samples for total chromium every sixth day. In addition, we proposed that facilities must implement the following work practice requirement: if an installed fenceline monitor has a 12-month rolling average delta c concentration—calculated as the annual average of the highest sample value for a given sample period minus the lowest sample value measured during that sample period—above the proposed action level of 0.1 μg/m^3 for total chromium, the facility must conduct a root cause analysis and take corrective action to prevent additional exceedances. Data would be reported electronically to the EPA's Compliance and Emissions Data Reporting Interface (CEDRI) on a quarterly basis and subsequently available to the public via the Web Factor Information Retrieval system (WebFIRE) website. Furthermore, we proposed a sunset provision whereby if the annual average delta c remain 50-percent or more below the action level (*i.e.,* 0.05 μg/m^3 or lower) for a 24-month period, then the facility can request to terminate the fenceline monitoring. Termination of the fenceline monitoring in no way impacts the requirement for facilities to meet all other obligations under this subpart including the general duty to minimize emissions of 40 CFR 63.7810(d).

Because a method has not yet been proposed or promulgated for fenceline monitoring of metals, we proposed that fenceline monitoring would begin no later than one year after the EPA's promulgation of a fenceline test method, or two years after the promulgation of the final rule, whichever is later. The EPA is working as expeditiously as possible to propose a new metals fenceline method. As part of the prior CAA section 114 information collection effort, we relied on a common ambient monitoring method [2] for the collection of the metals samples and associated analytical method [3] for multi-metals for the analysis. While these methods are robust and appropriate for ambient trends applications, EPA needs to further investigate and revise these approaches for a stationary source regulatory program to ensure improved precision and accuracy in the method, in the same manner EPA developed Method 327 [4] from TO–15 in the recent Synthetic Organic Chemical Manufacturing Industry: Organic National Emission Standards for Hazardous Air Pollutants (NESHAP)—40 CFR 63 Subparts F,G,H,I proposed rule, published on April 25, 2023 (88 FR 25080). The required determinations of whether the action level has been exceeded and any subsequent root cause investigation will begin once the first annual rolling average is acquired.

2. What comments did we receive on the monitoring requirements, and what are our responses?

Comment: Commenters stated that the proposed focus on chromium as a ''surrogate'' and the proposal to set an action level for only chromium is demonstrably inadequate. Emission standards under CAA section 112(d) must be ''comprehensive controls for each source category that must include limits on each hazardous air pollutant the category emits.'' (*LEAN,* 955 F.3d at 1095–96.) As identified in several background documents for this proposed rule, air pollutants from various facility processes include multiple toxic metals in addition to chromium including arsenic, mercury, and lead; toxic halogenated compounds including carbonyl sulfide, carbon disulfide, hydrogen chloride, hydrogen fluoride, D/F; and other toxic pollutants such as hydrocarbons and PM. The CAA requires ''as many limits as needed to control all the emitted air toxics of a

[2] Reference Method for the Determination of Suspended Particulates in the Atmosphere (High Volume Method), 40 CFR 50, Appendix B.

[3] Method IO–3, Determination of Metals in Ambient Particulate Matter Using Inductively Coupled Plasma (ICP) Spectroscopy.

[4] **Federal Register** Notice published on April 25, 2023 (88 FR 25080).

particular source category.'' (*Id.* at 1097.) Commenters stated that the 2023 Proposal is unlawful on its face for only requiring monitoring and action level standards for chromium.

Response: The EPA disagrees that conducting fenceline monitoring for only chromium is inadequate or unlawful. The EPA recognizes there are multiple toxic metals emitted by various facility processes from the iron and steel facilities. We reiterate that we did not intend to measure all pollutants, especially pollutants that are emitted from point sources that are directly measurable through source tests and continuous monitoring systems. These emissions sources and pollutants are subject to other standards under these MACT. We disagree that it is necessary to conduct fenceline monitoring for every HAP emitted from fugitive emission sources at integrated iron and steel facilities. Integrated iron and steel emissions can contain many different HAP and it is very difficult for any fenceline method to detect every HAP potentially emitted from integrated iron and steel facilities. The fenceline monitoring standard was proposed as part of the CAA section 112(d)(6) technology review to improve management of fugitive emissions of metal HAPs and not as a risk reduction measure. In order to meet that goal of improved management of fugitive emissions, it is not necessary to obtain an accurate picture of the level of all HAP emitted. We chose to propose fenceline measurements only for chromium because it was a risk driver in the 2020 RTR analyses and has been determined to be a good surrogate for other HAP metals, especially arsenic, which was the other HAP metal driving the risks in the 2020 RTR risk analyses. Additionally, at the fenceline, based on fenceline monitoring conducted in 2022–23 at Integrated Iron and Steel facilities in response to the section 114 request, the highest monitored lead levels were found to be 5 times lower than the current air quality health NAAQS value (last issued in 2015 to provide an ''adequate margin of safety to protect public health''). However, based on a lack of information on fugitive lead and other metal HAP emissions, the EPA does agree with this commenter that there is a need for more data gathering, both at the fenceline and from other sources on the facilities. EPA did not propose nor are we prepared to promulgate a requirement to monitor any metals other than chromium as part of the fenceline requirement, but we intend to gather more fenceline monitoring data for lead in 2024 at Integrated Iron and Steel facilities to better characterize fugitive lead emissions. Additionally, we intend to gather more data regarding HAP metals from sinter plant stacks through the use of PM continuous monitoring systems (PM CEMs). We intend to collect this data in a separate action under CAA section 114 that will follow this final rule.

Comment: Commenters stated that the EPA should require monitoring and set action level standards for all HAP metals emitted by II&S facilities. These commenters asserted that the incremental cost to monitor for all metals is insignificant and would have outsized benefits to the community by establishing multiple triggers for assessment and corrective action. As an alternative to required fenceline monitoring for all HAP metals, commenters stated the EPA should consider implementing a fenceline standard for lead because most communities surrounding II&S facilities are EJ communities exposed to lead from multiple sources. Commenters also specifically supported a fenceline monitoring requirement for arsenic.

Response: The EPA observes that it is technically feasible to require further speciation of metal HAPs collected within a single sample. Although increasing the analyte list does increase the analytical costs because additional calibration standards are required, the EPA agrees with commenters that the costs to monitor for additional metals would be relatively low. However, the incremental cost of monitoring for additional HAPs is not the only consideration in determining the scope of a fenceline monitoring requirement for this source category. The EPA must also consider the efficacy of instituting a fenceline monitoring requirement for additional HAPs, as well as practical implementation concerns. At this time, the EPA believes these factors weigh in favor of requiring fenceline monitoring for chromium while continuing to gather information on other metal HAPs.

As discussed above, the EPA previously determined in the 2020 RTR that chromium is one of the two principal drivers of health risk in this source category and is also an effective surrogate for arsenic, which is the other most significant contributor to risk. Because the principal purpose of fenceline monitoring in this source category is to assure compliance with the emission standards that address fugitive emissions of particulate HAP metals, implementing this development will provide ''necessary'' protection against fugitive emissions of metal HAPs (including those that pose greatest risks to public health). Fenceline monitoring is a development in practices, for the purpose of managing fugitive emissions. In sum, fenceline monitors will be placed at or near the perimeter of the applicable facility to measure pollutant concentrations; this measurement is coupled with the requirement to conduct applicable root cause analyses and implement corrective action upon triggering an actionable level. The utilization of fenceline monitors will serve to manage fugitive emissions with the intent to reduce emissions, as well as to reduce uncertainty associated with initial emissions estimation. The use of fenceline monitors, coupled with action levels, represents a development in work practices. Therefore, focusing fenceline monitoring requirements on chromium is appropriate as a development pursuant to CAA section 112(d)(6). Requiring fenceline monitoring for chromium alone also facilitates establishing an appropriate action level, reduces analytical costs, and simplifies the determination of compliance for integrated iron and steel owners and operators.

By contrast, including additional metal HAPs in the fenceline monitoring program would require the EPA to resolve a number of technical issues, including how an action level for additional HAPs would be set, and whether each metal HAP would have its own action level or instead a single action level for the sum of metal HAP measured. The EPA was not able to develop the information needed to address these issues within the timeframe for this rulemaking. Given that the available information indicates that HAP metals emitted from the integrated iron and steel facilities other than chromium and arsenic do not contribute to significant ambient concentrations at or near the facility boundaries (*e.g.,* fenceline) at these facilities, we have determined that at present the benefits of including other metal HAPs in the scope of the fenceline monitoring requirement are also unclear.

Although we did not propose nor are we prepared to promulgate a fenceline monitoring requirement for any metals other than chromium at this time, the EPA recognizes that further information on fugitive emissions of lead and other HAP metals would be useful in informing whether and how a fenceline monitoring requirement for additional HAP metals as part of a future rulemaking. Accordingly, we intend to gather more data to better characterize fugitive lead and other HAP metals through a separate action that will

follow this final rule as described in the previous response in this preamble.

Comment: Commenters stated that the EPA should not set an action level that would be triggered if the UFIP sources were meeting all of the proposed opacity limits and work practice standards, which is the EPA's stated purpose for establishing the fenceline monitoring program. Because the EPA did not consider or analyze whether II&S facilities could maintain UFIP emissions at rates to ensure that the action level would not be triggered or how much it would cost to maintain emissions below the action level, the EPA should not entertain these lower values of 0.08 and 0.09 μg/m³. Commenters stated that for the EPA to do so would be arbitrary and capricious per se.

Response: The EPA acknowledges the support and is finalizing the action level at 0.1 μg/m³ as proposed.

Comment: Commenters stated that regardless of the numeric value selected for the action level, the EPA should express the chromium action level in μg/m³ to at least two decimal places and clarify that rounding occurs to the second decimal place (*e.g.,* 0.11 μg/m³ would not round down to 0.10 μg/m³ and would therefore exceed the action level). The EPA states that ''[b]ecause of the variability and limitations in the data, to establish the proposed action level we rounded[. . .]to one significant figure (*i.e.,* 0.1 μg/m³).'' Commenters stated that there are two issues with this statement: (1) significant figures do not completely characterize numerical precision, and (2) reporting chromium concentrations in μg/m³ to one decimal place does not reflect the precision of modern sampling and analytical techniques. Commenters stated that in response to the first point, consider two hypothetical reported chromium concentrations: 0.1 μg/m³ and 0.01 μg/m³. Both have only one significant digit, but the second concentration is reported with a greater level of precision. As for the second point, Table 1 in EPA Compendium Method IO–3.5, which was the analytical method used to determine fenceline chromium concentrations as part of the EPA's CAA section 114 ICR, lists the estimated method detection limit for chromium as 0.01 ng/m³ (0.00001 μg/m³). This low method detection limit demonstrates the sensitivity and precision of modern sampling and analytical methods. As such, chromium concentrations measured with these methods should be reported to at least two decimal places (assuming units of μg/m³).

Response: The EPA disagrees with the commenter that more than one decimal place should be used for the action level and further disagrees with their definition of precision. Measurement precision relates to the degree of variation in repeated measurements, and not what decimal place a reading is. In the example proposed, 0.1 μg/m³ and 0.01 μg/m³, these are merely two values of differing magnitude, and not two values of different precision.

The EPA also disagrees that the detection limit of EPA Compendium Method IO–3.5 has meaning in this context. The detection limit is the lowest level at which a valid measurement can be collected, beyond indicating that, in this case, the measured values are within the measurable range, it has no practical impact upon the number of significant digits appropriate.

While the analytical techniques may be able to determine the concentration out to more than one significant figure, the setting of the action level is based not just upon the measurement itself, but upon projected gains under the newly required limits on UFIP and the calculation of delta c, further complicating the determination of an appropriate action level. The EPA is finalizing the action level at one significant figure as proposed.

Comment: Commenters stated that even if the EPA can sufficiently explain why an action level was set for chromium for II&S facilities based on fenceline monitoring, the EPA should set the action level below 0.1 μg/m³ because fenceline data collected as part of EPA's CAA section 114 collection request shows that a lower action level is achievable. Because the EPA did not request that all eight II&S facilities perform fenceline monitoring pursuant to the CAA section 114 request, the EPA did not identify the top five best performing facilities. However, two of the four facilities that conducted fenceline monitoring (Cleveland Works and Burns Harbor) had 6-month chromium delta c averages below 0.08 μg/m³, and a third facility (Granite City) is projected to be at 0.09 μg/m³ after implementing provisions of the rulemaking. The EPA has failed to explain why they are requiring an action level that constitutes the lowest number (0.1 μg/m³) instead of the level that three of the four facilities that conducted fenceline monitoring are able to meet (0.10 μg/m³). Accordingly, the EPA should set the action level below 0.1 μg/m³.

Response: Consistent with refineries and all other proposed fenceline monitoring standards, we are implementing the action level as a single significant digit as discussed further in the response to the previous comment of this section.

3. What are the revised standards for the fenceline monitoring requirements and how will compliance be demonstrated?

We are finalizing what we proposed: facilities must install four ambient air monitors at or near the fenceline at appropriate locations around the perimeter of the facility based on a site-specific plan that must be submitted to and approved by the EPA, regardless of facility size. These monitors shall collect and analyze samples for total chromium every sixth day. The facilities must also implement the following work practice requirement: if an installed fenceline monitor has a 12-month rolling average delta c concentration that is above the action level of 0.1 μg/m³ for total chromium, calculated as the annual average of the delta c determined during each sample period over the year (highest sample value for a given sample period minus the lowest sample value measured during that sample period), the facility must conduct a root cause analysis and take corrective action to prevent additional exceedances.

A facility may request to terminate fenceline monitoring after 24 months of consecutive results 50 percent or more below the action level. The EPA selected the monitoring locations and sampling frequency as specified to maintain the same basis of monitoring as that used in the derivation of the action level as discussed in the preamble to the proposed rule (88 FR 49414). The use of four monitors was selected and not expanded to the same number of monitoring sites as EPA Method 325A because, unlike EPA Method 325A that uses passive samplers, the methodology used for both the CAA section 114 request and the potential candidate method for this rule requires power at each sampling location, dramatically increasing the potential cost of each monitoring site. The sampling frequency of every six days was selected to both mimic that of the CAA section 114 request as well as to ensure operations on each day of the week would be represented in the calculation of the annual average delta c. Data will be reported electronically to CEDRI on a quarterly basis and subsequently available to the public via the WebFIRE website.

In response to many comments regarding fugitive emissions of lead and other metals, we recognize the need to gather more data to characterize these fugitive emissions at the fenceline and sinter plants. We intend to take a separate action on this data collection

for lead and potentially other metals action under CAA section 114.

D. Standards To Address Unregulated Point Sources for Both New and Existing Sources

1. What standards did we propose to address unregulated point sources?

In addition to the unregulated UFIP sources, we identified five unregulated HAP from sinter plant point sources (CS_2, COS, HCl, HF, and Hg); three unregulated HAP from BF stove and BOPF point sources (D/F, HCl and THC (as a surrogate for organic HAP other than D/F)); and two unregulated HAP from BF point sources (HCl and THC (as a surrogate for organic HAP other than D/F). The proposed MACT emission limits for these unregulated point sources are in Table 3.

TABLE 3—ESTIMATED HAP EMISSIONS AND PROPOSED MACT LIMITS FOR POINT SOURCES

Process	HAP	Estimated source category emissions	Proposed MACT limit
Sinter Plants	CS_2	42 tpy	Existing and new sources: 0.028 lb/ton sinter.
Sinter Plants	COS	57 tpy	Existing sources: 0.064 lb/ton sinter. New sources: 0.030 lb/ton sinter.
Sinter Plants	HCl	11 tpy	Existing sources: 0.025 lb/ton sinter. New sources: 0.0012 lb/ton sinter.
Sinter Plants	HF	1.2 tpy	Existing and new sources: 0.0011 lb/ton sinter.
Sinter Plants	Hg	66 pounds/yr	Existing sources: 3.5e–5 lb/ton sinter. New sources: 1.2e–5 lb/ton sinter.
BF casthouse control devices.	HCl	1.4 tpy	Existing sources: 0.0013 lb/ton iron. New sources: 5.9e–4 lb/ton iron.
BF casthouse control devices.	THC	270 tpy	Existing sources: 0.092 lb/ton iron. New sources: 0.035 lb/ton iron.
BOPF	D/F (TEQ [1])	3.6 grams/yr	Existing and new sources: 4.7e–8 lb/ton steel.
BOPF	HCl	200 tpy	Existing sources: 0.078 lb/ton steel. New sources: 1.9e–4 lb/ton steel.
BOPF	THC	13 tpy	Existing sources: 0.04 lb/ton steel. New sources: 0.0017 lb/ton steel.
BF Stove	D/F (TEQ)	0.076 grams/year	Existing and new sources: 3.8e–10 lb/ton iron.
BF Stove	HCl	4.5 tpy	Existing sources: 5.2e–4 lb/ton iron. New sources: 1.4e–4 lb/ton iron.
BF Stove	THC	200 tpy	Existing sources: 0.1 lb/ton iron. New sources: 0.0011 lb/ton iron.

[1] Toxic equivalency.

2. What comments did we receive on the unregulated point sources, and what are our responses?

Comment: Commenters state that they submitted additional stack tests in Appendix L that cover the EPA's proposed MACT standards for BF Stoves, BF Casthouses, and BOPF Primary Control Devices. These commenters do not represent that the additional data submitted in Appendix L alone or in combination with data underlying the EPA's proposed standards capture the full range of operating conditions for these point sources; however, they believe these additional data further indicate that the EPA's limited datasets do not sufficiently account for variability and, therefore, are not representative of best performing units in this source category. The same commenters state that the EPA's 15 proposed HAP limits for new sources rely on insufficient data and are unlikely to be technologically feasible. They are also concerned that any new sources would also not be able to meet the emission rates of the best performers given the lack of sufficient data underlying the EPA's proposed new source limits for the 15 HAPs that inherently do not capture process, operational, raw material, or seasonal and measurement variability of the EPA-designated best performing source. Achievability of the new source proposed limits is a concern because it is also unlikely that it would be technologically feasible for pollution control equipment to guarantee any degree of control of such low or dilute concentrations of D/F, PAHs, COS, CS_2, Hg, THC, HF, and HCl, which fall below the lowest target concentrations and capture limitations of such equipment. Further, the sources of raw materials and their impact on emissions variability cannot be reasonably predicted.

Response: The EPA has considered these additional data and, where deemed valid, incorporated the data into updated UPL calculations for the point sources and HAPs. The promulgated limits are based on MACT floor calculations (UPL) using the available valid data, which represents our best estimate of current average performance, accounting for variability (*i.e.,* UPL calculations), of the sources for which we have valid data (for affected sources). Additionally, based on industry comments, we: (1) used surrogate limits for some HAP; (2) changed the format of some limits; and (3) established work practices for HAP where majority of data were below detection.

Furthermore, based on the limited data we have, we estimate that all facilities will be able to meet these limits without the need for new add-on control devices (*e.g.,* we have no data indicating a source cannot currently comply with these limits). Nevertheless, we acknowledge that there are uncertainties because of the limited data. However, pursuant to section 112 of the CAA and the LEAN court decision, we must promulgate MACT emissions limits based on available data in order to fulfill our court ordered CAA section 112(d)(6) obligations.

Comment: Commenters stated that if EPA nonetheless proceeds with BF Stove limits, the form must be revised to lb/MMBtu, and that EPA erroneously used iron, rather than steel, production rates. The commenter said the agency should use contemporaneous iron production rates instead, which were provided on May 25, 2023. Notwithstanding these errors, emission limits for combustion units including BF stoves would be most appropriately expressed as lb/MMBtu, as although stove and blast furnace operations are interrelated, there are significant site specific differences in operation which make blast furnace production inappropriate to use when developing a limit for BF stoves. Lb/MMBtu would be more appropriate because the emissions per amount of heat released is more directly related to total quantity of emissions generated. Further, gas flow can be directly measured to account for varying BF stove operation. Iron production is intermittent with tapping and plugging of the furnace, so using emissions per ton could produce misleading results and should not be used.

Response: The EPA agrees that BF stove emission limits in the units of lb/MMBtu would be more appropriate than

unis of lb/ton. We have recalculated UPLs for BF stove emissions in the units of lb/MMBtu and are finalizing MACT floor limits for HCl and THC emissions from BF stoves in the units of lb/MMBtu. No additional costs are expected to meet these limits.

Comment: Commentors stated that the EPA should not finalize its proposed D/F limit for BF Stoves because D/F is not present, or, if present, is only in trace amounts. The EPA estimates that the 17 BF Stoves in the source category collectively emit 0.076 grams per year of D/F. Commentors said that basing the proposed D/F limit on only two tests, with a total of only 6 data points (5 of which are BDL) is not permissible. If the EPA nevertheless pursues D/F limits for BF Stoves, the EPA should review and revise the limits to ones that are representative of the emissions limitations being achieved by the best performers. The EPA should consider work practices, such as good combustion practices, in lieu of numerical limits.

Response: Pursuant to the LEAN decision, CAA section 112(d)(2)/(3) and the court order for the EPA to complete this final rule pursuant to CAA section 112(d)(6) by March 11, 2024, the EPA must establish standards for previously unregulated HAP based on available data in this final rule. The EPA collected emissions test data through the CAA section 114 requests. For D/F from BF stoves, when we made a determination of BDL according to the procedures outlined in Determination of ''non-detect'' from EPA Method 29 (multi-metals) and EPA Method 23 (dioxin/furan) test data when evaluating the setting of MACT floors versus work practice standards (Johnson 2014) (Johnson memo) available in the docket (EPA–HQ–OAR–2002–0083–1082), two of the six runs are determined to be non-detect. Though we disagree in the number of non-detect values with the commenter, we agree that, as only 33 percent of test runs were detected values, a work practice under CAA section 112(h) is appropriate for the control of D/F from BF Stoves. The EPA generally considers a work practice to be justified if a significant majority of emissions data available indicate that emissions are so low that they cannot be reliably measured (*e.g.,* more than 55 percent of test runs are non-detect) as discussed in the Johnson Memo. An appropriate work practice for D/F for the stoves, due to their similarity in operation with boilers and other heaters, is good combustion practices, represented for this source by the THC standard being finalized in this rule. The numerical THC standard provides assurance of good combustion practices, and a further tune-up style work practice requirement is not necessary.

Comment: Commentors stated that the EPA should not finalize its proposed CS_2 and HF limits for sinter/recycling plants because the available data demonstrates these pollutants are not emitted. The EPA estimates sinter/recycling plants emit: a total 1.3 tpy of HF and 23 tpy of CS_2 for the source category. The EPA bases its CS_2 estimate on a limited data set of six test runs where the EPA flagged 83 percent (5 out of 6) of those results as below detection limit (BDL). (2023 Data Memo at app. A) BDL means that emissions are so low they are not able to be accurately read, measured, or quantified. Similarly, 13 out of 14 (93 percent) of test runs for HF from sinter/recycling plants were flagged BDL by the EPA, indicating that HF is not emitted or emitted in trace amounts, and thus EPA should not set a numerical standard for HF for sinter/recycling plants. The commentor stated if the EPA nevertheless proceeds with such numerical limits, it must revise its proposed limits upwards to help to account for known data variability and limited datasets. Commentors stated that data underlying the EPA's proposed CS_2 and HF limits includes a significant number of readings below the detection limit. The EPA explains that ''greater than 50 percent of the data runs were BDL'' for HF and CS_2 from sinter/recycling plants. (2023 MACT Costs Memo at 19–21, tbl. 24.) The proposed limits for HF and CS_2 are not representative of current performance due to the frequency of near or BDL. The EPA has noted that ''section 112(d)(2) of the CAA specifically allows EPA to establish MACT standards based on emission controls that rely on pollution prevention techniques.'' Where a majority of BDL values exist, the EPA should instead consider pollution control techniques, such as a work practice, rather than individual limits for these HAPs. Thus, the EPA should rely on the oil-content and VOC limit pollution control techniques that are already in place for these pollutants.

Response: Pursuant to the LEAN decision, CAA section 112(d)(2)/(3) and the court's Order for EPA to complete this final rule pursuant to CAA section 112(d)(6) by March 11, 2024, the EPA must establish standards for previously unregulated HAP based on available data in this final rule. The EPA reviewed the data in question and agrees with the commenter's assessment of the number of non-detect results for CS_2 and HF. Further, the single test run for which HF was detected was only slightly above the detection limit (0.09 ppmv detected value versus the detection limit of 0.08 ppmv). The EPA generally considers a work practice to be justified if a significant majority of emissions data available indicate that emissions are so low that they cannot be reliably measured (*e.g.,* more than 55 percent of test runs are non-detect) as discussed in the Johnson Memo. Due to the extremely high percentage of non-detect values, 83 and 93 percent for CS_2 and HF respectively, it is appropriate for both of these compounds at the sinter plant to be represented by a work practice standard according to CAA section 112(h). For CS_2, the work practice being finalized consists of the existing requirement to control the oil content in the sinter or the VOC emissions at the windbox exhaust (40 CFR 63.7790(d)) to control the source of the sulfur, combined with the new numerical standard for COS being finalized in this rulemaking. For HF, where 93 percent of the values were below the detection limit and the only detected value is only slightly above, the numerical standard for HCl being finalized in this rule shall act as a work practice (or surrogate) for HF, as control of HCL will also control HF.

3. What are the revised standards for the unregulated point sources and how will compliance be demonstrated?

We are finalizing the MACT Floor emission limits mostly as we proposed, but with minor adjustments for some limits based on the inclusion of additional valid data in the UPL calculations, the revision of the format of BF Stove emission limits as advised in the comments received, and the incorporation of work practices and surrogates for CS_2 and HF at sinter plants and D/F from the BF Stove. These work practices are being finalized because under CAA section 112(h), the Administrator has determined that it is not feasible to prescribe or enforce an emissions standard for these unregulated point sources. Furthermore, based on consideration of public comments and further analyses, for mercury emissions from existing sinter plants, we are promulgating a BTF limit based on installation and operation of activated carbon injection (ACI), described in section III.E of this preamble. The emission limits, along with estimated annual emissions, for the unregulated point sources for the final rule are provided in Table 4.

TABLE 4—HAP EMISSIONS AND FINAL MACT LIMITS FOR PREVIOUSLY UNREGULATED POINT SOURCES

Process	HAP	Estimated source category emissions	Promulgated MACT emissions limit (or other applicable standard as noted below)
Sinter Plants	CS_2	23 tpy	Meet applicable COS limit and meet requirements of 40 CFR 63.7790(d).
Sinter Plants	COS	72 tpy	Existing sources: 0.064 lb/ton sinter. New sources: 0.030 lb/ton sinter.
Sinter Plants	HCl	12 tpy	Existing sources: 0.025 lb/ton sinter. New sources: 0.0012 lb/ton sinter.
Sinter Plants	HF	1.3 tpy	Meet the applicable HCl standard.
Sinter Plants	Hg	55 pounds/yr	Existing sources: 1.8e–5 lb/ton sinter.[2] New sources: 1.2e–5 lb/ton sinter.
BF casthouse control devices.	HCl	1.4 tpy	Existing sources: 0.0056 lb/ton iron. New sources: 5.9e–4 lb/ton iron.
BF casthouse control devices.	THC	270 tpy	Existing sources: 0.48 lb/ton iron. New sources: 0.035 lb/ton iron.
BOPF	D/F (TEQ[1])	3.6 grams/yr	Existing and new sources: 9.2e–10 lb/ton steel.
BOPF	HCl	200 tpy	Existing sources: 0.058 lb/ton steel. New sources: 2.8e–4 lb/ton steel.
BOPF	THC	13 tpy	Existing sources: 0.04 lb/ton steel. New sources: 0.0017 lb/ton steel.
BF Stove	D/F (TEQ)	0.076 grams/year	Good combustion practices demonstrated by meeting the THC limit.
BF Stove	HCl	4.5 tpy	Existing sources: 0.0012 lb/MMBtu. New sources: 4.2e–4 lb/MMBtu.
BF Stove	THC	200 tpy	Existing sources: 0.12 lb/MMBtu. New sources: 0.0054 lb/MMBtu.

[1] Toxic equivalency.
[2] See section III.E for description of the final mercury limit.

E. Reconsideration of Standards for D/F and PAH for Sinter Plants Under CAA Section 112(d)(6) Technology Review, and Beyond-the-Floor Limit for Mercury

1. What standards did we propose to address the reconsideration of the D/F and PAH standards for sinter plants, and new mercury limits from sinter plants?

We proposed emissions limits of 3.5E–08 lbs/ton of sinter for D/F toxic equivalency (TEQ) and 5.9E–03 lbs/ton of sinter for PAHs for existing sinter plant windboxes. These limits reflect the average current performance of the four existing sinter plants for D/F and PAHs pursuant to CAA section 112(d)(6). For mercury, we proposed a MACT Floor limit of 3.5E–05 lbs/ton sinter for existing sources, as described in section III.D of this preamble.

For new sources, we proposed emissions limits of 3.1E–09 lbs/ton of sinter for D/F (TEQ), and 1.5E–03 lbs/ton of sinter for PAHs for new sinter plant windboxes that reflect the current performance of the one best performing sinter plant pursuant to CAA section 112(d)(6). Regarding mercury, we proposed a MACT floor limit of 1.2E–05 lbs/ton sinter for new sinter plants.

2. What comments did we receive on the reconsideration of the D/F and PAH standards for sinter plants, and mercury emissions, and what are our responses?

Comment: Commenters stated that the Agency's review of ACI during the 2020 RTR found that the ACI add-on control technology for sinter/recycling plant windboxes would not be cost-effective. They said the Agency's BTF analysis and evaluation of ACI as a potential control option for sinter/recycling plants are flawed. Commenters said that they are unaware of any application of ACI with a wet scrubber for particulate control being sufficiently demonstrated in practice as a control technology for D/F. Commenters also assert that the assumed brominated powdered activated carbon (PAC) injection rate of 1.7 lb/MMacf based on 2012 test data from the Gerdau Sayreville, NJ electric arc furnace baghouse is unproven in the II&S industry and that the Agency may be underestimating the required injection rates.

Response: Based on our review of the available information and analyses, we estimate the brominated powdered activated carbon (PAC) can achieve 85 percent reduction of D/F when used with fabric filters. Regarding wet scrubbers, based on a scientific article by H.Ruegg and A. Sigg (See ''Dioxin Removal In a Wet Scrubber and Dry Particulate Removal'', Chemosphere, Vol. 25, No. 1–2, p. 143–148), we estimate ACI used with a wet scrubber will achieve 70 percent reduction. Given that PAHs and dioxins are both semi-volatile organic compounds, we assume the ACI with a wet scrubber will also achieve 70 percent reduction of PAHs from sinter plants with a wet scrubber. We note that only one of the 4 sinter plants is controlled with a wet venturi scrubber. The other three have baghouses.

Comment: Commenters stated the EPA's MACT limits for existing sinter plants should be lower, arguing that the EPA's establishment of separate MACT floors for COS, HCl, and mercury for new plants at less than half of the limit for existing sources indicates how outdated the 50 plus year-old existing sinter plants are. Commenters argued that the fact that only two integrated steel mills continue to operate sinter plants, down from nine facilities twenty years ago, further suggests that American sinter technology is outdated. In commenters' view, the EPA should not give these outdated sinter plants a ''pass'' on reducing their significant emissions of hazardous air pollutants.

Commenters further stated that the EPA should reconsider rejecting ACI as too expensive, arguing that steel mills can clearly afford this control measure based on recent profit margins. The EPA should more carefully consider an evaluation of the human health costs associated with the HAP emissions and factor that into the Agency's cost estimate. Alternatively, the commenters urged EPA to consider advanced or additional pollution controls on sinter windboxes, the most significant source of emissions from sinter plants. The proposed NESHAP does not appear to have considered the use of wet electrostatic precipitators, redundant baghouses, or other types of controls.

Response: To address the comments that sinter plants need more controls to reduce emissions of hazardous pollutants, specifically the addition of ACI controls, we are finalizing emissions limits pursuant to CAA section 112(d)(6) for D/F and PAHs, and CAA section 112(d)(2)/(3) BTF limits for mercury that reflect the installation and operation of ACI controls. We conclude that the estimated costs for these ACI controls (described below) are reasonable given that these controls will achieve significant reductions of these three HAPs, which are persistent, bioaccumulative and toxic (PBT) HAPs. For example, D/F are highly toxic carcinogens that bioaccumulate in various food sources such as beef and dairy products. Mercury, once it is converted to methylmercury in aquatic

ecosystems, is also known to bioaccumulate in some food sources, especially fish and marine mammals which are consumed by people, especially people who rely on subsistence fishing as an important food source. Methylmercury is a potent developmental neurotoxin, especially for developing fetuses. The PAHs are a subset of the polycyclic organic matter (POM), which are a group of HAP that EPA considers to be PB–HAP, and includes some known or probable carcinogens such as benzo-a-pyrene.

3. What are the revised standards for the D/F, PAH and mercury for sinter plants, and how will compliance be demonstrated?

Based on the comments received, we are finalizing emissions limits that reflect the installation and operation of ACI controls, which are emissions limits of 1.1E–08 lbs/ton of sinter for D/F (TEQ), 1.8E–03 lbs/ton of sinter for PAHs, and 1.8E–05 lbs/ton for mercury for existing sinter plant windboxes. Regarding new sources, we are promulgating limits of 1.1E–08 lbs/ton of sinter for D/F (TEQ), 1.5E–03 lbs/ton of sinter for PAHs, and 1.2E–05 lbs/ton for mercury for new sinter plant windboxes. The application of this ACI will achieve significant reductions of mercury, D/F and PAH emissions, important reductions given that all three HAP are highly toxic, persistent, bioaccumulative HAP (PB–HAP), as described above. We estimate these limits for the three separate HAP will result in total combined capital costs of $950K, annualized costs of $2.3M, will achieve 8 grams per year reductions of D/F TEQ emissions, 5.4 tpy reduction in PAHs, and 47 pounds of mercury. The estimated cost effectiveness (CE) for each HAP individually are: CE of $287K per gram D/F TEQ, $426K per ton of PAHs, and $49,000 per pound for mercury.

If the EPA evaluated these emissions limits individually (*i.e.,* without consideration of the co-control of D/F, PAHs and mercury), the EPA might have reached a different conclusion (*e.g.,* maybe not promulgated one or more of the individual final limits due to costs and cost effectiveness). For example, historically, EPA has accepted cost effectiveness for mercury up to about $32,000 per pound. Regarding the D/F and PAHs, we have not identified cost effectiveness values that have been accepted in the past as part of revising standards under EPA's technology reviews pursuant to CAA section 112(d)(6).

However, given that ACI is expected to be needed to achieve the limits for all three HAP (D/F, PAHs and mercury), as described previously in this section, we determined, similar to how we group non-Hg HAP metals when evaluating cost effectiveness, that it is appropriate to consider these three HAP as a group because they would be controlled by the same technology. We note that the Hg cost-effectiveness value is within a factor of 2 of values that we have accepted, and that these three HAP are persistent and bioaccumulative in the environment. Given that ACI is required to achieve the limits for all three PB–HAP (D/F, PAHs and mercury), as described previously in this section, we decided it was appropriate to establish these limits for these three HAP that reflect application of ACI. Because these three pollutants are PB–HAP, as described in more detail in response above, we conclude the estimated costs are reasonable, especially given that these annual costs are far less than 1 percent of revenues for the parent companies, which is discussed further in the economic impacts section of this preamble (see section IV.D).

F. Other Major Comments and Issues

Comment: Commenters stated the EPA's 2023 Proposal for II&S facilities poses many challenges to the domestic iron and steel manufacturing industries. They stated when taken in conjunction with other onerous EPA regulations, including the proposed revisions to the NAAQS for PM, the 2023 Taconite Risk and Technology Review proposal and the 2023 Coke Ovens and Pushing, Quenching, and Battery Stacks Risk and Technology Review proposal, the domestic II&S manufacturers will incur significant cost and will struggle to meet these additional, infeasible standards. They stated it is critical that the EPA understand this 2023 Proposal significantly jeopardizes the potential successes of the Bipartisan Infrastructure Law (BIL) and the Inflation Reduction Act (IRA), and, as a result, undercut the decarbonization priorities of the administration.

Commenters acknowledged the iron and steel industry faces significant impacts from the 2023 Proposal along with other EPA proposed rules including the Taconite MACT, the Coke MACT, the Good Neighbor Rule, and the $PM_{2.5}$ NAAQS. They stated their customers, coworkers, suppliers and themselves are concerned for the future of iron and steelmaking, an essential industry, in the U.S.

Commenters stated the regulations moving through the EPA at the current time are going to materially impact the Iron Range of Minnesota and the entire domestic steel industry. Commenters urged the EPA to be prudent and use caution before placing a single new regulation on these industries. Commenters asked the EPA to show favor in the Agency's decision making to the domestic iron and steel industry.

Response: As explained in the Regulatory Impact Analysis (RIA) and in section IV.D of this preamble, the projected economic impacts of the expected compliance costs of the rule are likely to be small. This rulemaking is estimated to cost less than 1% of the annual revenues of the parent companies. This rule should not be financially detrimental to the source category. See sections IV.C and IV.D of this preamble, and the RIA, for more details.

Comment: Commenters state that in 2020, the EPA conservatively determined that II&S source category risk was well below the acceptable levels established by the Congress and that existing standards are protective of public health with an ample margin of safety, and the proposal does not reopen or even question the EPA's conservative 2020 determination. As the proposal (briefly) recites, ''[i]n the 2020 final rule, the Agency found that risks due to emissions of air toxics from this source category were acceptable and concluded that the NESHAP provided an ample margin of safety to protect public health.'' (2023 Proposal) The EPA's decision not to revisit that conclusion confirms that the EPA supports the 2020 ample margin of safety determination and sees no reason for amendment. In fact, detailed corrected emission and modeling data show that the remaining risks are significantly smaller than even the low levels the EPA estimated in 2020.

Response: The EPA is revising the 2020 final rule to satisfy the *LEAN* decision, which requires the EPA to address any remaining unregulated sources of emissions from the iron and steel facilities. In meeting the requirements of this case law, the EPA collected more data to revisit the standards in the 2020 final rule under a technology review. Therefore, our revised standards are not based on assessment of risk, but instead based on evaluation of additional data. All the standards and other requirements in this final rule are being promulgated pursuant to CAA section 112(d)(2) and (3) or 112(d)(6). The EPA is not promulgating any new or revised standards under CAA section 112(f)(2) or revising its prior risk assessment results and conclusions, but instead are finalizing these standards and other requirements based on evaluation of additional data and applicable 112(d)

requirements that direct HAP emission reductions.

Comment: Commenters stated that the EPA's emissions estimates for UFIP sources are flawed and must be corrected. The EPA has attempted to estimate current HAP emission rates for all seven categories of UFIPs, and to estimate emission reductions that it projects would occur if the proposed opacity and work practice standards are achieved. The commenter claims that EPA's emissions estimates are based, in part, on the use of incorrect emission factors, which cause a significant overstatement of emissions from UFIPs, and therefore significantly overestimates risk from UFIPs. These errors result in significant cascading and compounding effects that reveal that the current proposal will be prohibitively expensive and cannot be justified, particularly given the low-risk determination that the EPA has already made.

Response: The EPA disagrees that the UFIP emission factors led to a significant overestimation of emissions from UFIP sources. The emission factors for UFIP sources were developed from the literature, first principles, discussions with the II&S industry, or a combination of all three. The emission factors used for most UFIP sources are described in the memorandum titled *Development of Emissions Estimates for Fugitive or Intermittent HAP Emission Sources for an Example Integrated Iron and Steel Manufacturing Industry Facility for Input to the RTR Risk Assessment* (Docket ID Item No. EPA–HQ–OAR–2002–0083–0956). The emission factor used for bell leaks was lower than the emission factor used in 2019 after incorporating previous feedback from industry that the 2019 emission factor for bell leaks was an overestimation. The emission factor used for bell leaks is described in the memorandum titled *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF* (Docket ID Item No. EPA–HQ–OAR–2002–0083–1447), this document is also referred to as the ''UFIP memorandum'' elsewhere in this preamble.

The PM emission factors for UFIP and capture and control efficiencies for control devices were taken primarily from a relatively recent (2006) EPA document. However, this document used as its primary source of data the 1995 update of the EPA's AP–42 section for the II&S manufacturing industry (section 12.5), which relied upon even older (1970) data in some cases. However, because the 2006 EPA document was developed by the EPA after the II&S manufacturing industry MACT was promulgated and was based on an expert evaluation of the available emission information, it is considered the most reliable source of information about PM emissions for the II&S manufacturing industry available to the EPA and, hence, the most reliable information to be used for UFIP sources.

Other data that were used to estimate UFIP emissions not available in the 2006 EPA document were taken from reliable sources in the literature. In some cases, for the purposes of the II&S manufacturing industry RTR, an emission factor from AP–42 for one II&S manufacturing industry source was used for another II&S manufacturing industry source based on good engineering judgment. For example, if EPA staff determined that the two sources were similar (*e.g.,* used similar processes, equipment, input materials, control devices, etc.), then staff used such a source to estimate emissions from another similar source. If not, staff searched for other relevant information to estimate emissions. Whenever possible, the original source of data referenced by the documents was obtained and reviewed; these references are cited in the ''Example Facility memorandum'' along with the 1995 EPA AP–42 document. Also, where available, AP–42 emission factor quality ratings were provided. In some cases, none of the available literature provided emission factors considered appropriate for today's industry. In these cases, the EPA developed emission factors from basic scientific principles, industry data and feedback, emission factors for similar sources, and the EPA's knowledge of the process. Further explanation and discussion of how emissions were estimated are available in the *Development of Emissions Estimates for Fugitive or Intermittent HAP Emission Sources for an Example Integrated Iron and Steel Manufacturing Industry Facility for Input to the RTR Risk Assessment* (Example facility memorandum) and/or the UFIP memorandum cited previously in this preamble, which are available in the docket for this action.

Comment: Commenters stated the EPA must consider additional data in setting limits. Although the EPA collected data in 2022 from the eight impacted facilities, the commenters urged the EPA to compile and consider additional data before finalizing these 2023 amendments. The limited data collection did not reflect the full range of variability due to seasonal effects and variable operating scenarios. While much of the industry meets the proposed limits at times, the variability may require investment in controls that are currently excluded from the cost estimates in the rules. The EPA must consider additional data and revise the proposed limits to adjust them upwards, as appropriate to account for variability, or eliminate the proposed limit where test results were below detectable levels.

Response: The EPA has made use of all valid test data, both received through the section 114 request in 2022 and submitted during the comment period to establish the emissions limits for sinter plants, BF stoves, BF Primary control devices and BOPF primary control devices. These ''point source'' emissions limits were derived using the UPL methodology using all the valid data. Regarding opacity limits for planned openings and slag processing, we used all valid data for 2022 that we received though the section 114 request in electronic format and that were gathered following the methods, instruction and conditions described in the section 114 request and because these data reflected the most current year. The fenceline monitoring requirements are based on evaluation all the available fenceline monitoring data that EPA received from 16 monitoring sites. EPA considered the variability across all 16 sites to determine the appropriate action level, which is described in detail in the proposed rule preamble published on July 31, 2023 (88 FR 49402). Regarding the work practice standards for Bell Leaks, beaching and unplanned openings, those standards wer developed using data collected through the section 114 requests along with additional data and information collected through public comments. For more details, see the technical memos cited in responses above.

Comment: Commenters stated that the EPA should expand the proposed standards to include best work practices that reduce toxic emissions from steel mills at a minimum by 65% as was shown possible in 2019. Commenters stated that the EPA should ensure air monitoring and testing includes ALL 12 toxic emissions, not simply chromium, as currently proposed.

Response: The change from the 65 percent emission reduction estimated in 2019 to the emission reductions calculated for this rule is primarily due to calculation improvements based on newly received data rather than changes to the set of work practices published. The EPA is finalizing many of the same UFIP work practices that were published for comment in 2019. However, through the 2022 section 114 collection the EPA received information about work practices that are currently being utilized by facilities. The data

showed that a subset of the facilities are already utilizing some of the UFIP work practices that are being finalized, which was not taken into account in the baseline emissions estimate conducted in 2019. In the emissions estimate conducted for this rulemaking, baseline emissions were adjusted based on facility-specific information on work practices that are already in use, resulting in lower baseline emissions. If a facility is already using a work practice that is being finalized in this rulemaking, the percent reduction of emissions estimated for that work practice was also removed from the total estimated emission reduction for that facility. The estimated baseline emissions and emission reductions are described in the memorandum titled *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF* (Docket ID Item No. EPA–HQ–OAR–2002–0083–1447).

G. Severability of Standards

This final rule includes MACT standards promulgated under CAA section 112(d)(2)–(3), as well as targeted updates to existing standards and work practices promulgated under section 112(d)(6). We intend each separate portion of this rule to operate independently of and to be severable from the rest of the rule.

First, each set of standards rests on stand-alone scientific determinations that do not rely on judgments made in other portions of the rule. For example, our judgments regarding the 112(d)(2)–(3) MACT Standard for *planned* bleeder valve openings rest on the best performing units' historical data, based on opacity values; in contrast, our judgments regarding 112(d)(6) work practice standards for the basic oxygen process furnace rest on different analyses, including updates to industry standards in practices. Thus, our assessment that the 112(d)(2)–(3) MACT standards are feasible and appropriate is fully independent of our judgments about the 112(d)(6) technology-review-update standards, and vice versa.

Further, EPA also finds that the implementation of each set of CAA 112(d)(2)–(3) MACT standards and each set of 112(d)(6) technology updates, including monitoring requirements, is independent. For example, there is nothing precluding a source from complying with its unplanned bleeder-valve-opening MACT limit, even if that source does not have any data from its fenceline monitors (which measure chromium), and vice versa. Thus, each aspect of EPA's overall approach to this source category could be implemented even in the absence of any one or more of the other elements included in this final rule.

Accordingly, EPA finds that each set of standards in this final rule is severable from and can operate independently of each other set of standards, and at a minimum, that the MACT emissions standards, as a group, are severable from the 112(d)(6) technology update standards (which include the fenceline monitoring requirement).

H. What are the effective and compliance dates?

All affected facilities must continue to comply with the previous provisions of 40 CFR part 63, subpart FFFFF until the applicable compliance date of this final rule. This final action meets the definition in 5 U.S.C. 804(2), so the effective date of the final rule will be 60 days after the promulgation date as specified in the Congressional Review Act. *See* 5 U.S.C. 801(a)(3)(A). The compliance dates are in Table 5. As shown in Table 5, EPA revised compliance dates for some of the final rule requirements. For explanation of revised compliance dates, see section 6 of the RTC.

TABLE 5—SUMMARY OF COMPLIANCE DATES FOR THE FINAL RULE

Source(s)	Rule requirement	Proposed compliance date	Final compliance date
All affected sinter plant windbox sources that commence construction or reconstruction on or before July 31, 2023.	New emissions limits for mercury, HCl, COS, D/F, and PAH.	6 months after the promulgation of the final rule.	3 years after the promulgation date of the final rule.
All affected sources that commence construction or reconstruction on or before July 31, 2023.	Fenceline monitoring requirements	Begin 1 year after the promulgation of the fenceline method for metals or 2 years after the promulgation date of the final rule, whichever is later.	Begin 1 year after the promulgation of the fenceline method for metals or 2 years after the promulgation date of the final rule, whichever is later.
All affected sources that commence construction or reconstruction on or before July 31, 2023.	Opacity limits for Planned Openings, Work Practices for Bell Leaks, and work practices for BOPF Shop.	12 months after the promulgation date of the final rule.	12 months after the promulgation date of the final rule.
All affected sources that commence construction or reconstruction on or before July 31, 2023.	Work Practices and Limits for Unplanned Openings, Work Practices for Beaching, and Opacity limit for Slag Processing.	12 months after the promulgation date of the final rule.	24 months after the promulgation date of the final rule.
All affected BF and BOPF sources that commence construction or reconstruction on or before July 31, 2023.	New emissions limits for HCl, THC, and D/F (see Table 4).	6 months after the promulgation date of the final rule.	3 years after the promulgation date of the final rule.
All affected sources that commence construction or reconstruction after July 31, 2023.	All new and revised provisions	Effective date of the final rule (or upon startup, whichever is later).	Effective date of the final rule (or upon startup, whichever is later).

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

The affected sources are facilities in the Integrated Iron and Steel Manufacturing Facilities source category. This includes any facility engaged in producing steel from iron ore. Integrated iron and steel manufacturing includes the following processes: sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BFs by the reduction of iron-bearing materials with a hot gas. The steel production process includes the BOPF. Based on the data we have, there are eight operating integrated iron and steel manufacturing facilities subject to this NESHAP, and one idle facility.

B. What are the air quality impacts?

We project emissions reductions of about 64 tpy of HAP metals and about 473 tpy of $PM_{2.5}$ from UFIP sources in the Integrated Iron and Steel Manufacturing Facilities source category due to the new and revised standards for UFIP sources.

C. What are the cost impacts?

The estimated capital costs are the same as the proposed estimate at $5.4M and annualized costs are $2.8M per year for the source category for the new UFIP control requirements. Also, compliance testing for all the new standards is estimated to cost the same as the proposed estimate at about $1.7M once every 5 years for the source category (which equates to about an average of roughly $320,000 per year). The estimated cost breakdown for the fenceline monitoring requirement is the same as proposed at $25,000 capital cost and $41,100 annual operating costs per monitor, $100,000 capital costs and $164,000 annual operating costs per facility, and $800,000 capital costs and $1.3M annual operating costs for the source category (assumes 8 operating facilities). Additional monitoring, recordkeeping, and reporting requirements associated with the final rule are expected to cost the same as the proposed estimate at $7,500 per facility per year ($60,000 for the source category per year, assuming eight facilities). The cost estimates were primarily revised in response to modifications of the rule requirements, with some BTF components being substituted for MACT floor options, as well as in response to contractor revisions. Additional adjustments were made to recategorize some annual costs that were initially miscategorized as capital costs. Based on the comments received, emission limits for sinter plants were revised to reflect the installation of ACI controls. ACI controls on the sinter plants are expected to cost $950,000 in total capital cost and $2.3 million in total annual cost. The total estimated capital costs are $7.1 million and total estimated annualized costs are $6.7 million for all the requirements for the source category. However, annual costs could decrease after facilities complete 2 years of fenceline monitoring because we have included a sunset provision whereby if facilities remain below the one half of the action level for 2 full years, they can request to terminate the fenceline monitoring. Termination of the fenceline monitoring in no way impacts the requirement for facilities to meet all other obligations under this subpart including the general duty to minimize emissions of 40 CFR 63.7810(d). There may be some energy savings from reducing leaks of BF gas from bells, which is one of the work practices described in this preamble, however those potential savings have not been quantified.

D. What are the economic impacts?

The EPA conducted an economic impact analysis for the final rule in the Regulatory Impact Analysis (RIA), which is available in the docket for this action. If the compliance costs, which are key inputs to an economic impact analysis, are small relative to the receipts of the affected industries, then the impact analysis may consist of a calculation of annual (or annualized) costs as a percent of sales for affected parent companies. This type of analysis is often applied when a partial equilibrium, or more complex economic impact analysis approach, is deemed unnecessary, given the expected size of the impacts. The annualized cost per sales for a company represents the maximum price increase in the affected product or service needed for the company to completely recover the annualized costs imposed by the regulation. We conducted a cost-to-sales analysis to estimate the economic impacts of this final action, given that the EAV of the compliance costs over the period 2026–2035 are $5.1 million using a 7 percent or $5.3 million using a 3 percent discount rate in 2022 dollars, which is small relative to the revenues of the steel industry.

There are two parent companies directly affected by the rule: Cleveland-Cliffs, Inc. and U.S. Steel. Each reported greater than $20 billion in revenue in 2021. The EPA estimated the annualized compliance cost each firm is expected to incur and determined the estimated cost-to-sales ratio for each firm is less than 0.02 percent. Therefore, the projected economic impacts of the expected compliance costs of the rule are likely to be small. The EPA also conducted a small business screening to determine the possible impacts of the rule on small businesses. Based on the Small Business Administration size standards and Cleveland-Cliffs, Inc. and U.S. Steel employment information, this source category has no small businesses.

E. What are the benefits?

The UFIP emissions work practices to reduce HAP emissions (with concurrent control of $PM_{2.5}$) are anticipated to improve air quality and the health of persons living in surrounding communities. The opacity limits and UFIP work practices are expected to reduce about 64 tpy of HAP metal emissions, including emissions of manganese, lead, arsenic, and chromium. Due to methodology and data limitations, we did not attempt to monetize the health benefits of reductions in HAP in this analysis. Instead, we are providing a qualitative discussion of the health effects associated with HAP emitted from sources subject to control under the rule in section 4.2 of the RIA, available in the docket for this action. The EPA remains committed to improving methods for estimating HAP-reduction benefits by continuing to explore additional aspects of HAP-related risk from the integrated iron and steel manufacturing sector, including the distribution of that risk.

The opacity limits and UFIP work practices are also estimated to reduce $PM_{2.5}$ emissions by about 473 tpy for the source category. The EPA estimated monetized benefits related to avoided premature mortality and morbidity associated with reduced exposure to $PM_{2.5}$ for 2026–2035. The present-value (PV) of the short-term benefits for the rule are estimated to be $1.8 billion at a 3 percent discount rate and $1.2 billion at a 7 percent discount rate with an equivalent annualized value (EAV) of $200 million and $170 million, respectively. The EAV represents a flow of constant annual values that would yield a sum equivalent to the PV. The PV of the long-term benefits for the rule range are estimated to be $3.7 billion at a 3 percent discount rate and $2.6 billion at a 7 percent discount rate with an EAV of $420 million and $340 million, respectively. All estimates are reported in 2022 dollars. For the full set of underlying calculations see the *Integrated Iron and Steel Benefits workbook,* available in the docket for this action.

F. What analysis of environmental justice did we conduct?

To examine the potential for any EJ issues that might be associated with Integrated Iron and Steel Manufacturing Facilities sources, we performed a proximity demographic assessment, which is an assessment of individual demographic groups of the populations living within 5 kilometers (km) and 50 km of the facilities. The EPA then compared the data from this assessment to the national average for each of the demographic groups. This assessment did not inform and was not used to develop the amended standards established in the final action. The amended standards were established based on the technical and scientific determinations described herein.

The EPA defines EJ as ''the just treatment and meaningful involvement of all people regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision-making and other Federal activities that affect human health and the environment so that people: (i) are fully protected from

disproportionate and adverse human health and environmental effects (including risks) and hazards, including those related to climate change, the cumulative impacts of environmental and other burdens, and the legacy of racism or other structural or systemic barriers; and (ii) have equitable access to a healthy, sustainable, and resilient environment in which to live, play, work, learn, grow, worship, and engage in cultural and subsistence practices.'' [5] In recognizing that communities with EJ concerns often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution.

For purposes of analyzing regulatory impacts, the EPA relies upon its June 2016 ''Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,'' which provides recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time, resource constraints, and analytical challenges will vary by media and circumstance. The Technical Guidance states that a regulatory action may involve potential EJ concerns if it could: (1) create new disproportionate impacts on communities with EJ concerns; (2) exacerbate existing disproportionate impacts on communities with EJ concerns; or (3) present opportunities to address existing disproportionate impacts on communities with EJ concerns through this action under development.

The EPA's EJ technical guidance states that ''[t]he analysis of potential EJ concerns for regulatory actions should address three questions: (A) Are there potential EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern in the baseline? (B) Are there potential EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern for the regulatory option(s) under consideration? (C) For the regulatory option(s) under consideration, are potential EJ concerns created or mitigated compared to the baseline?''[1]

The results of the proximity demographic analysis (see Table 6) indicate that, for populations within 5 km of the nine integrated iron and steel facilities, the percent of the population that is Black is more than twice the national average (27 percent versus 12 percent). In addition, the percentage of the population that is living below the poverty level (29 percent) and living below 2 times the poverty level (52 percent) is well above the national average (13 percent and 29 percent, respectively). Other demographics for the populations living within 5 km are below or near their respective national averages.

Within 50 km of the nine sources within the Integrated Iron and Steel Manufacturing Facilities category, the percent of the population that is Black is above the national average (20 percent versus 12 percent). Within 50 km the income demographics are similar to the national averages. Other demographics for the populations living within 50 km are below or near the respective national averages.

The methodology and the results of the demographic analysis are presented in the document titled *Analysis of Demographic Factors for Populations Living Near Integrated Iron and Steel Facilities,* which is available in the docket for this action.

As discussed in other subsections of the impacts of this action, in this action the EPA is adding requirements for facilities to improve UFIP emission control resulting in reductions of both metal HAP and $PM_{2.5}$. We estimate that all facilities will achieve reductions of HAP emissions as a result of this rule, including the facilities at which the percentage of the population living in close proximity who are Black and below poverty level is greater than the national average. The rule changes will have beneficial effects on air quality and public health for populations exposed to emissions from integrated iron and steel facilities.

TABLE 6—PROXIMITY DEMOGRAPHIC ASSESSMENT RESULTS FOR INTEGRATED IRON AND STEEL MANUFACTURING FACILITIES

Demographic group	Nationwide	Population within 50 km of 9 facilities	Population within 5 km of 9 facilities
Total Population	329,824,950	18,966,693	478,761
	Race and Ethnicity by Percent		
White	60	63	52
Black	12	20	27
Native American	0.6	0.1	0.2
Hispanic or Latino (includes white and nonwhite)	19	10	16
Other and Multiracial	9	7	5
	Income by Percent		
Below Poverty Level	13	13	29
Above Poverty Level	87	87	71
Below 2x Poverty Level	29	28	52
Above 2x Poverty Level	71	72	48
	Education by Percent		
Over 25 and without a High School Diploma	12	9	18
Over 25 and with a High School Diploma	88	91	82

[5] *https://www.federalregister.gov/documents/2023/04/26/2023-08955/revitalizing-our-nations-commitment-to-environmental-justice-for-all.*

TABLE 6—PROXIMITY DEMOGRAPHIC ASSESSMENT RESULTS FOR INTEGRATED IRON AND STEEL MANUFACTURING FACILITIES—Continued

Demographic group	Nationwide	Population within 50 km of 9 facilities	Population within 5 km of 9 facilities
	Linguistically Isolated by Percent		
Linguistically Isolated	5	3	6

Notes:
• The nationwide population count and all demographic percentages are based on the Census' 2016–2020 American Community Survey five-year block group averages and include Puerto Rico. Demographic percentages based on different averages may differ. The total population counts are based on the 2020 Decennial Census block populations.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories above: White, African American, Native American, Other and Multiracial, or Hispanic/Latino. A person who identifies as Hispanic or Latino is counted as Hispanic/Latino for this analysis, regardless of what race this person may have also identified as in the Census.

In addition to the analyses described above, the EPA completed a risk-based demographics analysis for the residual risk and technology review (RTR) proposed rule (84 FR 42704, August 16, 2019) and the 2020 RTR final rule (85 FR 42074, July 13, 2020). A description of the demographic analyses and the results are provided in those two **Federal Register** notices.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a ''significant regulatory action'' as defined under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, EPA, submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Any changes made in response to recommendations received as part of Executive Order 12866 review have been documented in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final action have been submitted for approval to OMB under the PRA. The information collection request (ICR) document that the EPA prepared has been assigned EPA ICR number 2003.10. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

Respondents/affected entities: Integrated iron and steel manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart FFFFF).

Estimated number of respondents: 8 facilities.

Frequency of response: One time.

Total estimated burden: The annual recordkeeping and reporting burden for facilities to comply with all of the requirements in the NESHAP is estimated to be 30,400 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting cost for all facilities to comply with all of the requirements in the NESHAP is estimated to be $3,950,000 per year, of which $3,140,000 per year is for this final rule, and $803,000 is for other costs related to continued compliance with the NESHAP including $108,000 for paperwork associated with operation and maintenance requirements.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The Agency confirmed through responses to a CAA section 114 information request that there are only eight integrated iron and steel manufacturing facilities currently operating in the United States and that these plants are owned by two parent companies that do not meet the definition of small businesses, as defined by the U.S. Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. No tribal governments own facilities subject to the NESHAP. Thus, Executive Order 13175 does not apply to this action.

G. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. Therefore, the EPA conducted searches for the Integrated Iron and Steel Manufacturing Facilities NESHAP through the Enhanced National Standards Systems Network (NSSN) Database managed by the American National Standards Institute

(ANSI). We also conducted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 17, 23, 25A, 26A, 29, and 30B of 40 CFR part 60, appendix A, 320 of 40 CFR part 63 appendix, and SW–846 Method 9071B. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's referenced method, the EPA ordered a copy of the standard and reviewed it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. This review requires significant method validation data that meet the requirements of EPA Method 301 for accepting alternative methods or scientific, engineering, and policy equivalence to procedures in the EPA referenced methods. The EPA may reconsider determinations of impracticality when additional information is available for particular VCS.

No applicable VCS was identified for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 17, 23, 25A, 26A, 29, 30B and SW–846 Method 9071B not already incorporated by reference in this subpart. The search identified one VCS that was potentially applicable for this rule in lieu of EPA Method 29. After reviewing the available standard, the EPA determined that the VCS identified for measuring emissions of pollutants subject to emissions standards in the rule would not be practical due to lack of equivalency. The EPA incorporates by reference VCS ASTM D6348–12 (Reapproved 2020), ''Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy,'' as an acceptable alternative to EPA Method 320 of appendix A to 40 CFR part 63 with caveats requiring inclusion of selected annexes to the standard as mandatory. The ASTM D6348–12 (R2020) method is an extractive FTIR spectroscopy-based field test method and is used to quantify gas phase concentrations of multiple target compounds in emission streams from stationary sources. This field test method provides near real time analysis of extracted gas samples. In the September 22, 2008, NTTAA summary, ASTM D6348–03(2010) was determined equivalent to EPA Method 320 with caveats. ASTM D6348–12 (R2020) is a revised version of ASTM D6348–03(2010) and includes a new section on accepting the results from direct measurement of a certified spike gas cylinder, but still lacks the caveats we placed on the D6348–03(2010) version. We are finalizing that the test plan preparation and implementation in the Annexes to ASTM D 6348–12 (R2020), Annexes Al through A8 are mandatory; and in ASTM D6348–12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). We are finalizing that, in order for the test data to be acceptable for a compound, %R must be 70% > R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the following equation:

$$Reported\ Results = \frac{Stack\ Concentration}{\%R} = 100$$

The ASTM D6348–12 (R2020) method is available at ASTM International, 1850 M Street NW, Suite 1030, Washington, DC 20036. See *www.astm.org/*.

The EPA is also incorporating by reference Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements, Version 2.0 (Final), March 2008 (EPA–454/B–08–002). The Quality Assurance Handbook for Air Pollution Measurement Systems; Volume IV: Meteorological Measurements is an EPA developed guidance manual for the installation, operation, maintenance and calibration of meteorological systems including the wind speed and direction using anemometers, temperature using thermistors, and atmospheric pressure using aneroid barometers, as well as the calculations for wind vector data for on-site meteorological measurements. This VCS may be obtained from the EPA's National Service Center for Environmental Publications (*www.epa.gov/nscep*).

Additional information for the VCS search and determination can be found in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing,* which is available in the docket for this action.

ASTM D7520–16 is already approved for the location in which it appears in the amendatory text.

H. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. For this action the EPA conducted an assessment of the various demographic groups living near Integrated Iron and Steel facilities (as described in section V.F of this preamble) that might potentially be impacted by emissions from Integrated Iron and Steel Facilities. For populations living within 5 km of the nine integrated iron and steel facilities, the percent of the population that is Black is more than twice the national average (27 percent versus 12 percent). Specifically, within 5 km of six of the nine facilities, the percent of the population that is Black is more than 1.5 times the national average (ranging between 1.5 times and 7 times the national average). The percentage of the population that is living below the poverty level (29 percent) and living below 2 times the poverty level (52 percent) is well above the national average (13 percent and 29 percent, respectively). Specifically, within 5 km of seven of the nine facilities, the percent of the population that is living below the poverty level is more than 1.5 times the national average (ranging from 1.5 times and 3 times the national average). Other demographics for the populations living within 5 km are below or near the respective national averages.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. This

action requires facilities to improve UFIP emission control resulting in reductions of about 64 tpy of metal HAP and about 473 tpy $PM_{2.5}$. We estimate that all facilities will achieve reductions of HAP emissions as a result of this rule, including the facilities at which the percentage of the population living in close proximity who are African American and below poverty level is greater than the national average.

The information supporting this Executive Order review is contained in sections IV and V of this preamble. The demographic analysis is available in a document titled *Analysis of Demographic Factors for Populations Living Near Integrated Iron and Steel Facilities,* which is available in the docket for this action.

I. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children.

J. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. We have concluded that this action is not likely to have any adverse energy effects because it contains no regulatory requirements that will have an adverse impact on productivity, competition, or prices in the energy sector.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit the rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Hydrogen chloride, Hydrogen fluoride, Incorporation by reference, Mercury, Reorting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 4701, *et seq.*

Subpart A—General Provisions

■ 2. Section 63.14 is amended by revising paragraphs (i)(88) and (110) and paragraph (o) introductory text and adding paragraph (o)(3) to read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(i) * * *

(88) ASTM D6348–12 (Reapproved 2020), Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy, including Annexes A1 through A8, Approved December 1; 2020, IBR approved for §§ 63.365(b); *63.7825(g)* and *(h).*

* * * * *

(110) ASTM D7520–16, Standard Test Method for Determining the Opacity of a Plume in the Outdoor Ambient Atmosphere, approved April 1, 2016; IBR approved for §§ 63.1625(b); table 3 to subpart LLLLL; 63.7823(c) through (f), 63.7833(g); 63.11423(c).

* * * * *

(o) U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; phone: (202) 272–0167; website: *www.epa.gov/aboutepa/forms/contact-epa.*

* * * * *

(3) EPA–454/B–08–002, Quality Assurance Handbook for Air Pollution Measurement Systems; Volume IV: Meteorological Measurements, Version 2.0 (Final), Issued March 2008, IBR approved for § 63.7792(b).

* * * * *

Subpart FFFFF—National Emission Standards for Hazardous Air Pollutants for Integrated Iron and Steel Manufacturing Facilities

■ 3. Amend § 63.7782 by revising paragraphs (c), (d), and (e) to read as follows:

§ 63.7782 What parts of my plant does this subpart cover?

* * * * *

(c) This subpart covers emissions from the sinter plant windbox exhaust, discharge end, and sinter cooler; the blast furnace casthouse; the blast furnace stove; and the BOPF shop including each individual BOPF and shop ancillary operations (hot metal transfer, hot metal desulfurization, slag skimming, and ladle metallurgy). This subpart also covers fugitive and intermittent particulate emissions from blast furnace unplanned bleeder valve openings, blast furnace planned bleeder valve openings, blast furnace and BOPF slag processing, handling, and storage, blast furnace bell leaks, beaching of iron from blast furnaces, blast furnace casthouse fugitives, and BOPF shop fugitives.

(d) A sinter plant, blast furnace, blast furnace stove, or BOPF shop at your integrated iron and steel manufacturing facility is existing if you commenced construction or reconstruction of the affected source before July 13, 2001.

(e) A sinter plant, blast furnace, blast furnace stove, or BOPF shop at your integrated iron and steel manufacturing facility is new if you commence construction or reconstruction of the affected source on or after July 13, 2001. An affected source is reconstructed if it meets the definition of reconstruction in § 63.2.

■ 4. Amend § 63.7783 by revising paragraph (a) introductory text and adding paragraph (g) to read as follows:

§ 63.7783 When do I have to comply with this subpart?

(a) If you have an existing affected source, you must comply with each emission limitation, standard, and operation and maintenance requirement in this subpart that applies to you by the dates specified in paragraphs (a)(1) and (2) of this section. This paragraph does not apply to the emission limitations for BOPF group: mercury (Hg); sinter plant windbox: Hg, hydrochloric acid (HCl), carbonyl sulfide (COS); Blast Furnace casthouse: HCl, total hydrocarbon (THC); Blast Furnace stove: HCl and total hydrocarbon (THC); primary emission control system for a BOPF: 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8–TCDD) toxic equivalent (TEQ), HCl, THC; fugitive and intermittent particulate sources.

* * * * *

(g) If you have an existing affected source or a new or reconstructed affected source for which construction or reconstruction commenced on or before July 31, 2023, each sinter plant windbox, BF casthouse, BF stove,

primary emission control system for a BOPF, and fugitive and intermittent particulate source at your facility must be in compliance with the applicable emission limits in table 1 of this subpart through performance testing under § 63.7825, April 3, 2025, except for the following:

(1) All affected sinter plant windbox sources that commence construction or reconstruction on or before July 31, 2023, must be in compliance with Hg, HCl, COS, TEQ, and PAH emissions limits in table 1 to this subpart through performance testing by April 3, 2027.

(2) All affected BF and BOPF sources that commence construction or reconstruction on or before July 31, 2023, must be in compliance with HCl, THC, and TEQ emissions limits in table 1 to this subpart through performance testing by April 3, 2027.

(3) All affected sources that commence construction or reconstruction on or before July 31, 2023 must be in compliance with work practices and limits for unplanned openings, work practices for beaching, and the opacity limit for slag processing in table 1 to this subpart through performance testing (or through reporting of number of unplanned openings for limits applicable to unplanned openings shown in table 1) by April 3, 2026.

(4) All affected sources that commence construction or reconstruction after July 31, 2023, must be in compliance with all new and revised provisions in table 1 to this subpart through performance testing by April 3, 2024 or upon startup, whichever is later.

■ 5. Amend § 63.7791 by revising the section heading to read as follows:

§ 63.7791 How do I comply with the requirements for the control of mercury from BOPF Groups?

* * * * *

■ 6. Add § 63.7792 to read as follows:

§ 63.7792 What fenceline monitoring requirements must I meet?

The owner or operator must conduct sampling along the facility property boundary and analyze the samples in accordance with paragraphs (a) through (g) of this section.

(a) Beginning either 1 year after promulgation of the test method for fenceline sampling of metals applicable to this subpart or April 3, 2026 whichever is later, the owner or operator must conduct sampling along the facility property boundary and analyze the samples in accordance with the method and paragraphs (a)(1) through (3) of this section.

(1) The owner or operator must monitor for total chromium.

(2) The owner or operator must use a sampling period and sampling frequency as specified in paragraphs (a)(2)(i) through (iii) of this section.

(i) *Sampling period.* A 24-hour sampling period must be used. A sampling period is defined as the period during active collection of a sample and does not include the time required to analyze the sample.

(ii) *Sampling frequency.* The frequency of sample collection must be samples at least every 6 calendar days, such that the beginning of each sampling period begins no greater than approximately 144 hours (±12 hours) from the end of the previous sample.

(iii) *Sunset provision.* When the annual rolling average Δc remains less than 0.05 μg/m^3 for 24 months in succession, a test waiver may be requested from the Administrator to remove or reduce fenceline sampling requirements. If the annual rolling average Δc exceeds 0.05μg/m^3, the determination of 24 consecutive annual average Δc months restarts.

(3) The owner or operator must determine sample locations in accordance with paragraphs (b)(3)(i) through (v) of this section.

(i) The monitoring perimeter must be located between the property boundary and the process unit(s), such that the monitoring perimeter encompasses all potential sources of the target analyte(s) specified in paragraph (a)(1) of this section.

(ii) The owner or operator must place a minimum of 4 samplers around the monitoring perimeter.

(iii) To determine sampling locations, measure the length of the monitoring perimeter.

(A) Locate the point downwind of the prevailing wind direction.

(B) Divide the monitoring perimeter equally into 4 evenly spaced sampling points, with one located in accordance with paragraph (a)(3)(iii)(A) of this section.

(4) The owner or operator must follow the procedures in of the fenceline metals test method to determine the detection limit of the target analyte(s) and requirements for quality assurance samples.

(b) The owner or operator must collect and record meteorological data according to the applicable requirements in paragraphs (b)(1) through (3) of this section.

(1) If monitoring is conducted under paragraph (b) of this section, if a near-field source correction is used as provided in paragraph (f)(2) of this section, or if an alternative test method is used that provides time-resolved measurements, the owner or operator must use an on-site meteorological station in accordance with the metals fenceline test method applicable to this subpart. Collect and record hourly average meteorological data, including temperature, barometric pressure, wind speed and wind direction and calculate daily unit vector wind direction and daily sigma theta.

(2) For cases other than those specified in paragraph (c)(1) of this section, the owner or operator must collect and record sampling period average temperature and barometric pressure using either an on-site meteorological station in accordance with the metals fenceline test method of this part or, alternatively, using data from a National Weather Service (NWS) meteorological station provided the NWS meteorological station is within 40 kilometers (25 miles) of the facility.

(3) If an on-site meteorological station is used, the owner or operator must follow the calibration and standardization procedures for meteorological measurements in EPA–454/B–08–002 (incorporated by reference, see § 63.14).

(c) Within 45 days of completion of each sampling period, the owner or operator must determine whether the results are above or below the action level as follows.

(1) The owner or operator must determine the facility impact on the concentration (Δc) for each sampling period according to either paragraph (d)(1)(i) or (ii) of this section, as applicable.

(i) Except when near-field source correction is used as provided in paragraph (d)(1)(ii) of this section, the owner or operator must determine the highest and lowest sample results individually from the sample pool and calculate the Δc as the difference in these concentrations. Co-located samples must be averaged together for the purposes of determining the concentration at a particular sampling location, and, if applicable, for determining Δc. The owner or operator must adhere to the following procedures when one or more samples for the sampling period are below the method detection limit for a particular compound:

(A) If the lowest detected value is below detection, the owner or operator must use zero as the lowest sample result when calculating Δc.

(B) If all sample results are below the method detection limit, the owner or operator must use the highest method detection limit for the sample set as the highest sample result and zero as the

lowest sample result when calculating Δc.

(ii) When near-field source correction is used as provided in paragraph (g) of this section, the owner or operator must determine Δc using the calculation protocols outlined in the approved site-specific monitoring plan and in paragraph (g) of this section.

(2) The owner or operator must calculate the annual average Δc based on the average of the Δc values for the 61 most recent sampling periods. The owner or operator must update this annual average value after receiving the results of each subsequent sampling period.

(3) The action level for chromium is 0.1 μg/m^3. If the annual average Δc value (rounded to 1 significant figure) is greater than the action level, the concentration is above the action level, and the owner or operator must conduct a root cause analysis and corrective action in accordance with paragraph (d) of this section.

(d) Once any action level in paragraph (c)(3) of this section has been exceeded, the owner or operator must take the following actions to bring the annual average Δc back below the action level(s).

(1) Within 5 days of updating the annual average value as required in (c)(2) and determining that any action level in paragraph (c)(3) of this section has been exceeded (*i.e.,* in no case longer than 50 days after completion of the sampling period), the owner or operator must initiate a root cause analysis to determine appropriate corrective action. A root cause analysis is an assessment conducted through a process of investigation to determine the primary underlying cause and all other contributing causes to an exceedance of the action level(s) set forth in paragraph (c)(3).

(2) The initial root cause analysis may include, but is not limited to:

(i) Visual inspection to determine the cause of the high emissions.

(ii) Operator knowledge of process changes (*e.g.,* a malfunction or release event).

(3) If the initial root cause cannot be identified using the type of techniques described in paragraph (d)(2) of this section, the owner or operator must employ more frequent sampling and analysis to determine the root cause of the exceedance.

(i) The owner or operator may first employ additional monitoring points or more frequent sampling to determine the root cause of the exceedance.

(ii) If the owner or operator has not determined the root cause of the exceedance within 30 days of determining that the action level has been exceeded, the owner or operator must employ the appropriate more time resolute sampling techniques (*e.g.,* continuous multi metals monitors) to locate the cause of the exceedance. If the root cause is not identified after 28 days, either the more time resolute monitor must be relocated or an additional more time resolute monitor must be added. Relocation or addition of extra monitors must continue after each 28-day period of nonidentification until the owner or operator can identify the root cause of the exceedance.

(4) If the underlying primary and other contributing causes of the exceedance are deemed to be under the control of the owner or operator, the owner or operator must take appropriate corrective action as expeditiously as possible to bring annual average fenceline concentrations back below the action level(s) set forth in paragraph (c)(2)(3) of this section. At a minimum, the corrective actions taken must address the underlying primary and other contributing cause(s) determined in the root cause analysis to prevent future exceedances from the same underlying cause(s).

(5) The root cause analysis must be completed and initial corrective actions taken no later than 45 days after determining there is an exceedance of an action level.

(e) An owner or operator must develop a corrective action plan if the conditions in either paragraph (e)(1) or (2) of this section are met. The corrective action plan must describe the corrective action(s) completed to date, additional measures that the owner or operator proposes to employ to expeditiously reduce annual average fenceline concentrations below the action level set forth in paragraph (c)(3) of this section, and a schedule for completion of these measures. The corrective action plan must identify actions to address the underlying primary and other contributing cause(s) determined in the root cause analysis to prevent future exceedances from the same underlying cause(s). The corrective action plan does not need to be approved by the Administrator. However, if upon review, the Administrator disagrees with the additional measures outlined in the plan, the owner or operator must revise and resubmit the plan within 7 calendar days of receiving comments from the Administrator.

(1) The owner or operator must develop a corrective action plan if, upon completion of the root cause analysis and initial corrective actions required in paragraph (d) of this section, the Δc value for the next sampling period, for which the sampling start time begins after the completion of the initial corrective actions, is greater than 0.1 μg/m^3. The owner or operator must submit the corrective action plan to the Administrator within 60 days after receiving the analytical results indicating that the Δc value for the sampling period following the completion of the initial corrective action is greater than 0.1 μg/m^3.

(2) The owner or operator must develop a corrective action plan if complete implementation of all corrective measures identified in the root cause analysis required by paragraph (d) of this section will require more than 45 days. The owner or operator must submit the corrective action plan to the Administrator no later than 60 days following the completion of the root cause analysis required in paragraph (d) of this section.

(f) An owner or operator may request approval from the Administrator for a site-specific monitoring plan to account for offsite upwind sources according to the requirements in paragraphs (f)(1) through (4) of this section.

(1) The owner or operator must prepare and submit a site-specific monitoring plan and receive approval of the site-specific monitoring plan prior to using the near-field source alternative calculation for determining Δc provided in paragraph (f)(2) of this section. The site-specific monitoring plan must include, at a minimum, the elements specified in paragraphs (f)(1)(i) through (v) of this section. The procedures in section 12 of Method 325A of appendix A of this part are not required, but may be used, if applicable, when determining near-field source contributions.

(i) Identification of the near-field source or sources.

(ii) Location of the additional monitoring stations that must be used to determine the uniform background concentration and the near-field source concentration contribution. Modeling may not be used in lieu of monitoring to identify uniform background concentration and near-field sources.

(iii) Identification of the fenceline monitoring locations impacted by the near-field source. If more than one near-field source is present, identify the near-field source or sources that are expected to contribute to the concentration at that monitoring location.

(iv) A description of (including sample calculations illustrating) the planned data reduction including the treatment of invalid data, data below detection limits, and data collected during calm wind periods; and

calculations to determine the near-field source concentration contribution for each monitoring location.

(v) A detailed description of the measurement technique, measurement location(s), the standard operation procedure, measurement frequency, recording frequency, measurement detection limit, and data quality indicators to ensure accuracy, precision, and validity of the data.

(2) When an approved site-specific monitoring plan is used, the owner or operator must determine Δc for comparison with the action level using the requirements specified in paragraphs (f)(2)(i) through (iii) of this section.

(i) For each monitoring location, calculate Δc_i using the following equation.

Equation 1 to paragraph (f)(1)(i)

$$\Delta c_i = MFC_i - NFS_i$$

Where:

Δc_i = The fenceline concentration, corrected for background, at measurement location i, micrograms per cubic meter ($\mu g/m^3$).

MFC_i = The measured fenceline concentration at measurement location i, $\mu g/m^3$.

NFS_i = The near-field source contributing concentration at measurement location i determined using the additional measurements and calculation procedures included in the site-specific monitoring plan, $\mu g/m^3$. For monitoring locations that are not included in the site-specific monitoring plan as impacted by a near-field source, use $NFS_i = 0$ $\mu g/m^3$.

(ii) When one or more samples for the sampling period are below the method detection limit, adhere to the following procedures:

(A) If the concentration at the monitoring location(s) used to determine the near-field source contributing concentration is below the method detection limit, the owner or operator must use zero for the monitoring location concentration when calculating NFS_i for that monitoring period.

(B) If a fenceline monitoring location sample result is below the method detection limit, the owner or operator must use the method detection limit as the sample result.

(iii) Determine Δc for the monitoring period as the maximum value of Δc_i from all of the fenceline monitoring locations for that monitoring period.

(3) The site-specific monitoring plan must be submitted and approved as described in paragraphs (f)(3)(i) through (iv) of this section.

(i) The site-specific monitoring plan must be submitted to the Administrator for approval.

(ii) The site-specific monitoring plan must also be submitted to the following address: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, U.S. EPA Mailroom (E143–01), Attention: Integrated Iron and Steel Sector Lead, 109 T.W. Alexander Drive, Research Triangle Park, NC 27711. Electronic copies in lieu of hard copies may also be submitted to *fencelineplan@epa.gov.*

(iii) The Administrator will approve or disapprove the plan in 90 days. The plan is considered approved if the Administrator either approves the plan in writing or fails to disapprove the plan in writing. The 90-day period begins when the Administrator receives the plan.

(iv) If the Administrator finds any deficiencies in the site-specific monitoring plan and disapproves the plan in writing, the owner or operator may revise and resubmit the site-specific monitoring plan following the requirements in paragraphs (f)(3)(i) and (ii) of this section. The 90-day period starts over with the resubmission of the revised monitoring plan.

(4) The approval by the Administrator of a site-specific monitoring plan will be based on the completeness, accuracy, and reasonableness of the request for a site-specific monitoring plan. Factors that the Administrator will consider in reviewing the request for a site-specific monitoring plan include, but are not limited to, those described in paragraphs (f)(4)(i) through (v) of this section.

(i) The identification of the near-field source or sources and evidence of how the sources impact the fenceline concentrations.

(ii) The monitoring location selected to determine the uniform background concentration or an indication that no uniform background concentration monitor will be used.

(iii) The location(s) selected for additional monitoring to determine the near-field source concentration contribution.

(iv) The identification of the fenceline monitoring locations impacted by the near-field source or sources.

(v) The appropriateness of the planned data reduction and calculations to determine the near-field source concentration contribution for each monitoring location, including the handling of invalid data, data below the detection limit, and data during calm periods.

(vi) If more frequent monitoring is proposed, the adequacy of the description of and rationale for the measurement technique, measurement location(s), the standard operation procedure, measurement frequency, recording frequency, measurement detection limit, and data quality indicators to ensure accuracy, precision, and validity of the data.

(g) The owner or operator must comply with the applicable recordkeeping and reporting requirements in § 63.7841 and § 63.7842.

(1) As outlined in § 63.7(f), the owner or operator may submit a request for an alternative test method. At a minimum, the request must follow the requirements outlined in paragraphs (f)(1)(i) through (vi) of this section.

(i) The alternative method may be used in lieu of all or a partial number of the sampling locations required under paragraph (a) of this section.

(ii) The alternative method must be validated according to Method 301 in appendix A of this part or contain performance-based procedures and indicators to ensure self-validation.

(iii) The method detection limit must nominally be at least three times below the action level. The alternate test method must describe the procedures used to provide field verification of the detection limit.

(iv) If the alternative test method will be used to replace some or all samplers required under paragraph (a) of this section, the spatial coverage must be equal to or better than the spatial coverage provided under paragraph (a).

(v) For alternative test methods capable of real time measurements (less than a 5-minute sampling and analysis cycle), the alternative test method may allow for elimination of data points corresponding to outside emission sources for purpose of calculation of the high point for the two week average. The alternative test method approach must have wind speed, direction, and stability class of the same time resolution and within the footprint of the instrument.

(vi) For purposes of averaging data points to determine the Δc for the individual sampling period, all results measured under the method detection limit must use the method detection limit. For purposes of averaging data points for the individual sampling period low sample result, all results measured under the method detection limit must use zero.

■ 7. Add § 63.7793 to read as follows:

§ 63.7793 What work practice standards must I meet?

(a) You must meet each work practice limit in table 1 to this subpart that applies to you.

(b) For unplanned bleeder valve openings on a new and existing blast furnace, you must meet each work practice standard listed in paragraphs (b)(1) through (3) of this section.

(1) Develop and operate according to a ''Slip Avoidance Plan'' to minimize slips and submit it to EPA for approval;

(2) Install devices to continuously measure/monitor material levels in the furnace (*i.e.,* stockline), at a minimum of three locations, with alarms to inform operators of static (*i.e.,* not moving) stockline conditions which increase the likelihood of slips; and

(3) Install and use instruments on the furnace to monitor temperature and pressure to help determine when a slip is likely to occur.

(c) For each large bell on a new and existing blast furnace, you must meet each work practice standard listed in paragraphs (c)(1) and (2) of this section.

(1) Maintain metal seats to minimize wear on seals and emissions; and

(2) Replace or repair large bell seals according to § 63.7833(j).

(d) For each small bell on a new and existing blast furnace, you must meet each work practice standard listed in paragraphs (d)(1) and (2) of this section.

(1) Maintain metal seats to minimize wear on seals; and

(2) You must repair or replace small bell seals prior to the time period or metal throughput limit that has been proven and documented to produce no opacity from the small bell.

(e) For each iron beaching operation, you must meet each work practice standard listed in paragraphs (e)(1) and (2) of this section.

(1) Minimize the drop height of molten metal to the ground, the slope or grade of the area where beaching occurs, and the rate at which molten metal is poured onto the ground; and

(2) Use carbon dioxide shielding during beaching event; and/or use full or partial (hoods) enclosures around beached iron.

(f) For each BOPF at a new or existing shop, you must develop and operate according to a ''BOPF Shop Operating Plan'' to minimize fugitive emissions and detect openings and leaks and submit it to EPA for approval. Your BOPF Shop Operating Plan may include, but is not limited to, any of the items listed in paragraphs (f)(1) through (8) of this section.

(1) List all events that generate VE, including slopping and other steps company will take to reduce incidence rate. State the specific actions that operators will take when slag foaming approaches the mouth of the vessel in order to prevent slopping;

(2) Minimize hot iron pour/charge rate (minutes) and set a maximum pour rate in tons/second;

(3) Schedule of regular inspections of BOPF shop structure for openings and leaks to the atmosphere;

(4) Optimize positioning of hot metal ladles with respect to hood face and furnace mouth;

(5) Optimize furnace tilt angle during charging and set a maximum tilt angle during charging;

(6) Keep all openings, except roof monitors, closed, especially during transfer, to extent feasible and safe. All openings shall be closed unless the opening was in the original design of the Shop;

(7) Use higher draft velocities to capture more fugitives at a given distance from hood, if possible; and

(8) Monitor opacity periodically (*e.g.,* once per month) from all openings with EPA Method Alt-082 (camera) or with EPA Method 9 in appendix A–4 to part 60 of this chapter.

■ 8. Amend § 63.7800 by revising paragraph (b) introductory text and adding paragraphs (b)(8) and (9) to read as follows:

§ 63.7800 What are my operation and maintenance requirements?

* * * * *

(b) You must prepare and operate at all times according to a written operation and maintenance plan for each capture system or control device subject to an operating limit in § 63.7790(b). Each plan must address the elements in paragraphs (b)(1) through (9) of this section.

* * * * *

(8) Small Bell repair or replacement period, in weeks, or mass of material throughput, in tons, and the specific begin date and end date for the chosen repair or replacement period or throughput over which there were no visible emissions observed.

(9) Building drawings of the BF Casthouse and BOPF shop that show and list by number the openings, including doors and vents, that are part of the original design of the building.

■ 9. Amend § 63.7820 by revising paragraph (e) to read as follows:

§ 63.7820 By what date must I conduct performance tests or other initial compliance demonstrations?

* * * * *

(e) Notwithstanding the deadlines in this section, existing and new affected sources must comply with the deadlines for making the initial compliance demonstrations for the BOPF Group mercury emission limit set forth in paragraphs (e)(1) through (4) in this section.

* * * * *

■ 10. Revise § 63.7821 to read as follows:

§ 63.7821 When must I conduct subsequent performance tests?

(a) You must conduct subsequent performance tests to demonstrate compliance with all applicable emission and opacity limits in table 1 to this subpart at the frequencies specified in paragraphs (b) through (m) of this section.

(b) For each sinter cooler at an existing sinter plant and each emissions unit equipped with a control device other than a baghouse, you must conduct subsequent particulate matter and opacity performance tests no less frequently than twice (at mid-term and renewal) during each term of your title V operating permit.

(c) For each emissions unit equipped with a baghouse, you must conduct subsequent particulate matter and opacity performance tests no less frequently than once during each term of your title V operating permit.

(d) For sources without a title V operating permit, you must conduct subsequent particulate matter and opacity performance tests every 2.5 years.

(e) For each BOPF Group, if demonstrating compliance with the mercury emission limit in table 1 to this subpart through performance testing under §§ 63.7825 and 63.7833, you must conduct subsequent performance tests twice per permit cycle (*i.e.,* mid-term and initial/final) for sources with title V operating permits, and every 2.5 years for sources without a title V operating permit, at the outlet of the control devices for the BOPF Group.

(f) For each sinter plant windbox, you must conduct subsequent mercury, hydrogen chloride, carbonyl sulfide, dioxin/furan, and polycyclic aromatic hydrocarbon performance tests every 5 years.

(g) For each blast furnace stove and BOPF shop primary emission control device, you must conduct subsequent hydrogen chloride and total hydrocarbon testing every 5 years. For the BOPF shop primary emission control device, you must also conduct subsequent dioxin/furan testing every 5 years.

(h) For each blast furnace casthouse and BOPF shop, you must conduct subsequent opacity tests two times per

month during a cast, or during a full heat cycle, as appropriate.

(i) For planned bleeder valve openings on each blast furnace, you must conduct opacity tests according to § 63.7823(f) for each planned opening.

(j) For slag processing, handling, and storage operations for each blast furnace or BOPF, you must conduct subsequent opacity tests once per week for a minimum of 18 minutes for each: BF pit filling; BOPF slag pit filling; BF pit digging; BOPF slag pit digging; and one slag handling (either truck loading or dumping slag to slag piles).

(k) For large bells on each blast furnace, you must conduct visible emissions testing on the interbell relief valve according to EPA Method 22 in appendix A–7 to part 60 of this chapter, unless specified in paragraphs (k)(1) through (3) of this section. Testing must be conducted monthly, for 15 minutes.

(1) If visible emissions are detected for a large bell during the monthly visible emissions testing, you must conduct EPA Method 9 (in appendix A–4 to part 60 of this chapter) opacity tests in place of EPA Method 22 testing on that bell once per month, taking 3-minute averages for 15 minutes, until the large bell seal is repaired or replaced.

(2) If the average of 3 instantaneous visible emission readings taken while the interbell relief valve is exhausting exceeds 20 percent, you must initiate corrective action within five business days.

(3) Ten business days after the initial opacity exceedance of 20 percent, you must conduct an EPA Method 9 opacity test, taking 3-minute averages for 15 minutes. If the average of 3 instantaneous visible emissions readings from this test exceeds 20 percent, you must repair or replace that bell seal within 4 months.

(l) For small bells on each blast furnace, you must conduct visible emissions testing according to EPA Method 22 in appendix A–7 to part 60 of this chapter. Testing must be conducted monthly for 15 minutes. If visible emissions are observed, you must compare the period between the visible emissions being present and the most recent bell seal repair or replacement. If this time period or throughput is shorter or lower than the period or throughput stated in the O&M plan required by 63.7800, this new shorter period or lower limit shall be placed in the O&M plan as the work practice limit.

(m) For each blast furnace casthouse, you must conduct subsequent hydrogen chloride and total hydrocarbon testing every 5 years.

■ 11. Amend § 63.7823 by revising paragraph (a) and adding paragraphs (c)(3), (d)(6), and (f) through (h) to read as follows:

§ 63.7823 What test methods and other procedures must I use to demonstrate initial compliance with the opacity limits?

(a) For each discharge end of a sinter plant, sinter plant cooler, blast furnace casthouse, BOPF shop, and large bell on a blast furnace, you must conduct each performance test that applies to your affected source based on representative performance (*i.e.,* performance based on normal operating conditions) of the affected source for the period being tested, according to the conditions detailed in paragraphs (b) through (d) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

(c) * * *

(3) For the blast furnace casthouse, make observations at each opening:

(i) If EPA Method 9 is used, observations should be made separately at each opening.

(ii) If ASTM D7520–16 (incorporated by reference, see § 63.14) is used, observations may be read for more than one opening at the same time.

(d) * * *

(6) Make observations at each opening:

(i) If EPA Method 9 in appendix A–4 to part 60 of this chapter is used, observations should be made separately at each opening.

(ii) If ASTM D7520–16 (incorporated by reference, see § 63.14) is used, observations may be read for more than one opening at the same time.

* * * * *

(f) To determine compliance with the applicable opacity limit in table 1 to this subpart for planned bleeder valve openings at a blast furnace:

(1) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A–4 to part 60 of this chapter. Alternatively, ASTM D7520–16 (incorporated by reference, see § 63.14) may be used with the following conditions:

(i) During the DCOT certification procedure outlined in Section 9.2 of ASTM D7520–16 (incorporated by reference, see § 63.14), the owner or operator or the DCOT vendor must be present the plumes in front of various backgrounds of color and contrast representing conditions anticipated during field use such as blue sky, trees, and mixed backgrounds (clouds and/or a sparse tree stand).

(ii) The owner or operator must also have standard operating procedures in place including daily or other frequency quality checks to ensure the equipment is within manufacturing specifications as outlined in Section 8.1 of ASTM D7520–16 (incorporated by reference, see § 63.14).

(iii) The owner or operator must follow the recordkeeping procedures outlined in § 63.10(b)(1) for the DCOT certification, compliance report, data sheets, and all raw unaltered JPEGs used for opacity and certification determination.

(iv) The owner or operator or the DCOT vendor must have a minimum of four independent technology users apply the software to determine the visible opacity of the 300 certification plumes. For each set of 25 plumes, the user may not exceed 15-percent opacity of any one reading and the average error must not exceed 7.5-percent opacity.

(v) Use of this approved alternative does not provide or imply a certification or validation of any vendor's hardware or software. The onus to maintain and verify the certification and/or training of the DCOT camera, software, and operator in accordance with ASTM D7520–16 (incorporated by reference, see § 63.14) and these requirements is on the facility, DCOT operator, and DCOT vendor.

(2) Conduct opacity observations in 6-minute block averages starting as soon as event begins or sunrise whichever is later and ending either when the bleeder valve closes, sunset, or after the first 6-minute block average where all readings are zero percent opacity, but in no case shall the opacity observation period be less than 6 minutes.

(g) To determine compliance with the applicable opacity limit in table 1 to this subpart for slag processing, handling, and storage operations for a blast furnace or BOPF:

(1) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A–4 to part 60 of this chapter.

(2) Conduct opacity observations in 6-minute blocks for 30 minutes at each: slag dumping to BF pit; BOPF slag dumping to pit; BF pit digging, BOPF pit digging; slag dumping to a pile, slag

dumping to a piece of slag handling equipment such as crusher.

(h) To determine compliance with the work practice trigger for large bells on a blast furnace:

(1) Using a certified observer, determine the opacity of emissions according to EPA Method 9 in appendix A–4 to part 60 of this chapter.

(2) Conduct opacity observations of 15 instantaneous interbell relief valve emissions.

■ 12. Amend § 63.7825 by:

■ a. Revising the section heading, paragraph (a) introductory text, and paragraphs (b)(1)(v), (b)(2), and (c); and

■ b. Adding paragraphs (g) through (k).

The revisions and additions read as follows:

§ 63.7825 What test methods and other procedures must I use to demonstrate initial compliance with the emission limits for hazardous air pollutants?

(a) If demonstrating compliance with the emission limits in Table 1 to this subpart through performance testing, you must conduct a performance test to demonstrate initial compliance with the emission limit. If demonstrating compliance with the emission limit through performance testing, you must conduct each performance test that applies to your affected source based on representative performance (*i.e.,* performance based on normal operating conditions) of the affected source for the period being tested, according to the conditions detailed in paragraphs (b) through (k) of this section. Representative conditions exclude periods of startup and shutdown. You shall not conduct performance tests during periods of malfunction. Initial compliance tests must be conducted by the deadlines in § 63.7820(e).

* * * * *

(b) * * *

(1) * * *

(v) EPA Method 29 or 30B in appendix A–8 to part 60 of this chapter to determine the concentration of mercury from the exhaust stream stack of each unit. If performing measurements using EPA Method 29, you must collect a minimum sample volume of 1.7 dscm (60 dscf). Alternative test methods may be considered on a case-by-case basis per § 63.7(f).

(2) Three valid test runs are needed to comprise a performance test of each unit in table 1 to this subpart as applicable. If the performance testing results for any of the emission points yields a non-detect value, then the method detection limit (MDL) must be used to calculate the mass emissions (lb) for that emission unit and, in turn, for calculating the sum of the emissions (in units of pounds of mercury per ton of steel scrap or pounds of mercury per ton of product sinter) for all units subject to the emission standard for determining compliance. If the resulting mercury emissions are greater than the MACT emission standard, the owner or operator may use procedures that produce lower MDL results and repeat the mercury performance testing one additional time for any emission point for which the measured result was below the MDL. If this additional testing is performed, the results from that testing must be used to determine compliance (*i.e.,* there are no additional opportunities allowed to lower the MDL).

* * * * *

(c) Calculate the mass emissions, based on the average of three test run values, for each BOPF Group unit (or combination of units that are ducted to a common stack and are tested when all affected sources are operating pursuant to paragraph (a) of this section) using equation 1 to this paragraph (c) as follows:

Equation 1 to paragraph (c)

$$E = \frac{C_s \times Q \times t}{454{,}000 \times 35.31} \quad \text{(Eq. 1)}$$

Where:

E = Mass emissions of pollutant, pounds (lb);
C_s = Concentration of pollutant in stack gas, mg/dscm;
454,000 = Conversion factor (mg/lb);
Q = Volumetric flow rate of stack gas, dscf/min;
35.31 = Conversion factor (dscf/dscm); and
t = Duration of test, minutes.

* * * * *

(g) To demonstrate compliance with the emission limit for hydrogen chloride in table 1 to this subpart through performance testing, follow the test methods and procedures in paragraphs (g)(1) through (3) of this section.

(1) Determine the concentration of hydrogen chloride according to the following test methods:

(i) The methods specified in paragraphs (b)(1)(i) through (iv) of this section, and

(ii) EPA Method 26A in appendix A–8 to part 60 of this chapter to determine the concentration of hydrogen chloride from the exhaust stream stack of each unit, with the following conditions; or

(A) Collect a minimum sample volume of 70 dscf (2 dscm) of gas during each run.

(B) [Reserved]

(iii) EPA Method 320 in appendix A to this part to determine the concentration of hydrogen chloride and hydrogen fluoride from the exhaust stream stack of each unit. Alternatively, ASTM D6348–12(R2020), (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) The test plan preparation and implementation in the Annexes to ASTM D 6348–12(R2020), Annexes A1 through A8 are mandatory; and

(B) In ASTM D6348–12(R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be 70% ≥ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the equation 2 o to this paragraph (g)(1)(iii)(B) as follows:

Equation 2 to paragraph (g)(1)(iii)(B)

$$Reported\ Results = \frac{c_S}{\%R} \times 100 \quad \text{(Eq. 2)}$$

Where

c_s = measured concentration in stack.

(2) At least three valid test runs are needed to comprise a performance test of each unit in table 1 to this subpart. If the performance testing results for any of the emission points yields a non-detect value, then the MDL must be used to calculate the mass emissions (lb) for that unit and, in turn, for calculating the emissions rate (lb/ton of product sinter, lb/ton of iron, or lb/ton of steel).

(3) Calculate the emissions from each new and existing affected source in pounds of hydrogen chloride per ton of throughput processed or unit of energy (tons of product sinter, tons of iron, tons of steel, or MMBtu) to determine initial compliance with the emission limits in table 1 to this subpart.

(h) To demonstrate compliance with the emission limit for carbonyl sulfide in table 1 to this subpart through performance testing, follow the test methods and procedures in paragraphs (h)(1) through (3) of this section.

(1) Determine the concentration of carbonyl sulfide according to the following test methods:

(i) The methods specified in paragraphs (b)(1)(i) through (iv) of this section, and

(ii) EPA Method 15 in appendix A–5 to part 60 of this chapter to determine the concentration of carbonyl sulfide from the exhaust stream stack of each unit; or

(iii) EPA Method 320 in appendix A to this part to determine the concentration of carbon disulfide and carbonyl sulfide from the exhaust stream stack of each unit. Alternatively, ASTM D6348–12 (R2020), (incorporated by reference, see § 63.14) may be used with the following conditions:

(A) The test plan preparation and implementation in the Annexes to ASTM D 6348–12 (R2020), Annexes A1 through A8 are mandatory; and

(B) In ASTM D6348–12 (R2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be 70% ≥ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the Equation 2 of this section.

(2) Three valid test runs at least one hour in duration are needed to comprise a performance test of each unit in table 1 to this subpart. If the performance testing results for any of the emission points yields a non-detect value, then the MDL must be used to calculate the mass emissions (lb) for that unit and, in turn, for calculating the emissions rate (lb/ton of product sinter).

(3) Calculate the emissions from each new and existing affected source in pounds of carbonyl sulfide per ton of product sinter to determine initial compliance with the emission limits in table 1 to this subpart .

(i) To demonstrate compliance with the emission limit for total hydrocarbons in table 1 to this subpart through performance testing, follow the test methods and procedures in paragraphs (i)(1) through (5) of this section.

(1) Determine the concentration of total hydrocarbons according to the following test methods:

(i) The methods specified in paragraphs (b)(1)(i) through (iv) of this section, and

(ii) EPA Method 25A in appendix A–7 to part 60 of this chapter to determine the concentration of total hydrocarbons as propane from the exhaust stream stack of each unit.

(2) Three valid test runs at least one hour in duration are needed to comprise a performance test of each unit in table 1 to this subpart. If the performance testing results for any of the emission points yields a non-detect value, then the MDL must be used to calculate the mass emissions (lb) for that unit and, in turn, for calculating the emissions rate (lb/ton of iron or lb/ton of steel).

(3) For BOPF tests, the test runs must include at least one full production cycle (from scrap charge to 3 minutes after slag is emptied from the vessel) for each run, except for BOPF with closed hood systems, where sampling should be performed only during the primary oxygen blow and only for 20 heat cycles.

(4) For blast furnaces, each test run duration must be a minimum of 1 hour.

(5) Calculate the emissions from each new and existing affected source in pounds of total hydrocarbons as propane per ton of throughput processed or unit of energy (tons of iron, tons of steel, or MMBtu) to determine initial compliance with the emission limits in table 1 to this subpart.

(j) To demonstrate compliance with the emission limit for D/F TEQ in table 1 to this subpart through performance testing, follow the test methods and procedures in paragraphs (j)(1) through (4) of this section.

(1) Determine the concentration of each dioxin and furan listed in table 5 to this subpart according to the following test methods:

(i) The methods specified in paragraphs (b)(1)(i) through (iv) of this section, and

(ii) EPA Method 23 in appendix A–7 to part 60 of this chapter to determine the concentration of each dioxin and furan listed in table 5 to this subpart from the exhaust stream stack of each unit. You must collect a minimum sample volume of 105 dscf (3 dscm) of gas during each test run.

(2) Three valid test runs are needed to comprise a performance test of each unit in table 1 to this subpart. For determination of TEQ, zero may be used in subsequent calculations for values less than the estimated detection limit (EDL). For estimated maximum pollutant concentration (EMPC) results, when the value is greater than the EDL, the EMPC value must be used in determination of TEQ, when the EMPC is less than the EDL, zero may be used.

(3) For BOPF tests, the test runs must include at least one full production cycle (from scrap charge to 3 minutes after slag is emptied from the vessel) for each run, except for BOPF with closed hood systems, where sampling should be performed only during the primary oxygen blow and only for 20 heat cycles or the collection of 105 dscf (3 dscm) sample volume, whichever is less.

(4) Calculate the sum of the D/F TEQ per ton of throughput processed (tons of product sinter or tons of steel) to determine initial compliance with the emission limits in table 1 using equation 3 to this paragraph (j)(4) as follows:

Equation 3 to paragraph (j)(4)

$$TEQ = \frac{\sum_{i=1}^{n}(M_i \times TEF_i)}{T_r \times P} \text{ (Eq. 3)}$$

Where:

TEQ = sum of the 2,3,7,8-TCDD TEQs, lb/ton of throughput processed

M_i = mass of dioxin or furan cogener i during performance test run, lbs

TEF_i = 2,3,7,8-TCDD toxic equivalency factor (TEF) for cogener i, as provided in Table 5 of this subpart

n = number of cogeners included in TEQ

T_r = time of performance test run, hours

P = production rate during performance test run, tons of throughput processed per hour.

(k) To demonstrate compliance with the emission limit for polycyclic aromatic hydrocarbons in table 1 to this subpart through performance testing, follow the test methods and procedures in paragraphs (k)(1) through (3) of this section.

(1) Determine the concentration of each polycyclic aromatic hydrocarbon listed in table 6 to this subpart according to the following test methods:

(i) The methods specified in paragraphs (b)(1)(i) through (iv) of this section, and

(ii) EPA Method 23 in appendix A–7 to part 60 of this chapter to determine the concentration of each polycyclic aromatic hydrocarbon listed in table 6 to this subpart from the exhaust stream stack of each unit. You must collect a minimum sample volume of 105 dscf (3 dscm) of gas during each test run.

(2) Three valid test runs are needed to comprise a performance test of each unit in table 1 to this subpart. If the performance testing results for any of the emission points yields a non-detect value, then the EDL must be used to calculate the mass emissions (lb) for that unit and, in turn, for calculating the emissions rate (lb/ton of product sinter).

(3) Calculate the sum of polycyclic aromatic hydrocarbons per ton of product sinter to determine initial compliance with the emission limits in table 1 to this subpart using equation 4 to this paragraph (k)(3) as follows:

Equation 4 to paragraph (k)(3)

$$E = \frac{\sum_{i=1}^{n} M_i}{T_r \times P} \text{ (Eq. 4)}$$

Where:

E = emission rate of polycyclic aromatic hydrocarbons, lb/ton of sinter

M_i = mass of polycyclic aromatic hydrocarbon i, as provided in Table 6 to this subpart, during performance test run, lbs

n = number of polycyclic aromatic hydrocarbons included in emissions

T_r = time of performance test run, hours

P = production rate during performance test run, tons of product sinter per hour.

■ 13. Amend § 63.7830 by revising paragraph (e)(2) to read as follows:

§ 63.7830 What are my monitoring requirements?

* * * * *

(e) * * *

(2) Compute and record the 30-day rolling average of the volatile organic compound emissions (lbs/ton of sinter) for each operating day using the procedures in § 63.7824(e).

■ 14. Amend § 63.7833 by adding paragraph (j) to read as follows:

§ 63.7833 How do I demonstrate continuous compliance with the emission limitations that apply to me?

* * * * *

* * * * *

(j) For large bells on each blast furnace, you must demonstrate continuous compliance by following the requirements specified in paragraphs (j)(1) and (2) of this section if a bell seal exceeds a 20 percent average of 3 instantaneous opacity readings of the interbell relief valve emissions.

(1) Initiate corrective action within five business days.

(2) Ten business days after the initial opacity exceedance of 20 percent, if the average of 3 instantaneous visible emissions readings from this test exceeds 20 percent, you must repair or replace that bell seal within 4 months.

■ 15. Amend § 63.7840 by removing paragraphs (g)(3) and (h)(3) and adding paragraph (i).

The addition reads as follows:

§ 63.7840 What notifications must I submit and when?

* * * * *

(i) Confidential business information (CBI): For notifications and reports required to be submitted to CEDRI:

(1) The EPA will make all the information submitted through CEDRI available to the public without further notice to you. Do not use CEDRI to submit information you claim as CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (h) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA.

(2) The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website.

(3) Clearly mark the part or all of the information that you claim to be CBI. Information not marked as CBI may be authorized for public release without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

(4) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings and be flagged to the attention of the Group Leader, Measurement Policy Group. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link.

(5) If you cannot transmit the file electronically, you may send CBI information through the postal service to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection

Agency, Research Triangle Park, North Carolina 27711, Attention Group Leader, Measurement Policy Group. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

(6) All CBI claims must be asserted at the time of submission. Anything submitted using CEDRI cannot later be claimed CBI. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

(7) You must submit the same file submitted to the CBI office with the CBI omitted to the EPA via the EPA's CDX as described in paragraphs (g) or (h) of this section.

■ 16. Amend § 63.7841 by adding paragraph (b)(14), revising paragraph (d), and adding paragraph (h) to read as follows:

§ 63.7841 What reports must I submit and when?

* * * * *

(b) * * *

(14) For each unplanned bleeder valve opening for each blast furnace, you must include the information in paragraphs (b)(14)(i) through (iii) of this section.

(i) The date and time of the event.

(ii) The duration of the event.

(iii) Any corrective actions taken in response to the event.

* * * * *

(d) *CEDRI submission.* If you are required to submit reports following the procedure specified in this paragraph, you must submit reports to the EPA via CEDRI, which can be accessed through EPA's CDX (*https://cdx.epa.gov/*). You must use the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. Do not use CEDRI to submit information you claim as CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information in the report, you must submit a complete file, including information claimed to be CBI, to the EPA following the procedures in paragraphs (d)(1) and (2) of this section. Clearly mark the part or all of the information that you claim to be CBI. Information not marked as CBI may be authorized for public release without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. All CBI claims must be asserted at the time of submission. Anything submitted using CEDRI cannot later be claimed CBI. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available. You must submit the same file submitted to the CBI office with the CBI omitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(1) The preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol, or other online file sharing services. Electronic submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings and be flagged to the attention of the Integrated Iron and Steel Sector Lead. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link.

(2) If you cannot transmit the file electronically, you may send CBI information through the postal service to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Integrated Iron and Steel Sector Lead. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

* * * * *

(h) *Fenceline monitoring reports.* For fenceline monitoring systems subject to § 63.7792, each owner or operator must submit Fenceline Monitoring Reports on a quarterly basis using the appropriate electronic report template on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/cedri*) for this subpart and following the procedure specified in paragraph (d) of this section. The first quarterly report must be submitted once the owner or operator has obtained 12 months of data. The first quarterly report must cover the period beginning on the date one year after the promulgation of the metals fenceline method and ending on March 31, June 30, September 30 or December 31, whichever date is the first date that occurs after the owner or operator has obtained 12 months of data (*i.e.,* the first quarterly report will contain between 12 and 15 months of data). Each subsequent quarterly report must cover one of the following reporting periods: Quarter 1 from January 1 through March 31; Quarter 2 from April 1 through June 30; Quarter 3 from July 1 through September 30; and Quarter 4 from October 1 through December 31. Each quarterly report must be electronically submitted no later than 45 calendar days following the end of the reporting period.

(1) Facility name and address.

(2) Year and reporting quarter (*i.e.,* Quarter 1, Quarter 2, Quarter 3, or Quarter 4).

(3) For each sampler: The latitude and longitude location coordinates; the sampler name; and identification of the type of sampler (*e.g.,* regular monitor, extra monitor, duplicate, field blank, inactive). Coordinates shall be in decimal degrees with at least five decimal places.

(4) The beginning and ending dates for each sampling period.

(5) Individual sample results for each monitored compound, reported in units of $\mu g/m^3$, for each monitor for each sampling period that ends during the reporting period. Results below the method detection limit shall be flagged as below the detection limit and reported at the method detection limit.

(6) Data flags for each outlier determined in accordance with the fenceline metals method. For each outlier, the owner or operator must submit the individual sample result of the outlier, as well as the evidence used to conclude that the result is an outlier.

(7) The biweekly concentration difference (Δc) for each sampling period and the annual average Δc for each sampling period.

(8) Indication of whether the owner or operator was required to develop a corrective action plan under § 63.7792(e).

■ 17. Amend § 63.7842 by revising paragraph (d) and adding paragraphs (f) and (g) to read as follows.

§ 63.7842 What records must I keep?

* * * * *

(d) You must keep the records required in §§ 63.7823, 63.7833, and 63.7834 to show continuous compliance with each emission limitation and operation and maintenance requirement that applies to you. This includes a record of each large and small bell repair and replacement, a record of the date on which the large bell opacity has

exceeded 20 percent, and the most current time period or throughput over which no opacity was observed from the small bell.

* * * * *

(f) For fenceline monitoring systems subject to § 63.7792 of this subpart, each owner or operator must keep the records specified in paragraphs (f)(1) through (11) of this section.

(1) Coordinates of samplers, including co-located samplers and field blanks, and if applicable, the meteorological station. The owner or operator shall determine the coordinates using an instrument with an accuracy of at least 3 meters. The coordinates shall be in decimal degrees with at least five decimal places.

(2) The start and stop times and dates for each sample, as well as the sample identifying information.

(3) Sampling period average temperature and barometric pressure measurements.

(4) For each outlier determined in accordance with the procedures specified in the fenceline metals method, the sampler location and the concentration of the outlier and the evidence used to conclude that the result is an outlier.

(5) For samples that will be adjusted for uniform background, the location of and the concentration measured simultaneously by the background sampler, and the perimeter samplers to which it applies.

(6) Individual sample results, the calculated Δc for each sampling period and the two samples used to determine it, whether background correction was used, and the annual average Δc calculated after each sampling period.

(7) Method detection limit for each sample, including co-located samples and blanks.

(8) Documentation of the root cause analysis and any resulting corrective action taken each time an action level is exceeded, including the dates the root cause analysis was initiated and the resulting correction action(s) were taken.

(9) Any corrective action plan developed under § 63.7792(e).

(10) Other records as required by the sampling method.

(11) If a near-field source correction is used as provided in § 63.7792(f), or if an alternative test method is used that provides time-resolved measurements, records of hourly meteorological data, including temperature, barometric pressure, wind speed and wind direction, calculated daily unit vector wind direction, and daily sigma theta, and other records specified in the site-specific monitoring plan.

(g) For each unplanned bleeder valve opening for each blast furnace, you must keep the records specified in paragraphs (g)(1) through (3) of this section.

(1) The start date and start time of the event.

(2) The duration of the event in minutes.

(3) Any corrective actions taken in response to the event.

■ 18. Amend § 63.7852 by adding definitions for ''Iron beaching operation'', Large blast furnace'', ''Planned bleeder valve opening'', ''Slip'', ''Small blast furnace'', ''Total hydrocarbons (THC)'', and ''Unplanned bleeder valve opening'' to read as follows:

§ 63.7852 What definitions apply to this subpart?

* * * * *

Iron beaching operation means pouring hot molten iron from a torpedo car onto the ground when the iron from the blast furnace cannot be charged to the basic oxygen process furnace.

* * * * *

Large blast furnace means a blast furnace with a working volume of greater than 2,500 m^3.

* * * * *

Planned bleeder valve opening means the opening of a blast furnace pressure relief safety valve that is initiated by an operator.

* * * * *

Slip means when raw materials loaded in the top of the furnace fail to descend smoothly in the furnace and bind together to form a ''bridge'' which than ''hangs'' (*i.e.,* accumulates) in one position in the furnace. When a ''hang'' eventually falls, or ''slips,'' it creates a pressure surge that may open the bleeder valves, releasing emissions in the form of a large dust cloud.

Small blast furnace means a blast furnace with a working volume of less than 2,500 m^3.

* * * * *

Total hydrocarbons (THC) means the sum of organic compounds measured as carbon using EPA Method 25A (appendix A–7 to part 60 of this chapter).

Unplanned bleeder valve opening means the opening of a blast furnace pressure relief safety valve that is not a planned bleeder valve opening.

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■ 19. Revise tables 1 through 4 to subpart FFFFF to read as follows:

Table 1 to Subpart FFFFF of Part 63—Emission, Opacity, and Work Practice Limits

As required in § 63.7790(a), you must comply with each applicable emission, opacity, and work practice limit in the following table:

For . . .	You must comply with each of the following . . .
1. Each windbox exhaust stream at an existing sinter plant.	a. You must not cause to be discharged to the atmosphere any gases that contain particulate matter in excess of 0.4 lb/ton of product sinter; b. You must not cause to be discharged to the atmosphere any gases that contain mercury in excess of 0.000018 lb/ton of product sinter; c. You must not cause to be discharged to the atmosphere any gases that contain hydrogen chloride in excess of 0.025 lb/ton of product sinter; d. You must not cause to be discharged to the atmosphere any gases that contain carbonyl sulfide in excess of 0.064 lb/ton of product sinter; e. You must not cause to be discharged to the atmosphere any gases that contain D/F TEQs in excess of 1.1E–08 lb/ton of product sinter; and f. You must not cause to be discharged to the atmosphere any gases that contain polycyclic aromatic hydrocarbons in excess of 0.0018 lb/ton of product sinter.
2. Each windbox exhaust stream at a new sinter plant.	a. You must not cause to be discharged to the atmosphere any gases that contain particulate matter in excess of 0.3 lb/ton of product sinter; b. You must not cause to be discharged to the atmosphere any gases that contain mercury in excess of 0.000012 lb/ton of product sinter; c. You must not cause to be discharged to the atmosphere any gases that contain hydrogen chloride in excess of 0.0012 lb/ton of product sinter; d. You must not cause to be discharged to the atmosphere any gases that contain carbonyl sulfide in excess of 0.030 lb/ton of product sinter; e. You must not cause to be discharged to the atmosphere any gases that contain D/F TEQs in excess of 1.1E–08 lb/ton of product sinter; and

For . . .	You must comply with each of the following . . .
	f. You must not cause to be discharged to the atmosphere any gases that contain polycyclic aromatic hydrocarbons in excess of 0.0015 lb/ton of product sinter.
3. Each discharge end at an existing sinter plant.	a. You must not cause to be discharged to the atmosphere any gases that exit from one or more control devices that contain, on a flow-weighted basis, particulate matter in excess of 0.02 gr/dscf; [1] [2] and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the building or structure housing the discharge end that exhibit opacity greater than 20 percent (6-minute average).
4. Each discharge end at a new sinter plant.	a. You must not cause to be discharged to the atmosphere any gases that exit from one or more control devices that contain, on a flow weighted basis, particulate matter in excess of 0.01 gr/dscf; and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the building or structure housing the discharge end that exhibit opacity greater than 10 percent (6-minute average).
5. Each sinter cooler at an existing sinter plant.	You must not cause to be discharged to the atmosphere any emissions that exhibit opacity greater than 10 percent (6-minute average).
6. Each sinter cooler at a new sinter plant.	You must not cause to be discharged to the atmosphere any gases that contain particulate matter in excess of 0.01 gr/dscf.
7. Each casthouse at an existing blast furnace.	a. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.01 gr/dscf; [2] b. You must not cause to be discharged to the atmosphere any secondary emissions that exit all openings in the casthouse or structure housing the blast furnace that exhibit opacity greater than 20 percent (6-minute average); c. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain hydrogen chloride in excess of 0.0056 lb/ton of iron; d. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain total hydrocarbons as propane in excess of 0.48 lb/ton of iron; and e. You must not cause unplanned bleeder valve openings in excess of 4 events per year for large blast furnaces or 15 events per year for small blast furnaces.
8. Each casthouse at a new blast furnace.	a. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.003 gr/dscf; and b. You must not cause to be discharged to the atmosphere any secondary emissions that exit all openings in the casthouse or structure housing the blast furnace that exhibit opacity greater than 15 percent (6-minute average); c. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain hydrogen chloride in excess of 0.00059 lb/ton of iron; d. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain total hydrocarbons as propane in excess of 0.035 lb/ton of iron; and e. You must not cause unplanned bleeder valve openings in excess of zero events per year.
9. Each BOPF at a new or existing shop	a. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF with a closed hood system at a new or existing BOPF shop that contain, on a flow-weighted basis, particulate matter in excess of 0.03 gr/dscf during the primary oxygen blow; [2] [3] b. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF with an open hood system that contain, on a flow-weighted basis, particulate matter in excess of 0.02 gr/dscf during the steel production cycle for an existing BOPF shop [2] [3] or 0.01 gr/dscf during the steel production cycle for a new BOPF shop; [3] c. You must not cause to be discharged to the atmosphere any gases that exit from a control device used solely for the collection of secondary emissions from the BOPF that contain particulate matter in excess of 0.01 gr/dscf for an existing BOPF shop [2] or 0.0052 gr/dscf for a new BOPF shop; d. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF that contain hydrogen chloride in excess of 0.058 lb/ton of steel for existing sources and 2.8E–04 lb/ton steel for new sources; e. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF that contain THC as propane in excess of 0.04 lb/ton of steel for existing sources and 0.0017 lb/ton of steel for new sources; and f. You must not cause to be discharged to the atmosphere any gases that exit from a primary emission control system for a BOPF that contain D/F TEQs in excess of 9.2E–10 lb/ton of steel.
10. Each hot metal transfer, skimming, and desulfurization operation at a new or existing BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.01 gr/dscf for an existing BOPF shop [2] or 0.003 gr/dscf for a new BOPF shop.
11. Each ladle metallurgy operation at a new or existing BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain particulate matter in excess of 0.01 gr/dscf for an existing BOPF shop [2] or 0.004 gr/dscf for a new BOPF shop.
12. Each existing BOPF shop	You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the BOPF shop or any other building housing the BOPF or BOPF shop operation that exhibit opacity greater than 20 percent (3-minute average).
13. Each new BOPF shop	a. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the BOPF shop or other building housing a bottom-blown BOPF or BOPF shop operations that exhibit opacity (for any set of 6-minute averages) greater than 10 percent, except that one 6-minute period not to exceed 20 percent may occur once per steel production cycle; or b. You must not cause to be discharged to the atmosphere any secondary emissions that exit any opening in the BOPF shop or other building housing a top-blown BOPF or BOPF shop operations that exhibit opacity (for any set of 3-minute averages) greater than 10 percent, except that one 3-minute period greater than 10 percent but less than 20 percent may occur once per steel production cycle.
14. Each BOPF Group at an existing BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from the collection of BOPF Group control devices that contain mercury in excess of 0.00026 lb/ton of steel scrap input to the BOPF.
15. Each BOPF Group at a new BOPF shop.	You must not cause to be discharged to the atmosphere any gases that exit from the collection of BOPF Group control devices that contain mercury in excess of 0.000081 lb/ton of steel scrap input to the BOPF.
16. Each planned bleeder valve opening at a new or existing blast furnace.	You must not cause to be discharged to the atmosphere any emissions that exhibit opacity greater than 8 percent (6-minute average).
17. Each slag processing, handling and storage operation for a new or existing blast furnace or BOPF.	You must not cause to be discharged to the atmosphere any emissions that exhibit opacity greater than 10 percent (6-minute average).
18. Each existing blast furnace stove	a. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain HCl in excess of 0.0012 lb/MMBtu; and b. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain THC in excess of 0.12 lb/MMBtu.
19. Each new blast furnace stove	a. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain HCl in excess of 4.2e–4 lb/MMBtu; and

For . . .	You must comply with each of the following . . .
	b. You must not cause to be discharged to the atmosphere any gases that exit from a control device that contain THC in excess of 0.0054 lb/MMBtu.

[1] This limit applies if the cooler is vented to the same control device as the discharge end.
[2] This concentration limit (gr/dscf) for a control device does not apply to discharges inside a building or structure housing the discharge end at an existing sinter plant, inside a casthouse at an existing blast furnace, or inside an existing BOPF shop if the control device was installed before August 30, 2005.
[3] This limit applies to control devices operated in parallel for a single BOPF during the oxygen blow.

Table 2 to Subpart FFFFF of Part 63—Initial Compliance With Emission and Opacity Limits

As required in § 63.7826(a)(1), you must demonstrate initial compliance with the emission and opacity limits according to the following table:

For . . .	You have demonstrated initial compliance if . . .
1. Each windbox exhaust stream at an existing sinter plant.	a. The process-weighted mass rate of particulate matter from a windbox exhaust stream, measured according to the performance test procedures in § 63.7822(c), did not exceed 0.4 lb/ton of product sinter; b. The process-weighted mass rate of mercury from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.000018 lb/ton of product sinter; c. The process-weighted mass rate of hydrogen chloride from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.025 lb/ton of product sinter; d. The process-weighted mass rate of carbonyl sulfide from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.064 lb/ton of product sinter; e. The process-weighted mass rate of D/F TEQs from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 1.1E–08 lb/ton of product sinter; and f. The process-weighted mass rate of polycyclic aromatic hydrocarbons from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.0018 lb/ton of product sinter.
2. Each windbox exhaust stream at a new sinter plant.	a. The process-weighted mass rate of particulate matter from a windbox exhaust stream, measured according to the performance test procedures in § 63.7822(c), did not exceed 0.3 lb/ton of product sinter; b. The process-weighted mass rate of mercury from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.000012 lb/ton of product sinter; c. The process-weighted mass rate of hydrogen chloride from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.0012 lb/ton of product sinter; d. The process-weighted mass rate of carbonyl sulfide from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.030 lb/ton of product sinter; e. The process-weighted mass rate of D/F TEQs from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 1.1E–08 lb/ton of product sinter; and f. The process-weighted mass rate of polycyclic aromatic hydrocarbons from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.0015 lb/ton of product sinter.
3. Each discharge end at an existing sinter plant.	a. The flow-weighted average concentration of particulate matter from one or more control devices applied to emissions from a discharge end, measured according to the performance test procedures in § 63.7822(d), did not exceed 0.02 gr/dscf; and b. The opacity of secondary emissions from each discharge end, determined according to the performance test procedures in § 63.7823(c), did not exceed 20 percent (6-minute average).
4. Each discharge end at a new sinter plant.	a. The flow-weighted average concentration of particulate matter from one or more control devices applied to emissions from a discharge end, measured according to the performance test procedures in § 63.7822(d), did not exceed 0.01 gr/dscf; and b. The opacity of secondary emissions from each discharge end, determined according to the performance test procedures in § 63.7823(c), did not exceed 10 percent (6-minute average).
5. Each sinter cooler at an existing sinter plant.	The opacity of emissions, determined according to the performance test procedures in § 63.7823(e), did not exceed 10 percent (6-minute average).
6. Each sinter cooler at a new sinter plant.	The average concentration of particulate matter, measured according to the performance test procedures in § 63.7822(b), did not exceed 0.01 gr/dscf.
7. Each casthouse at an existing blast furnace.	a. The average concentration of particulate matter from a control device applied to emissions from a casthouse, measured according to the performance test procedures in § 63.7822(e), did not exceed 0.01 gr/dscf; b. The opacity of secondary emissions from each casthouse, determined according to the performance test procedures in § 63.7823(c), did not exceed 20 percent (6-minute average); c. The process-weighted mass rate of hydrogen chloride from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.0056 lb/ton of iron; d. The process-weighted mass rate of total hydrocarbons from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.48 lb/ton of iron; and e. The number of unplanned bleeder valve openings in one year, as reported according to the specifications in § 63.7841(b)(14), did not exceed 4 events for large blast furnaces or 15 events for small blast furnaces.
8. Each casthouse at a new blast furnace.	a. The average concentration of particulate matter from a control device applied to emissions from a casthouse, measured according to the performance test procedures in § 63.7822(e), did not exceed 0.003 gr/dscf; and b. The opacity of secondary emissions from each casthouse, determined according to the performance test procedures in § 63.7823(c), did not exceed 15 percent (6-minute average); c. The process-weighted mass rate of hydrogen chloride from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.00059 lb/ton of iron; d. The process-weighted mass rate of total hydrocarbons from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.035 lb/ton of iron; and e. The number of unplanned bleeder valve openings in one year, as reported according to the specifications in § 63.7841(b)(14), did not exceed zero events.
9. Each BOPF at a new or existing BOPF shop.	a. The average concentration of particulate matter from a primary emission control system applied to emissions from a BOPF with a closed hood system, measured according to the performance test procedures in § 63.7822(f), did not exceed 0.03 gr/dscf for a new or existing BOPF shop; b. The average concentration of particulate matter from a primary emission control system applied to emissions from a BOPF with an open hood system, measured according to the performance test procedures in § 63.7822(g), did not exceed 0.02 gr/dscf for an existing BOPF shop or 0.01 gr/dscf for a new BOPF shop;

For . . .	You have demonstrated initial compliance if . . .
	c. The average concentration of particulate matter from a control device applied solely to secondary emissions from a BOPF, measured according to the performance test procedures in § 63.7822(g), did not exceed 0.01 gr/dscf for an existing BOPF shop or 0.0052 gr/dscf for a new BOPF shop; d. The process-weighted mass rate of hydrogen chloride from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.058 lb/ton of steel for an existing BOPF shop or 0.00028 lb/ton of steel for a new BOPF shop; e. The process-weighted mass rate of total hydrocarbons from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.04 lb/ton of steel for an existing BOPF shop or 0.0017 lb/ton of steel for a new BOPF shop; and f. The process-weighted mass rate of D/F TEQs from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 9.2e–10 lb/ton of steel.
10. Each hot metal transfer skimming, and desulfurization at a new or existing BOPF shop.	The average concentration of particulate matter from a control device applied to emissions from hot metal transfer, skimming, or desulfurization, measured according to the performance test procedures in § 63.7822(h), did not exceed 0.01 gr/dscf for an existing BOPF shop or 0.003 gr/dscf for a new BOPF shop.
11. Each ladle metallurgy operation at a new or existing BOPF shop.	The average concentration of particulate matter from a control device applied to emissions from a ladle metallurgy operation, measured according to the performance test procedures in § 63.7822(h), did not exceed 0.01 gr/dscf for an existing BOPF shop or 0.004 gr/dscf for a new BOPF shop.
12. Each existing BOPF shop	The opacity of secondary emissions from each BOPF shop, determined according to the performance test procedures in § 63.7823(d), did not exceed 20 percent (3-minute average).
13. Each new BOPF shop	a. The opacity of the highest set of 6-minute averages from each BOPF shop housing a bottom-blown BOPF, determined according to the performance test procedures in § 63.7823(d), did not exceed 20 percent and the second highest set of 6-minute averages did not exceed 10 percent; or b. The opacity of the highest set of 3-minute averages from each BOPF shop housing a top-blown BOPF, determined according to the performance test procedures in § 63.7823(d), did not exceed 20 percent and the second highest set of 3-minute averages did not exceed 10 percent.
14. Each BOPF Group at an existing BOPF shop.	If demonstrating compliance through performance testing, the average emissions of mercury from the collection of BOPF Group control devices applied to the emissions from the BOPF Group, measured according to the performance test procedures in § 63.7825, did not exceed 0.00026 lb/ton steel scrap input to the BOPF.
15. Each BOPF Group at a new BOPF shop.	If demonstrating compliance through performance testing, the average emissions of mercury from the collection of BOPF Group control devices applied to the emissions from the BOPF Group, measured according to the performance test procedures in § 63.7825, did not exceed 0.000081 lb/ton steel scrap input to the BOPF.
16. Each planned bleeder valve opening at a new or existing blast furnace.	The opacity of emissions, determined according to the performance test procedures in § 63.7823(f), did not exceed 8 percent (6-minute average).
17. Each slag processing, handling and storage operation for a new or existing blast furnace or BOPF.	The opacity of emissions, determined according to the performance test procedures in § 63.7823(g), did not exceed 10 percent (6-minute average).
18. Each existing blast furnace stove	a. The process-weighted mass rate of HCl from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.0012 lb/MMBtu; and b. The process-weighted mass rate of THC from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.12 lb/MMBtu.
19. Each new blast furnace stove	a. The process-weighted mass rate of HCl from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 4.2e–4 lb/MMBtu; and b. The process-weighted mass rate of THC from a windbox exhaust stream, measured according to the performance test procedures in § 63.7825, did not exceed 0.0054 lb/MMBtu.

Table 3 to Subpart FFFFF of Part 63—Continuous Compliance With Emission and Opacity Limits

As required in § 63.7833(a), you must demonstrate continuous compliance with the emission and opacity limits according to the following table:

For . . .	You must demonstrate continuous compliance by . . .
1. Each windbox exhaust stream at an existing sinter plant.	a. Maintaining emissions of particulate matter at or below 0.4 lb/ton of product sinter; b. Conducting subsequent performance tests at the frequencies specified in § 63.7821; c. Maintaining emissions of mercury at or below 0.000018 lb/ton of product sinter; d. Maintaining emissions of hydrogen chloride at or below 0.025 lb/ton of product sinter; e. Maintaining emissions of carbonyl sulfide at or below 0.064 lb/ton of product sinter; f. Maintaining emissions of D/F TEQs at or below 1.1E–08 lb/ton of product sinter; and g. Maintaining emissions of polycyclic aromatic hydrocarbons at or below 0.0018 lb/ton of product sinter.
2. Each windbox exhaust stream at a new sinter plant.	a. Maintaining emissions of particulate matter at or below 0.3 lb/ton of product sinter; b. Conducting subsequent performance tests at the frequencies specified in § 63.7821; c. Maintaining emissions of mercury at or below 0.000012 lb/ton of product sinter; d. Maintaining emissions of hydrogen chloride at or below 0.0012 lb/ton of product sinter; e. Maintaining emissions of carbonyl sulfide at or below 0.030 lb/ton of product sinter; f. Maintaining emissions of D/F TEQs at or below 1.1E–08 lb/ton of product sinter; and g. Maintaining emissions of polycyclic aromatic hydrocarbons at or below 0.0015 lb/ton of product sinter.
3. Each discharge end at an existing sinter plant.	a. Maintaining emissions of particulate matter from one or more control devices at or below 0.02 gr/dscf; and b. Maintaining the opacity of secondary emissions that exit any opening in the building or structure housing the discharge end at or below 20 percent (6-minute average); and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
4. Each discharge end at a new sinter plant.	a. Maintaining emissions of particulate matter from one or more control devices at or below 0.01 gr/dscf; and b. Maintaining the opacity of secondary emissions that exit any opening in the building or structure housing the discharge end at or below 10 percent (6-minute average); and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
5. Each sinter cooler at an existing sinter plant.	a. Maintaining the opacity of emissions that exit any sinter cooler at or below 10 percent (6-minute average); and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
6. Each sinter cooler at a new sinter plant.	a. Maintaining emissions of particulate matter at or below 0.1 gr/dscf; and

For . . .	You must demonstrate continuous compliance by . . .
	b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
7. Each casthouse at an existing blast furnace.	a. Maintaining emissions of particulate matter from a control device at or below 0.01 gr/dscf; b. Maintaining the opacity of secondary emissions that exit all openings in the casthouse or structure housing the casthouse at or below 20 percent (6-minute average); c. Conducting subsequent performance tests at the frequencies specified in § 63.7821; d. Maintaining emissions of hydrogen chloride at or below 0.0056 lb/ton of iron; e. Maintaining emissions of total hydrocarbons at or below 0.48 lb/ton of iron; and f. Maintaining unplanned bleeder valve openings at or below 4 events per year for large blast furnaces or 15 events per year for small blast furnaces.
8. Each casthouse at a new blast furnace.	a. Maintaining emissions of particulate matter from a control device at or below 0.003 gr/dscf; b. Maintaining the opacity of secondary emissions that exit all openings in the casthouse or structure housing the casthouse at or below 15 percent (6-minute average); c. Conducting subsequent performance tests at the frequencies specified in § 63.7821; d. Maintaining emissions of hydrogen chloride at or below 0.00059 lb/ton of iron; e. Maintaining emissions of total hydrocarbons at or below 0.035 lb/ton of iron; and f. Maintaining unplanned bleeder valve openings at zero events per year.
9. Each BOPF at a new or existing BOPF shop.	a. Maintaining emissions of particulate matter from the primary control system for a BOPF with a closed hood system at or below 0.03 gr/dscf; b. Maintaining emissions of particulate matter from the primary control system for a BOPF with an open hood system at or below 0.02 gr/dscf for an existing BOPF shop or 0.01 gr/dscf for a new BOPF shop; c. Maintaining emissions of particulate matter from a control device applied solely to secondary emissions from a BOPF at or below 0.01 gr/dscf for an existing BOPF shop or 0.0052 gr/dscf for a new BOPF shop; d. Conducting subsequent performance tests at the frequencies specified in § 63.7821; e. Maintaining emissions of hydrogen chloride from a primary emission control system for a BOPF at or below 0.058 lb/ton of steel for existing sources and 2.8E–04 lb/ton steel for new sources; f. Maintaining emissions of THC from a primary emission control system for a BOPF at or below 0.04 lb/ton of steel for existing sources and 0.0017 lb/ton of steel for new sources; and g. Maintaining emissions of D/F TEQs from a primary emission control system for a BOPF at or below 9.2E–10 lb/ton of steel.
10. Each hot metal transfer, skimming, and desulfurization operation at a new or existing BOPF shop.	a. Maintaining emissions of particulate matter from a control device at or below 0.01 gr/dscf at an existing BOPF or 0.003 gr/dscf for a new BOPF; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
11. Each ladle metallurgy operation at a new or existing BOPF shop.	a. Maintaining emissions of particulate matter from a control device at or below 0.01 gr/dscf at an existing BOPF shop or 0.004 gr/dscf for a new BOPF shop; and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
12. Each existing BOPF shop	a. Maintaining the opacity of secondary emissions that exit any opening in the BOPF shop or other building housing the BOPF shop or shop operation at or below 20 percent (3-minute average); and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
13. Each new BOPF shop	a. Maintaining the opacity (for any set of 6-minute averages) of secondary emissions that exit any opening in the BOPF shop or other building housing a bottom-blown BOPF or shop operation at or below 10 percent, except that one 6-minute period greater than 10 percent but no more than 20 percent may occur once per steel production cycle; b. Maintaining the opacity (for any set of 3-minute averages) of secondary emissions that exit any opening in the BOPF shop or other building housing a top-blown BOPF or shop operation at or below 10 percent, except that one 3-minute period greater than 10 percent but less than 20 percent may occur once per steel production cycle; and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
14. Each BOPF Group at an existing BOPF shop.	a. Maintaining emissions of mercury from the collection of BOPF Group control devices at or below 0.00026 lb/ton steel scrap input to the BOPF; and b. If demonstrating compliance through performance testing, conducting subsequent performance tests at the frequencies specified in § 63.7821; and c. If demonstrating compliance through § 63.7791(c), (d), or (e), maintaining records pursuant to § 63.7842(e).
15. Each BOPF Group at a new BOPF shop.	a. Maintaining emissions of mercury from the collection of BOPF Group control devices at or below 0.000081 lb/ton steel scrap input to the BOPF; and b. If demonstrating compliance through performance testing, conducting subsequent performance tests at the frequencies specified in § 63.7821; and c. If demonstrating compliance through § 63.7791(c), (d), or (e), maintaining records pursuant to § 63.7842(e).
16. Each planned bleeder valve opening at a new or existing blast furnace.	a. Maintaining the opacity of emissions that exit any bleeder valve as a result of a planned opening at or below 8 percent (6-minute average); and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
17. Each slag processing, handling and storage operation for a new or existing blast furnace or BOPF.	a. Maintaining the opacity of emissions that exit any slag processing, handling, or storage operation at or below 10 percent (6-minute average); and b. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
18. Each existing blast furnace stove	a. Maintaining emissions of HCl at or below 0.0012 lb/MMBtu; b. Maintaining emissions of THC at or below 0.12 lb/MMBtu; and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.
19. Each new blast furnace stove	a. Maintaining emissions of HCl at or below 4.2e–4 lb/MMBtu; b. Maintaining emissions of THC at or below 0.0054 lb/MMBtu; and c. Conducting subsequent performance tests at the frequencies specified in § 63.7821.

Table 4 to Subpart FFFFF of Part 63—Applicability of General Provisions to Subpart FFFFF

As required in § 63.7850, you must comply with the requirements of the NESHAP General Provisions (subpart A of this part) shown in the following table:

Citation	Subject	Applies to subpart FFFFF	Explanation
§ 63.1	Applicability	Yes.	
§ 63.2	Definitions	Yes.	
§ 63.3	Units and Abbreviations	Yes.	

Citation	Subject	Applies to subpart FFFFF	Explanation
§ 63.4	Prohibited Activities	Yes.	
§ 63.5	Construction/Reconstruction	Yes.	
§ 63.6(a), (b), (c), (d), (e)(1)(iii), (f)(2)–(3), (g), (h)(2)(ii)–(h)(9).	Compliance with Standards and Maintenance Requirements.	Yes.	
§ 63.6(e)(1)(i)	General Duty to Minimize Emissions	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7810(d) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to Correct Malfunctions ASAP.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes, on or before January 11, 2021, and No thereafter.	
§ 63.6(e)(3)	SSM Plan Requirements	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7810(c).
§ 63.6(f)(1)	Compliance except during SSM	No	See § 63.7810(a).
§ 63.6(h)(1)	Compliance except during SSM	No	See § 63.7810(a).
§ 63.6(h)(2)(i)	Determining Compliance with Opacity and VE Standards.	No	Subpart FFFFF specifies methods and procedures for determining compliance with opacity emission and operating limits.
§ 63.6(i)	Extension of Compliance with Emission Standards.	Yes.	
§ 63.6(j)	Exemption from Compliance with Emission Standards.	Yes.	
§ 63.7(a)(1)–(2)	Applicability and Performance Test Dates.	No	Subpart FFFFF and specifies performance test applicability and dates.
§ 63.7(a)(3), (b)–(d), (e)(2)–(4), (f)–(h)	Performance Testing Requirements	Yes.	
§ 63.7(e)(1)	Performance Testing	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See §§ 63.7822(a), 63.7823(a), and 63.7825(a).
§ 63.8(a)(1)–(3), (b), (c)(1)(ii), (c)(2)–(3), (c)(4)(i)–(ii), (c)(5)–(6), (c)(7)–(8), (d)(1)–(2), (e), (f)(1)–(5), (g)(1)–(4).	Monitoring Requirements	Yes	CMS requirements in § 63.8(c)(4)(i)–(ii), (c)(5)–(6), (d)(1)–(2), and (e) apply only to COMS.
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Subpart FFFFF does not require flares.
§ 63.8(c)(1)(i)	General Duty to Minimize Emissions and CMS Operation.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	
§ 63.8(c)(1)(iii)	Requirement to Develop SSM Plan for CMS.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	
§ 63.8(c)(4)	Continuous Monitoring System Requirements.	No	Subpart FFFFF specifies requirements for operation of CMS.
§ 63.8(d)(3)	Written procedures for CMS	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7842(b)(3).
§ 63.8(f)(6)	RATA Alternative	No.	
§ 63.8(g)(5)	Data Reduction	No	Subpart FFFFF specifies data reduction requirements.
§ 63.9	Notification Requirements	Yes	Additional notifications for CMS in § 63.9(g) apply only to COMS.
§ 63.10(a), (b)(1), (b)(2)(x), (b)(2)(xiv), (b)(3), (c)(1)–(6), (c)(9)–(14), (d)(1)–(4), (e)(1)–(2), (e)(4), (f).	Recordkeeping and Reporting Requirements.	Yes	Additional records for CMS in § 63.10(c)(1)–(6), (9)–(14), and reports in § 63.10(d)(1)–(2) apply only to COMS.
§ 63.10(b)(2)(i)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	

Citation	Subject	Applies to subpart FFFFF	Explanation
§ 63.10(b)(2)(ii)	Recordkeeping of Failures to Meet a Standard.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7842(a)(2)–(4) for recordkeeping of (1) date, time, and duration of failure to meet the standard; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes.	
§ 63.10(b)(2)(iv)	Actions Taken to Minimize Emissions During SSM.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7842(a)(4) for records of actions taken to minimize emissions.
§ 63.10(b)(2)(v)	Actions Taken to Minimize Emissions During SSM.	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7842(a)(4) for records of actions taken to minimize emissions.
§ 63.10(b)(2)(vi)	Recordkeeping for CMS Malfunctions	Yes.	
§ 63.10(b)(2)(vii)–(ix)	Other CMS Requirements	Yes.	
§ 63.10(b)(2)(xiii)	CMS Records for RATA Alternative	No.	
§ 63.10(c)(7)–(8)	Records of Excess Emissions and Parameter Monitoring Exceedances for CMS.	No	Subpart FFFFF specifies record requirements; see § 63.7842.
§ 63.10(c)(15)	Use of SSM Plan	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	
§ 63.10(d)(5)(i)	Periodic SSM Reports	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	See § 63.7841(b)(4) for malfunction reporting requirements.
§ 63.10(d)(5)(ii)	Immediate SSM Reports	No, for new or reconstructed sources which commenced construction or reconstruction after August 16, 2019. For all other affected sources, Yes on or before January 11, 2021, and No thereafter.	
§ 63.10(e)(3)	Excess Emission Reports	No	Subpart FFFFF specifies reporting requirements; see § 63.7841.
§ 63.11	Control Device Requirements	No	Subpart FFFFF does not require flares.
§ 63.12	State Authority and Delegations	Yes.	
§ 63.13–§ 63.16	Addresses, Incorporations by Reference, Availability of Information and Confidentiality, Performance Track Provisions.	Yes.	

■ 20. Add tables 5 and 6 to subpart FFFFF to read as follows:

Table 5 to Subpart FFFFF of Part 63—Toxic Equivalency Factors

As stated in § 63.7825(u), you must demonstrate compliance with each dioxin/furan emission limit that applies to you by calculating the sum of the 2,3,7,8-TCDD TEQs using the 2005 World Health Organization (WHO) toxicity equivalence factors (TEF) presented in the following table:

For each dioxin/furan congener . . .	You must calculate its 2,3,7,8-TCDD TEQ using the following TEF . . .
2,3,7,8-tetrachlorodibenzo-p-dioxin	1
1,2,3,7,8-pentachlorodibenzo-p-dioxin	1
1,2,3,4,7,8-hexachlorodibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorodibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorodibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin	0.01
Octachlorodibenzo-p-dioxin	0.0003
2,3,7,8-tetrachlorodibenzofuran	0.1
1,2,3,7,8-pentachlorodibenzofuran	0.03
2,3,4,7,8-pentachlorodibenzofuran	0.3
1,2,3,4,7,8-hexachlorodibenzofuran	0.1
1,2,3,6,7,8-hexachlorodibenzofuran	0.1

For each dioxin/furan congener . . .	You must calculate its 2,3,7,8-TCDD TEQ using the following TEF . . .
1,2,3,7,8,9-hexachlorodibenzofuran	0.1
2,3,4,6,7,8-hexachlorodibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorodibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorodibenzofuran	0.01
Octachlorodibenzofuran	0.0003

Table 6 to Subpart FFFFF of Part 63—List of Polycyclic Aromatic Hydrocarbons

As stated in § 63.7825(x), you must demonstrate compliance with each polycyclic aromatic hydrocarbon emission limit that applies to you by calculating the sum of the emissions of each polycyclic aromatic hydrocarbon in the following table:

Pollutant name	CAS No.
Acenaphthene	83–32–9
Acenaphthylene	208–96–8
Anthracene	120–12–7
Benz[a]anthracene	56–55–3
Benzo[a]pyrene	50–32–8
Benzo[b]fluoranthene	205–99–2
Benzo[g,h,i]perylene	191–24–2
Benzo[k]fluoranthene	207–08–9
Chrysene	218–01–9
Dibenz[a,h]anthracene	53–70–3
Fluoranthene	206–44–0
Fluorene	86–73–7
Indeno (1,2,3-cd) pyrene	193–39–5
Naphthalene	91–20–3
Phenanthrene	85–01–8
Perylene	198–55–0
Pyrene	129–00–0

[FR Doc. 2024–05850 Filed 4–2–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL REGISTER

Vol. 89 Wednesday,
No. 65 April 3, 2024

Part VI

Department of the Treasury

Internal Revenue Service
26 CFR Part 54

Department of Labor

Employee Benefits Security Administration
29 CFR Part 2590

Department of Health and Human Services

45 CFR Parts 144, 146, and 148
Short-Term, Limited-Duration Insurance and Independent, Noncoordinated Excepted Benefits Coverage; Final Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9990]

RIN 1545–BQ28

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AC12

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, and 148

[CMS–9904–F]

RIN 0938–AU67

Short-Term, Limited-Duration Insurance and Independent, Noncoordinated Excepted Benefits Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document sets forth final rules that amend the definition of short-term, limited-duration insurance, which is excluded from the definition of individual health insurance coverage under the Public Health Service Act. This document also sets forth final rules that amend the regulations regarding the requirements for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit in the group and individual health insurance markets.

DATES: These regulations are effective on June 17, 2024.

FOR FURTHER INFORMATION CONTACT: Shannon Hysjulien or Rebecca Miller, Employee Benefits Security Administration, Department of Labor at (202) 693–8335; Jason Sandoval, Internal Revenue Service, Department of the Treasury at (202) 317–5500; Cam Clemmons, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (206) 615–2338; Lisa Cuozzo, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (667) 290–8537.

SUPPLEMENTARY INFORMATION:

I. Background

These final rules set forth revisions to the definition of ''short-term, limited-duration insurance'' (STLDI) for purposes of its exclusion from the definition of ''individual health insurance coverage'' in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 144. The definition of STLDI is also relevant for purposes of the disclosure and reporting requirements in section 2746 of the Public Health Service Act (the PHS Act), which require health insurance issuers offering individual health insurance coverage or STLDI to disclose to enrollees with individual health insurance or STLDI coverage, and to report annually to the Department of Health and Human Services (HHS), any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage.

These final rules also set forth amendments to the regulations regarding the requirements for hospital indemnity and other fixed indemnity insurance to be treated as an excepted benefit in the group and individual health insurance markets (fixed indemnity excepted benefits coverage).[1] As explained in greater detail later in this section of the preamble, the Department of the Treasury (Treasury Department), the Department of Labor, and HHS (collectively, the Departments) are not finalizing certain aspects of the proposed rules regarding fixed indemnity excepted benefits coverage and the Treasury Department and the Internal Revenue Service (IRS) are not finalizing the proposed amendments to Treasury Reg. § 1.105–2 at this time.

In proposed rules published on July 12, 2023, in the **Federal Register** titled ''Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance'' (2023 proposed rules),[2] the Departments proposed revisions to define and more clearly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage. Comprehensive coverage is coverage that is subject to the Federal consumer protections and requirements established under chapter 100 of the Internal Revenue Code (Code), part 7 of the Employee Retirement Income Security Act of 1974 (ERISA), and title XXVII of the PHS Act (hereinafter referred to as the Federal consumer protections and requirements for comprehensive coverage),[3] such as the prohibition on exclusions for preexisting conditions, the prohibition on health status discrimination, and the requirement to cover certain preventive services without cost sharing. The Departments proposed these revisions to promote equitable access to high-quality, affordable, comprehensive coverage by increasing consumers' understanding of their health coverage options and reducing misinformation about STLDI and fixed indemnity excepted benefits coverage, consistent with Executive Orders 14009 and 14070 as described in section I.B of this preamble. The Treasury Department and the IRS also proposed amendments to Treasury Reg. § 1.105–2 to clarify the tax treatment of benefit payments in fixed amounts under hospital indemnity or other fixed indemnity coverage purchased on a pre-tax basis.

The Departments also solicited comments regarding coverage only for a specified disease or illness that qualifies as excepted benefits (specified disease excepted benefits coverage),[4] and regarding level-funded plan arrangements[5] to better understand the key features and characteristics of these arrangements and whether additional guidance or rulemaking is needed to clarify plan sponsors' and issuers' obligations with respect to coverage provided through these arrangements. While specified disease excepted benefits coverage and level-funded plan arrangements are not addressed in these final rules, the Departments appreciate the comments received on these topics and will take them into consideration as they determine whether additional guidance or rulemaking is warranted in the future.

A. General Statutory Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, August 21, 1996) added chapter 100 to the Code, part 7

[1] For simplicity and readability, this preamble refers to hospital indemnity or other fixed indemnity insurance that meets all requirements to be considered an excepted benefit under the Federal framework as ''fixed indemnity excepted benefits coverage'' to distinguish it from hospital indemnity or other fixed indemnity insurance that does not meet all such requirements.

[2] 88 FR 44596 (July 12, 2023).

[3] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

[4] 88 FR 44596 at 44632 (July 12, 2023).

[5] *Id.* at 44632–34.

to ERISA, and title XXVII to the PHS Act, which set forth portability and nondiscrimination rules with respect to health coverage. These provisions of the Code, ERISA, and the PHS Act were later augmented by other laws, including the Mental Health Parity Act of 1996 (Pub. L. 104–204, September 26, 1996), the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343, October 3, 2008), the Newborns' and Mothers' Health Protection Act (Pub. L. 104–204, September 26, 1996), the Women's Health and Cancer Rights Act (Pub. L. 105–277, October 21, 1998), the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233, May 21, 2008), the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3, February 4, 2009), Michelle's Law (Pub. L. 110–381, October 9, 2008), the Patient Protection and Affordable Care Act (Pub. L. 111–148, March 23, 2010) (as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010) (collectively known as the Affordable Care Act (ACA)), and Division BB of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), which includes the No Surprises Act.

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 9815 of the Code and section 715 of ERISA to incorporate the provisions of part A of title XXVII of the PHS Act, as amended or added by the ACA, into the Code and ERISA, making them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The provisions of the PHS Act incorporated into the Code and ERISA, as amended or added by the ACA, are sections 2701 through 2728.

In addition to market-wide provisions applicable to group health plans and health insurance issuers in the group and individual markets, the ACA established Health Benefit Exchanges (Exchanges) aimed at promoting access to high-quality, affordable, comprehensive coverage. Section 1401(a) of the ACA added section 36B to the Code, providing a premium tax credit (PTC) for certain individuals with annual household income that is at least 100 percent but not more than 400 percent of the Federal poverty level (FPL) who enroll in, or who have a member of their tax household enrolled in, an individual market qualified health plan (QHP) through an Exchange who are not otherwise eligible for minimum essential coverage (MEC). Section 1402 of the ACA provides for, among other things, reductions in cost sharing for essential health benefits for qualified low- and moderate-income enrollees in silver-level QHPs purchased through the individual market Exchanges. Section 1402 also provides for reductions in cost sharing for American Indians enrolled in QHPs purchased through the individual market Exchanges at any metal level.

Section 5000A of the Code, added by section 1501(b) of the ACA, provides that individuals must maintain MEC, or make a payment known as the individual shared responsibility payment with their Federal tax return for the year in which they did not maintain MEC, if they are not otherwise exempt.[6] On December 22, 2017, the Tax Cuts and Jobs Act (Pub. L. 115–97) was enacted, which included a provision under which the individual shared responsibility payment under section 5000A of the Code was reduced to $0, effective for months beginning after December 31, 2018.

The American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) was enacted on March 11, 2021. Among other policies intended to address the health care and economic needs of the country during the coronavirus disease 2019 (COVID–19) pandemic, the ARP increased the PTC amount for individuals with annual household income at or below 400 percent of the FPL and extended PTC eligibility for the first time to individuals with annual household incomes above 400 percent of the FPL. Although the expanded PTC subsidies under the ARP were applicable only for 2021 and 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022) extended the subsidies for an additional 3 years, through December 31, 2025.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the CAA, 2021. The No Surprises Act added new provisions in Subchapter B of chapter 100 of the Code, part 7 of ERISA, and part D of title XXVII of the PHS Act, applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. These provisions provide protections against surprise medical bills for certain out-of-network services and generally require plans, issuers, providers, and facilities to make certain disclosures regarding balance billing protections to the public and to individual participants, beneficiaries, and enrollees. In addition to the new provisions applicable to group health plans and issuers of group or individual health insurance coverage, the No Surprises Act added a new part E to title XXVII of the PHS Act, establishing corresponding requirements applicable to health care providers, facilities, and providers of air ambulance services. The CAA, 2021 also amended title XXVII of the PHS Act to, among other things, add section 2746, which requires health insurance issuers offering individual health insurance coverage or STLDI to disclose the direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in individual health insurance coverage or STLDI to the enrollees in such coverage as well as to report such compensation annually to HHS.

The Secretaries of the Treasury, Labor, and HHS have authority to issue such regulations as may be necessary or appropriate to carry out the parallel provisions under the Code, ERISA, and the PHS Act, including the definitions in section 9832 of the Code, section 733 of ERISA, and section 2791 of the PHS Act.[7] [8]

B. Recent Executive Orders

On January 28, 2021, President Biden issued Executive Order 14009, ''Strengthening Medicaid and the Affordable Care Act,'' which directed the Departments to review policies to ensure their consistency with the Administration's goal of protecting and strengthening the ACA and making high-quality health care accessible and affordable for every American.[9] Executive Order 14009 also directed Federal agencies to examine policies or practices that may undermine protections for people with preexisting conditions and that may reduce the affordability of coverage or financial

[6] Section 5000A of the Code and Treasury regulations at 26 CFR 1.5000A–3 provide exemptions from the requirement to maintain MEC for the following individuals: (1) members of recognized religious sects; (2) members of health care sharing ministries; (3) exempt noncitizens; (4) incarcerated individuals; (5) individuals with no affordable coverage; (6) individuals with household income below the income tax filing threshold; (7) members of Federally recognized Indian tribes; (8) individuals who qualify for a hardship exemption certification; and (9) individuals with a short coverage gap of a continuous period of less than 3 months in which the individual is not covered under MEC. The eligibility standards for exemptions can be found at 45 CFR 155.605.

[7] Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

[8] *See also* 64 FR 70164 (December 15, 1999).

[9] Executive Order 14009 of January 28, 2021, 86 FR 7793 (February 2, 2021).

assistance for coverage. Executive Order 14009 also revoked the previous Administration's Executive Order 13813, ''Promoting Healthcare Choice and Competition Across the United States,'' which directed agencies to expand the availability of STLDI.[10] On April 5, 2022, President Biden issued Executive Order 14070, ''Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage,'' which directed the heads of Federal agencies with responsibilities related to Americans' access to health coverage to examine polices or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage; that strengthen benefits and improve access to health care providers; that improve the comprehensiveness of coverage and protect consumers from low-quality coverage; and that help reduce the burden of medical debt on households.[11]

In addition, on January 21, 2021, President Biden issued Executive Order 13995, ''Ensuring an Equitable Pandemic Response and Recovery,'' which directed the Secretaries of Labor and HHS, and the heads of all other agencies with authorities or responsibilities relating to the COVID–19 pandemic response and recovery, to consider any barriers that have restricted access to preventive measures, treatment, and other health services for populations at high risk for COVID–19 infection, and modify policies to advance equity.[12]

Consistent with these executive orders, the Departments reviewed the regulatory provisions related to STLDI and fixed indemnity excepted benefits coverage and, after carefully considering public comments received, are finalizing amendments to those provisions in these final rules.

C. Short-Term, Limited-Duration Insurance (STLDI)

STLDI is a type of health insurance coverage sold by health insurance issuers that typically fills temporary gaps in coverage that may occur when an individual is transitioning from one plan or coverage to another, such as transitioning between health coverage offered by one employer to health coverage offered by another employer. Section 2791(b)(5) of the PHS Act provides that ''[t]he term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited duration insurance.'' [13] The PHS Act does not, however, define the phrase ''short-term, limited duration insurance.'' Sections 733(b)(4) of ERISA and 2791(b)(4) of the PHS Act provide that group health insurance coverage means, ''in connection with a group health plan, health insurance coverage offered in connection with such plan.'' Sections 733(a)(1) of ERISA and 2791(a)(1) of the PHS Act provide that a group health plan is generally any plan, fund, or program established or maintained by an employer (or employee organization or both) for the purpose of providing medical care to employees or their dependents (as defined under the terms of the plan) directly, or through insurance, reimbursement, or otherwise. There is no corresponding provision excluding STLDI from the definition of group health insurance coverage. Thus, any health insurance that is sold in the group market and purports to be STLDI must nonetheless comply with applicable Federal group market consumer protections and requirements for comprehensive coverage, unless the coverage satisfies the requirements of one or more types of group market excepted benefits.

Because STLDI is not individual health insurance coverage, it is generally exempt from the Federal individual market consumer protections and requirements for comprehensive coverage. STLDI is not subject to PHS Act provisions that apply to individual health insurance coverage under the ACA including, for example, the prohibition of preexisting condition exclusions or other discrimination based on health status (section 2704 of the PHS Act), the prohibition on discrimination against individual participants and beneficiaries based on health status (section 2705 of the PHS Act), nondiscrimination in health care (section 2706 of the PHS Act), and the prohibition on lifetime and annual dollar limits on essential health benefits (section 2711 of the PHS Act). In addition, STLDI is not subject to the Federal consumer protections and requirements added to the PHS Act by other laws that apply to individual health insurance coverage, including MHPAEA (Pub. L. 110–343, October 3, 2008) (section 2726 of the PHS Act), and the No Surprises Act, as added by the CAA, 2021. Thus, individuals who enroll in STLDI are not guaranteed these key consumer protections under Federal law.[14] The lack of these key Federal consumer protections is especially problematic when the differences between STLDI and comprehensive individual health insurance coverage are not readily apparent to consumers.

In 1997, the Departments issued interim final rules implementing the portability and renewability requirements of HIPAA (1997 HIPAA interim final rules).[15] Those interim final rules included definitions of individual health insurance coverage, as well as STLDI. That definition of STLDI, which was finalized in rules issued in 2004 and applied through 2016, defined ''short-term, limited-duration insurance'' as ''health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract.'' [16]

To address the issue of STLDI being sold as a type of primary coverage, as well as concerns regarding possible adverse selection impacts on the individual market risk pools that were created under the ACA,[17] the Departments published proposed rules on June 10, 2016, in the **Federal Register** titled ''Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance'' (2016 proposed rules). Those rules proposed to revise the Federal definition of STLDI by shortening the permitted duration of such coverage, and adopting a consumer notice provision.[18] On October 31, 2016, the Departments published final rules in the **Federal Register** titled ''Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance'' (2016 final rules).[19] The 2016 final rules amended the definition

[10] Executive Order 13813 of October 12, 2017, 82 FR 48385 (October 17, 2017).

[11] Executive Order 14070 of April 5, 2022, 87 FR 20689 (April 5, 2022).

[12] Executive Order 13995 of January 21, 2021, 86 FR 7193 (January 26, 2021).

[13] The definition of individual health insurance coverage (and its exclusion of STLDI) has some limited relevance with respect to certain provisions that apply to group health plans and group health insurance issuers. For example, an individual who loses coverage due to moving out of a health maintenance organization (HMO) service area in the individual market is eligible for a special enrollment period to enroll in a group health plan. *See* 26 CFR 54.9801–6(a)(3)(i)(B), 29 CFR 2590.701–6(a)(3)(i)(B), and 45 CFR 146.117(a)(3)(i)(B).

[14] Some State laws apply some consumer protections and requirements that parallel those in the ACA to STLDI.

[15] 62 FR 16894 (April 8, 1997).

[16] 62 FR 16894 at 16928, 16942, 16958 (April 8, 1997); *see also* 69 FR 78720 (December 30, 2004).

[17] *See* Public Law 111–148, March 23, 2010, section 1312(c)(1) and 45 CFR 156.80.

[18] 81 FR 38019 (June 10, 2016).

[19] 81 FR 75316 (October 31, 2016).

of STLDI to specify that the maximum coverage period must be less than 3 months, taking into account any extensions that may be elected by the policyholder with or without the issuer's consent.[20] In addition, the 2016 final rules stated that the following notice must be prominently displayed in the contract and in any application materials provided in connection with enrollment in STLDI, in at least 14 point type:

THIS IS NOT QUALIFYING HEALTH COVERAGE (''MINIMUM ESSENTIAL COVERAGE'') THAT SATISFIES THE HEALTH COVERAGE REQUIREMENT OF THE AFFORDABLE CARE ACT. IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE, YOU MAY OWE AN ADDITIONAL PAYMENT WITH YOUR TAXES.[21]

On June 12, 2017, HHS published a request for information (RFI) in the **Federal Register** titled ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients,'' [22] which solicited comments about potential changes to existing regulations and guidance that could promote consumer choice, enhance affordability of coverage for individual consumers, and affirm the traditional regulatory authority of the States in regulating the business of health insurance, among other goals.[23] In response to this RFI, HHS received comments that recommended maintaining the definition of STLDI adopted in the 2016 final rules, and comments that recommended expanding the definition to allow for a longer period of coverage. Commenters in support of maintaining the definition adopted in the 2016 final rules expressed concern that expanding the definition could leave enrollees in STLDI at risk for significant out-of-pocket costs and cautioned that expanding the definition of STLDI could facilitate its sale to individuals as their primary form of health coverage, even though such insurance lacks key Federal consumer protections that apply to individual health insurance coverage. Commenters in favor of maintaining the definition in the 2016 final rules also suggested that amending the 2016 final rules to include coverage lasting 3 months or more could have the effect of pulling healthier people out of the individual market risk pools, thereby increasing overall premium costs for enrollees in individual health insurance coverage and destabilizing the individual market.

In contrast, several other commenters stated that changes to the 2016 final rules may provide an opportunity to achieve the goals outlined in the RFI (for example, to promote consumer choice, enhance affordability, and affirm the traditional authority of the States in regulating the business of insurance). These commenters stated that shortening the permitted length of STLDI policies in the 2016 final rules had deprived individuals of affordable coverage options. One commenter explained that due to the increased costs of comprehensive coverage, many financially stressed individuals could be faced with a choice between purchasing STLDI or going without any coverage at all. One commenter highlighted the need for STLDI for individuals who are between jobs for a relatively long period and for whom enrolling in Consolidated Omnibus Budget Reconciliation Act (COBRA) [24] continuation coverage is financially infeasible. Another commenter noted that States have the primary responsibility to regulate STLDI and encouraged the Departments to defer to the States' authority with respect to such coverage.

On February 21, 2018, the Departments published proposed rules in the **Federal Register** titled ''Short-Term, Limited-Duration Insurance'' (2018 proposed rules) in which the Departments proposed changing the definition of STLDI to have a maximum coverage period of less than 12 months after the original effective date of the contract, taking into account any extensions that may be elected by the policyholder without the issuer's consent.[25] Among other things, the Departments solicited comments on whether the maximum length of STLDI should be less than 12 months or some other duration and under what conditions issuers should be able to allow such coverage to continue for 12 months or longer.[26] In addition, the Departments proposed to revise the content of the consumer notice that must appear in the contract and any application materials provided in connection with enrollment in STLDI. The 2018 proposed rules included two variations of the consumer notice—one for policies that had a coverage start date before January 1, 2019, and the other for policies that had a coverage start date on or after January 1, 2019, the latter of which excluded language referencing the individual shared responsibility payment (which was reduced to $0 for months beginning after December 2018).[27] [28]

Some commenters on the 2018 proposed rules acknowledged that STLDI fills an important role by providing temporary coverage but stated that STLDI should not take the place of comprehensive coverage. These commenters expressed concern that allowing STLDI to be marketed as a viable alternative to comprehensive coverage would subject uninformed consumers to potentially severe financial risks. Commenters who opposed the proposed changes to the definition also expressed concern that such plans would siphon off healthier individuals from the market for individual health insurance coverage, thereby raising premiums for individual health insurance coverage.

Many of these commenters also expressed concerns about the lack of protections for consumers who purchase STLDI, stating that such policies are not a viable option for people with serious or chronic medical conditions due to potential coverage exclusions and benefit limitations in STLDI policies. These commenters further observed that STLDI policies can discriminate against individuals with serious illnesses or preexisting conditions, including individuals with mental health and substance use disorders, older consumers, women, transgender patients, persons with gender identity-related health concerns, and victims of rape and domestic violence. Many of these commenters also expressed concern about aggressive and deceptive marketing practices utilized by marketers of STLDI.

Other commenters highlighted the important role that STLDI could play in providing temporary coverage to individuals who would otherwise be uninsured. These commenters, who supported the proposed changes to the definition, also noted that such changes would allow purchasers of STLDI to obtain the coverage they want at a more affordable price for a longer period.

With respect to the maximum length of the initial contract term for STLDI, most commenters opposed extending the maximum duration beyond 3

[20] *Id.* at 75317–75318.

[21] *Id.*

[22] 82 FR 26885 (June 12, 2017).

[23] *See also* Executive Order 13813 of October 12, 2017, 82 FR 48385 (October 17, 2017) (directing the Secretaries of the Treasury, Labor and HHS ''. . . to consider proposing regulations or revising guidance, consistent with law, to expand the availability of [STLDI]. To the extent permitted by law and supported by sound policy, the Secretaries should consider allowing such insurance to cover longer periods and be renewed by the consumer.'').

[24] Public Law 99–272, April 7, 1986. COBRA added parallel provisions at Code section 4980B, ERISA sections 601–608, and PHS Act sections 2201–2208.

[25] 83 FR 7437 (February 21, 2018).

[26] *Id.* at 7441.

[27] *Id.* at 7440–7441.

[28] Public Law 115–97, December 22, 2017.

months. Others suggested periods such as less than 6 or 8 months. However, most commenters who supported extending the maximum initial contract term beyond 3 months suggested it should be 364 days. A few commenters suggested more than 1 year. Other commenters stated the maximum length of coverage should be left to the States. Commenters who supported the 2018 proposed rules generally favored permitting renewals of STLDI policies, while those who opposed the 2018 proposed rules generally opposed permitting such renewals.

After reviewing comments and feedback received from interested parties, on August 3, 2018, the Departments published final rules in the **Federal Register** titled ''Short-Term, Limited-Duration Insurance'' (2018 final rules) [29] with some modifications from the 2018 proposed rules. Specifically, in the 2018 final rules, the Departments amended the definition of STLDI to provide that STLDI is coverage with an initial term specified in the contract that is less than 12 months after the original effective date of the contract, and taking into account renewals or extensions, has a duration of no longer than 36 months in total.[30] The 2018 final rules also finalized the provision that issuers of STLDI must display one of two versions of a notice prominently in the contract and in any application materials provided in connection with enrollment in such coverage, in at least 14-point type. Under the 2018 final rules, the notice must read as follows (with the final two sentences omitted for policies sold on or after January 1, 2019): [31]

This coverage is not required to comply with certain Federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not ''minimum essential coverage.'' If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

[29] 83 FR 38212 (August 3, 2018).

[30] *Id.*

[31] *See id.* at 38222–38225.

D. Independent, Noncoordinated Excepted Benefits: Hospital Indemnity or Other Fixed Indemnity Insurance

Section 9831 of the Code, section 732 of ERISA, and sections 2722(b)–(c) and 2763 of the PHS Act provide that the respective Federal consumer protections and requirements for comprehensive coverage do not apply to any individual coverage or any group health plan (or group health insurance coverage offered in connection with a group health plan) in relation to its provision of certain types of benefits, known as ''excepted benefits.'' These excepted benefits are described in section 9832(c) of the Code, section 733(c) of ERISA, and section 2791(c) of the PHS Act.

HIPAA defined certain types of coverage as ''excepted benefits'' that were exempt from its portability requirements.[32] The same definitions are applied to describe benefits that are not required to comply with the ACA requirements.[33] There are four statutory categories of excepted benefits: independent, noncoordinated excepted benefits, which are the subject of these final rules; benefits that are excepted in all circumstances; [34] limited excepted benefits; [35] and supplemental excepted benefits.[36]

[32] *See* sections 9831(b)–(c) and 9832(c) of the Code, sections 732(b)–(c) and 733(c) of ERISA, and sections 2722(b)–(c), 2763 and 2791(c) of the PHS Act.

[33] Section 1551 of the ACA. *See also* section 1563(a) and (c)(12) of the ACA. Excepted benefits are also not subject to the consumer protections and requirements added by other Federal laws that apply to comprehensive coverage, including MHPAEA, the Newborns' and Mothers' Health Protection Act, the Women's Health and Cancer Rights Act, the Children's Health Insurance Program Reauthorization Act of 2009, Michelle's Law, and Division BB of the CAA, 2021.

[34] Under section 9832(c)(1) of the Code, section 733(c)(1) of ERISA, and section 2791(c)(1) of the PHS Act, this category includes, for example, accident and disability income insurance, automobile medical payment insurance, liability insurance and workers compensation, as well as ''[o]ther similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.''.

[35] Under section 9832(c)(2) of the Code, section 733(c)(2) of ERISA, and section 2791(c)(2) of the PHS Act, this category includes limited scope vision or dental benefits, benefits for long-term care, nursing home care, home health care, or community-based care, or other, similar limited benefits specified by the Departments through regulation.

[36] Under section 9832(c)(4) of the Code, section 733(c)(4) of ERISA, and section 2791(c)(4) of the PHS Act, this category includes Medicare supplemental health insurance (also known as Medigap), TRICARE supplemental programs, or ''similar supplemental coverage provided to coverage under a group health plan.'' To be considered ''similar supplemental coverage'' and thus an excepted benefit, the coverage, whether offered in the group or individual market, must supplement coverage provided under a group health plan. This category does not include coverage that supplements individual health insurance coverage. 26 CFR 54.9831–1(c)(5), 29 CFR 2590.732(c)(5), 45 CFR 146.145(b)(5) and 148.220(b)(7).

The category ''independent, noncoordinated excepted benefits'' includes coverage for only a specified disease or illness (such as cancer-only policies) and hospital indemnity or other fixed indemnity insurance. These benefits are excepted under section 9831(c)(2) of the Code, section 732(c)(2) of ERISA, and section 2722(c)(2) of the PHS Act only if all of the following conditions are met: (1) the benefits are provided under a separate policy, certificate, or contract of insurance; (2) there is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor; and (3) the benefits are paid with respect to an event without regard to whether benefits are provided with respect to such event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.[37] In addition, under existing regulations, hospital indemnity and other fixed indemnity insurance in the group market must pay a fixed dollar amount per day (or other period) of hospitalization or illness, regardless of the amount of expenses incurred, to be considered an excepted benefit.[38] By contrast, in the individual market, under existing regulations, hospital indemnity and other fixed indemnity insurance must also pay benefits in a fixed dollar amount, regardless of the amount of expenses incurred, to be considered an excepted benefit, but is permitted to pay on either a per period of hospitalization or illness, or a per-service basis (for example, $100/day or $50/visit).[39] [40]

The amendments to the regulations regarding independent, noncoordinated excepted benefits coverage that were

[37] *See also* section 2763(b) of the PHS Act (providing that ''[the] requirements of this part [related to the HIPAA individual market reforms] shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in paragraph (2), (3), or (4) of section 2791(c) if the benefits are provided under a separate policy, certificate or contract of insurance.'').

[38] 26 CFR 54.9831–1(c)(4), 29 CFR 2590.732(c)(4), and 45 CFR 146.145(b)(4).

[39] 45 CFR 148.220(b)(4)(iii).

[40] As discussed further in section I.D.2 of this preamble, the existing individual market regulation also provides that hospital indemnity and other fixed indemnity insurance cannot coordinate between the provision of benefits and an exclusion of benefits under any health coverage to be considered an excepted benefit. See 45 CFR 148.220(b)(4)(ii).

proposed in the 2023 proposed rules and those finalized in these final rules address the conditions that must be met for hospital indemnity and other fixed indemnity insurance in the group or individual markets to be considered excepted benefits under the Federal regulations.

Like other forms of excepted benefits, fixed indemnity excepted benefits coverage does not provide comprehensive coverage. Rather, its primary purpose is to provide income replacement benefits.[41] Benefits under this type of coverage are paid in a flat (''fixed'') cash amount following the occurrence of a health-related event, such as a period of hospitalization or illness, subject to the terms of the contract. In addition, benefits are provided at a pre-determined level regardless of any health care costs incurred by a covered individual with respect to the health-related event. Although a benefit payment may equal all or a portion of the cost of care related to an event, it is not necessarily designed to do so, and the benefit payment is made without regard to the amount of health care costs incurred.[42]

Traditionally, benefits under fixed indemnity excepted benefits coverage are paid directly to a policyholder, rather than to a health care provider or facility. The policyholder has discretion over how to use such benefits—including using the payment to cover non-medical expenses, such as childcare or transportation—that may or may not be related to the event that precipitated the payment.[43]

[41] The original version of HIPAA that the House Ways & Means Committee referred to the House floor referred to hospital indemnity or other fixed indemnity insurance as a ''hospital or fixed indemnity *income-protection policy*'' (emphasis added). *See* H.R. Rep. No. 104–496 part I, at 32 (1996), available at: *https://www.govinfo.gov/content/pkg/CRPT-104hrpt496/pdf/CRPT-104hrpt496-pt1.pdf. See also* 79 FR 15818 (March 21, 2014) (''The primary reason fixed indemnity insurance is considered to be an excepted benefit . . . is that its primary purpose is not to provide major medical coverage but to provide a cash-replacement benefit for those individuals with other health coverage.'').

[42] Jost, Timothy (2017). ''ACA Round-Up: Market Stabilization, Fixed Indemnity Plans, Cost Sharing Reductions, and Penalty Updates,'' *Health Affairs,* available at: *https://www.healthaffairs.org/do/10.1377/forefront.20170208.058674/full.* (''Fixed indemnity coverage is excepted benefit coverage that pays a fixed amount per-service or per-time period of service without regard to the cost of the service or the type of items or services provided.'').

[43] America's Health Insurance Plans (2019). ''Supplemental Health Insurance: Hospital or Other Fixed Indemnity, Accident-Only, Critical Illness,'' available at: *https://www.ahip.org/documents/Supplemental-Health-Insurance-Fast-Facts.pdf.*

1. Group Market Regulations and Guidance

The Departments' 1997 interim final rules implementing the portability and renewability requirements of HIPAA codified at 26 CFR 54.9831–1(c)(4), 29 CFR 2590.732(c)(4), and 45 CFR 146.145(b)(4) established requirements for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the group market. These requirements, which were effective until February 27, 2005, provided that coverage for hospital indemnity or other fixed indemnity insurance is excepted only if it meets each of the following conditions: (1) the benefits are provided under a separate policy, certificate or contract of insurance; (2) there is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and (3) the benefits are paid with respect to an event without regard to whether benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.[44]

The Departments' group market regulations for fixed indemnity excepted benefits coverage were first amended in the 2004 HIPAA group market final rules. Those amendments added language to further clarify that to be hospital indemnity or other fixed indemnity insurance that is an excepted benefit, the insurance must pay a fixed dollar amount per day (or per other time period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred.[45] An example was also added as part of these amendments illustrating that a policy providing benefits only for hospital stays at a fixed percentage of hospital expenses up to a maximum amount per day does not qualify as an excepted benefit.[46] As explained in the 2004 HIPAA group market final rules, the result is the same even if, in practice, the policy pays the maximum for every day of hospitalization.[47]

The Departments later released Frequently Asked Questions (FAQ) on January 24, 2013, to offer additional guidance on the types of hospital indemnity or other fixed indemnity insurance that meet the criteria for fixed indemnity excepted benefits coverage.[48] The Departments issued the FAQ in response to reports that policies were being advertised as fixed indemnity coverage, but were paying a fixed amount on a per-service basis (for example, per doctor visit or surgical procedure) rather than a fixed amount per period (for example, per day or per week). The FAQ affirmed that, under the 2004 HIPAA group market final rules, to qualify as fixed indemnity excepted benefits coverage, the policy must pay benefits on a per-period basis as opposed to on a per-service basis.[49] The FAQ also affirmed that group health insurance coverage that provides benefits in varying amounts based on the type of procedure or item, such as the type of surgery actually performed or prescription drug provided, does not qualify as fixed indemnity excepted benefits coverage because it does not meet the condition that benefits be provided on a per-period basis, regardless of the amount of expenses incurred.[50]

The Departments proposed amendments to the group market regulations for fixed indemnity excepted benefits coverage in the 2016 proposed rules.[51] As explained in those proposed rules, the Departments were concerned that some individuals may mistake these policies for comprehensive coverage that would be considered MEC.[52] To address this confusion, the Departments proposed to adopt a notice provision to inform enrollees and potential enrollees that the coverage is a supplement to, rather than a substitute for, comprehensive coverage, and also proposed to add two illustrative examples to further clarify the condition that benefits must be provided on a per-period basis.[53] The Departments also requested comments on whether to more substantively align the rules for hospital indemnity or other fixed indemnity insurance in the group and individual markets.[54] After consideration of comments, the Departments did not finalize the proposed changes to the group market

[44] 62 FR 16894 at 16903, 16939 through 16940, 16954, and 16971 (April 8, 1997).

[45] 69 FR 78720 at 78735, 78762, 78780, and 78798–78799 (December 30, 2004).

[46] *Id. See also* 26 CFR 54.9831–1(c)(4)(iii), 29 CFR 2590.732(c)(4)(iii), and 45 CFR 146.145(b)(4)(iii).

[47] *Id.*

[48] Frequently Asked Questions about Affordable Care Act Implementation (Part XI) (Jan. 24, 2013), Q7, available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xi.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11.*

[49] *Id.*

[50] *Id.*

[51] 81 FR 38019 at 38031–38032, 38038, 38042–38043, and 38045–38046 (June 10, 2016).

[52] *Id.* at 38031–38032.

[53] *Id.* at 38031–38032, 38038, 38042–38043, and 38045–38046.

[54] As described in section I.D.2 of this preamble, HHS amended the individual market fixed indemnity excepted benefits coverage regulation to provide additional flexibility, subject to several additional requirements that do not apply in the group market. 79 FR 30239 (May 27, 2014).

regulation but noted their intention to address hospital indemnity and other fixed indemnity insurance in future rulemaking.[55]

2. Individual Market Regulations and Guidance

HHS also issued an interim final rule in 1997 establishing the regulatory framework for the HIPAA individual market Federal requirements and addressing the requirements for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the individual market.[56] The initial HIPAA individual market fixed indemnity excepted benefits coverage regulation, which was effective until July 27, 2014, provided an exemption from the Federal individual market consumer protections and requirements for comprehensive coverage if the hospital indemnity or other fixed indemnity insurance provided benefits under a separate policy, certificate, or contract of insurance and met the noncoordination-of-benefits requirements outlined in the HHS group market excepted benefits regulations.[57]

Following issuance of the Departments' January 24, 2013 FAQ,[58] State insurance regulators and industry groups representing health insurance issuers expressed concerns that prohibiting hospital indemnity and other fixed indemnity insurance from payment on a per-service basis to qualify as an excepted benefit could limit consumer access to an important supplemental coverage option.[59] Based on this feedback, HHS announced in an FAQ released in January 2014 that it intended to propose amendments to the individual market fixed indemnity excepted benefits coverage regulation to allow hospital indemnity or other fixed indemnity insurance sold in the individual market to be considered an excepted benefit if four conditions were met.[60] First, such coverage would be sold only to individuals who have other health coverage that is MEC, within the meaning of section 5000A(f) of the Code. Second, no coordination between the provision of benefits and an exclusion of benefits under any other health coverage would be permitted. Third, benefits would be paid in a fixed dollar amount regardless of the amount of expenses incurred and without regard to whether benefits are provided with respect to an event or service under any other health insurance coverage. Finally, a notice would have to be prominently displayed to inform policyholders that the coverage is not MEC and would not satisfy the individual shared responsibility requirements of section 5000A of the Code. HHS explained that if these proposed revisions were implemented, hospital indemnity or other fixed indemnity insurance in the individual market would no longer have to pay benefits solely on a per-period basis to qualify as an excepted benefit.

In the proposed rule, titled ''Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond'' (2014 proposed rule), HHS proposed to amend the criteria in 45 CFR 148.220 for fixed indemnity insurance to be treated as an excepted benefit in the individual market.[61] Consistent with the framework outlined in the January 2014 FAQ, the amendments proposed to eliminate the requirement that individual market fixed indemnity excepted benefits coverage must pay benefits only on a per-period basis (as opposed to a per-service basis) and instead proposed to require, among other things, that it be sold only as secondary to other health coverage that is MEC to qualify as an excepted benefit.[62]

On July 28, 2014, in the rule titled ''Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond'' (2014 final rule), HHS finalized the proposed amendments to 45 CFR 148.220(b)(4) with some modifications. Pursuant to the finalized amendments, hospital indemnity or other fixed indemnity insurance in the individual market may qualify as fixed indemnity excepted benefits coverage if payments are made on a per-period and/or per-service basis subject to several additional requirements that do not apply to fixed indemnity excepted benefits coverage in the group market.[63] Under 45 CFR 148.220(b)(4)(i), to qualify as excepted benefits coverage, benefits under an individual market hospital indemnity or other fixed indemnity insurance policy may only be provided to individuals who attest in their application that they have other health coverage that is MEC within the meaning of section 5000A(f) of the Code, or that they are treated as having MEC due to their status as a bona fide resident of any possession of the United States pursuant to section 5000A(f)(4)(B) of the Code.[64] Further, to qualify as an excepted benefit, 45 CFR 148.220(b)(4)(iv) outlines specific notice language that must be prominently displayed in the application materials for individual market hospital indemnity or other fixed indemnity insurance. Finally, consistent with the group market fixed indemnity excepted benefits coverage regulations, 45 CFR 148.220(b)(4)(ii) implements the statutory noncoordination standard and requires that there is no coordination between the provision of benefits under the individual market fixed indemnity excepted benefits insurance policy and an exclusion of benefits under any other health coverage.

HHS made these changes in the 2014 final rule for two reasons. First, as stated previously, interested parties, including State insurance regulators and industry groups representing health insurance issuers, communicated to HHS that fixed indemnity plans that paid benefits on a per-service basis were widely available as a complement to comprehensive coverage in the group and individual markets. The National Association of Insurance Commissioners (NAIC) also expressed that State insurance regulators believed fixed indemnity plans that paid benefits on a per-service basis provided consumers an important supplemental coverage option by helping consumers that purchase MEC pay for out-of-pocket costs.[65]

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[55] 81 FR 75316 at 75317 (October 31, 2016).

[56] 62 FR 16985 at 16992 and 17004 (April 8, 1997).

[57] *Id.;* 45 CFR 146.145(b)(4)(ii)(B) and (C).

[58] Frequently Asked Questions about Affordable Care Act Implementation (Part XI) (Jan. 24, 2013), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xi.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11.*

[59] While the FAQ only addressed fixed indemnity insurance sold in the group market, the same statutory framework and legal analysis also applies to hospital indemnity and fixed indemnity insurance sold in the individual market.

[60] Frequently Asked Questions about Affordable Care Act Implementation (Part XXVIII) and Mental Health Parity Implementation (Jan. 9, 2014), Q11, available at: *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xviii.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.*

[61] 79 FR 15807 at 15818–15820, 15869 (March 21, 2014).

[62] *Id.*

[63] 79 FR 30239 (May 27, 2014).

[64] As discussed later in this section and in section III.B.2 of this preamble, the U.S. Court of Appeals for the District of Columbia vacated the requirement at 45 CFR 148.220(b)(4)(i) that an individual attest to having MEC prior to purchasing a hospital indemnity or other fixed indemnity policy in order for the policy to qualify as an excepted benefit. *Central United Life Insurance Company* v. *Burwell,* 827 F.3d 70 (D.C. Cir. 2016).

[65] National Association of Insurance Commissioners (2013). ''Letter to Secretaries of Labor, Treasury, and Health and Human Services,'' available at: *https://naic.soutronglobal.net/Portal/Public/en-GB/RecordView/Index/23541.* (''State regulators believe hospital and other fixed indemnity coverage with variable fixed amounts based on service type could provide important options for consumers as supplemental coverage.

Second, beginning in 2014, most consumers were required to have MEC to avoid being subject to an individual shared responsibility payment under section 5000A of the Code. HHS adopted the MEC attestation requirement to prevent fixed indemnity excepted benefits coverage in the individual market from being offered as a substitute for comprehensive coverage while also accommodating the concerns of interested parties who supported allowing fixed indemnity excepted benefits coverage in the individual market to pay benefits on a per-service basis, rather than only on a per-period basis.[66] However, in its 2016 decision in *Central United Life Insurance Company* v. *Burwell,* the U.S. Court of Appeals for the District of Columbia invalidated the requirement at 45 CFR 148.220(b)(4)(i) that an individual must attest to having MEC prior to purchasing fixed indemnity excepted benefits coverage in the individual market.[67] The Court did not engage in a severability analysis to determine whether HHS would have intended to leave the remaining provisions of the regulation in place, and left intact the language permitting fixed indemnity excepted benefits coverage in the individual market to provide benefits on a per-service basis.

E. Tax Treatment and Substantiation Requirements for Amounts Received From Fixed Indemnity Insurance and Certain Other Arrangements

As part of the 2023 proposed rules, the Treasury Department and the IRS proposed amendments to 26 CFR 1.105–2. For the reasons that follow, the Treasury Department and the IRS are not finalizing the proposed amendments at this time.

Hospital indemnity or other fixed indemnity insurance, as well as coverage only for a specified disease or illness, generally are considered ''accident or health insurance'' under sections 104, 105, and 106 of the Code, regardless of whether they are ''excepted benefits'' as defined in section 9832(c) of the Code. Premiums paid by an employer (including by salary reduction pursuant to section 125 of the Code) for accident or health insurance are excluded from an employee's gross income under section 106(a) of the Code. The Treasury Department and the IRS also have recognized the ability of employers and employees to agree to include them in employees' gross income notwithstanding section 106(a) of the Code.[68]

Amounts received through accident or health insurance are excluded from an employee's gross income under section 104(a)(3) of the Code if the premiums were paid on an after-tax basis. However, amounts received are included in an employee's gross income if the amounts are attributable to contributions by an employer that were excluded from the employee's gross income under section 106(a) of the Code. Whether amounts received by an employee through accident or health insurance are excluded from an employee's gross income where the premiums or contributions were paid on a pre-tax basis is determined under section 105. Section 105(a) of the Code provides that such amounts are included in gross income except as otherwise provided in section 105 of the Code. Section 105(b) of the Code excludes such amounts from gross income amounts if they are paid to reimburse the employee's expenses for medical care (as defined in section 213(d) of the Code). Under 26 CFR 1.105–2, this means the exclusion ''applies only to amounts which are paid specifically to reimburse the taxpayer for expenses incurred by him for the prescribed medical care.'' [69]

The 2023 proposed amendments to 26 CFR 1.105–2 would provide that the exclusion from gross income under section 105(b) of the Code does not apply to amounts that are paid without regard to the amount of incurred medical expenses as defined in section 213(d) of the Code. The proposed amendments also would clarify that, consistent with guidance issued by the Treasury Department and the IRS relating to certain specific types of health plans, the substantiation requirements for qualified medical expenses apply to reimbursements under all types of accident and health plans.[70] Finally, the proposed amendments would update several cross-references in 26 CFR 1.105–2 to reflect statutory changes since the rules were issued in 1956.[71]

The Treasury Department and the IRS issued the proposed amendments because uncertainty regarding the exclusion under section 105(b) of the Code has resulted in inconsistent treatment by taxpayers of benefits under different types of accident and health plans and has encouraged some taxpayers to apply the exclusion to situations where the amount or even the existence of medical expenses is doubtful. The Treasury Department and the IRS also are concerned that uncertainty regarding the related Federal Insurance Contributions Act (FICA) [72] and Federal Unemployment Tax Act (FUTA) [73] exclusions, and the Federal income tax withholding rules,[74] has resulted in instances where no FICA, FUTA, or Federal income taxes are withheld from or paid with respect to taxable benefits from accident and health plans and policies by either employers or payors. Although these issues are not limited to fixed indemnity plans and policies, the Treasury Department's and the IRS's concerns have recently escalated after identifying an increasing number of arrangements, some involving fixed indemnity plans and policies, that distribute cash benefit payments, purportedly for medical expenses, even if any expenses incurred may already have been reimbursed through other coverage, or participants do not incur any medical expenses within the meaning of section 213(d) of the Code. In some cases, no medical expenses are incurred and participants simply complete certain health-related activities. Benefit payments from such accident and health plans that are not made on account of medical expenses

Consumers who purchase comprehensive coverage that meets the definition of 'minimum essential coverage' may still wish to buy fixed indemnity coverage to help meet out-of-pocket medical and other costs.'').

[66] 79 FR 30239 at 30255 (May 27, 2014).

[67] 827 F.3d 70 (D.C. Cir. July 1, 2016).

[68] *See, for example,* IRS Rev. Rul. 2004–55, which concludes that long-term disability benefits received by an employee who has irrevocably elected, prior to the beginning of the plan year, to have the coverage paid by the employer on an after-tax basis for the plan year in which the employee becomes disabled are attributable solely to after-tax employee contributions and are excludable from the employee's gross income under section 104(a)(3) of the Code.

[69] Additionally, an employer-provided accident or health insurance policy or plan that reimburses an employee for any expenses incurred for medical care is a group health plan subject to section 4980B of the Code, regardless of whether the reimbursements are included in an employee's income under section 105(a) of the Code or excluded under section 104(a)(3) or 105(b) of the Code. In contrast, a policy or plan that does not reimburse an employee for any expenses incurred for medical care is not a group health plan subject to section 4980B of the Code (and section 105(b) of the Code cannot apply to it).

[70] *See, for example,* 84 FR 28888, 28917 (June 20, 2019) (describing substantiation requirements for employer-sponsored health reimbursement arrangements); *see also* Q44–55 of IRS Notice 2017–67, 2017–47 IRB 517; Prop. Treas. Reg. § 1.125–6(b)(4) (2007); IRS Notice 2002–45, 2002–2 CB 93.

[71] The current rules reference section 105(d) of the Code, which has been repealed. The rules also reference the definition of a dependent in section 152(f) of the Code which may, in some circumstances, not include children up to the age of 26 that must be eligible to enroll in a group health plan or group or individual health insurance coverage under section 2714 of the PHS Act (which is incorporated by reference in section 9815 of the Code) if the plan or coverage makes available dependent coverage of children.

[72] Subtitle C, chapter 21 of the Code.

[73] Subtitle C, chapter 23 of the Code.

[74] Subtitle C, chapter 24 of the Code.

incurred generally would not qualify for exclusion from gross income, FICA, FUTA, or Federal income tax withholding.

The Treasury Department and the IRS received comments in support of and in opposition to the proposed amendments to 26 CFR 1.105–2. Commenters who opposed the proposed amendments primarily argued that the exclusion under section 105(b) of the Code should apply with respect to the amount of any medical expenses associated with the health-related event that precipitates payments under accident or health insurance, even if the amount paid is determined without regard to the amount of actual medical expenses incurred (as is required for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit). These commenters generally argued that only the amount in excess of the medical expenses associated with the health-related event should be included in gross income.

The preamble to the 2023 proposed rules noted that, if the proposed amendments to 26 CFR 1.105–2 were finalized, taxpayers would need to consider the impact the proposal would have on determinations of whether amounts received under accident and health plans constitute wages for employment tax and income tax withholding purposes. Many commenters responded that the proposed amendments would, if finalized, prompt the need for additional guidance regarding collecting and paying employment taxes on some or all of the amounts paid through accident or health insurance that are not excluded from gross income, and proper reporting of such amounts on the employee's Form W–2. Commenters also requested further clarification on how incurred medical expenses must be substantiated.

The Treasury Department and the IRS intend to address these issues in more detail in future guidance. Accordingly, to provide more time to study the issues and concerns raised by commenters, the Treasury Department and the IRS are not finalizing the proposed amendments to 26 CFR 1.105–2 at this time. No inference should be drawn regarding whether or the extent to which the Treasury Department or the IRS agree with any comments on the scope of section 105(b) of the Code based on this decision.

IRS compliance efforts regarding the exclusion from gross income under section 105(b) of the Code will continue to assist taxpayers to satisfy their existing tax responsibilities. Employers are reminded that amounts received through accident or health insurance are not taxable if premiums for the coverage are paid on an after-tax basis, thereby avoiding many of the practical concerns relating to benefits that do not meet the criteria to be excluded from gross income. The Treasury Department and IRS understand that is how most premiums for hospital indemnity or other fixed indemnity insurance are paid.

II. Promoting Access to High-Quality, Affordable, and Comprehensive Coverage

The Departments recognize that STLDI can provide temporary health coverage for individuals who are experiencing brief periods without comprehensive coverage (for example, due to application of a waiting period for employer coverage). They also recognize that fixed indemnity excepted benefits coverage can provide consumers with income replacement that can be used to cover out-of-pocket expenses not covered by comprehensive coverage or to defray non-medical expenses (for example, mortgage or rent) upon the occurrence of a health-related event. Both STLDI and fixed indemnity excepted benefits coverage generally provide limited benefits at lower premiums than comprehensive coverage,[75] and enrollment is typically available at any time (sometimes subject to medical underwriting) rather than being restricted to open and special enrollment periods. However, the Departments are concerned about the financial and health risks that consumers face if they use either form of coverage as a substitute for comprehensive coverage, particularly as a long-term substitute. Consumers who do not understand key differences between STLDI, fixed indemnity excepted benefits coverage, and comprehensive coverage may unknowingly take on significant financial and health risks if they purchase STLDI or fixed indemnity excepted benefits coverage under the misapprehension that such products provide comprehensive coverage. Consumer confusion can be exacerbated when the products are designed in ways that resemble comprehensive coverage. As discussed further in this section II of this preamble, given significant changes in the legal landscape and market conditions since the Departments last addressed STLDI and fixed indemnity excepted benefits coverage, and the low value that STLDI and fixed indemnity excepted benefits coverage provide to some consumers when used as a substitute for comprehensive coverage, the Departments have determined that it is necessary and appropriate to amend the existing Federal regulations governing both types of coverage to more clearly distinguish them from comprehensive coverage and increase consumer awareness of coverage options that include the full range of Federal consumer protections and requirements.

A. Access to Affordable Coverage

In the preamble to the 2018 final rules, the Departments explained the decision to amend the definition of STLDI to expand the initial term and total duration of such policies by citing STLDI as an important means to provide more affordable coverage options and more choices for consumers.[76] The Departments cited a 21 percent increase in individual health insurance coverage premiums between 2016 and 2017, and a 20 percent decrease in average monthly enrollment for individuals who did not receive PTC, along with a 10 percent overall decrease in monthly enrollment during the same period.[77] Additionally, the Departments noted that in 2018 about 26 percent of enrollees (living in 52 percent of counties) had access to just one issuer on the Exchange.[78]

Since the publication of the 2018 final rules, comprehensive coverage for individuals has generally become more accessible and affordable. For example, a study examining issuer participation trends from 2014 to 2021 in every county in the United States found that the number of consumers with multiple issuer options for individual health insurance coverage on the Exchanges has grown consistently since 2018. In 2021, 78 percent of enrollees (living in 46 percent of counties) had a choice of three or more health insurance issuers, up from 67 percent of enrollees in 2020, 58 percent of enrollees in 2019, and 46 percent of enrollees in 2018. Only 3

[75] Although it is typically true that the unsubsidized premium price for comprehensive coverage is greater than STLDI or fixed indemnity excepted benefits coverage, consistent with the greater level of benefits provided under comprehensive coverage, *see* the additional discussion in this section II of this preamble regarding the availability of financial subsidies for eligible individuals to reduce the premium and out-of-pocket costs for comprehensive coverage purchased on an Exchange.

[76] 83 FR 38212 at 38217 (October 2, 2018).

[77] *Id.* at 38214 (citing CMS (2018). ''Trends in Subsidized and Unsubsidized Individual Health Insurance Market Enrollment,'' available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-2.pdf.*)

[78] *Id.* (citing KFF (2017). ''Insurer Participation on ACA Marketplaces, 2014–2018,'' now available at: *https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/.*)

percent of enrollees (residing in 10 percent of counties) resided in single-issuer counties in 2021—down from 26 percent of enrollees (residing in 52 percent of counties) in 2018.[79] Issuer participation in the Exchanges has continued to trend positively in recent years, with the average number of issuers offering individual health insurance coverage on the Exchanges per State increasing from 5 in 2021 to 6 in 2024.[80] The Centers for Medicare & Medicaid Services (CMS) reported that a record 21.3 million people enrolled in Exchange coverage during the 2024 Open Enrollment Period, including 5 million consumers (approximately 24 percent of total enrollments) who were new to Exchanges in 2024, and 16.3 million returning customers.[81] Nearly 5 million more consumers signed up for coverage during the 2024 Open Enrollment Period compared to the same period in 2023 (an increase of more than 30 percent). This follows an increase of approximately 13 percent in 2023 and an increase of approximately 21 percent in 2022.[82] The enrollment gains in recent years were influenced by the expansion of PTC subsidies, as first provided under the ARP and then extended through 2025 under the IRA, as discussed in section I.A of this preamble.[83] In an analysis prior to the passage of the IRA, the Congressional Budget Office stated that if the ARP subsidies were made permanent, they would attract 4.8 million new people to the Exchanges each year, and that 2.2 million fewer individuals would be without health insurance, on average, over the period from 2023 through 2032.[84]

Additionally, on October 13, 2022, the Treasury Department and the IRS issued final regulations under section 36B of the Code to provide that affordability of employer-sponsored MEC for family members of an employee is determined based on the employee's share of the cost of covering the employee and those family members, not the cost of covering only the employee (2022 affordability rule).[85] It was estimated that this rule change, aimed at addressing the issue often called the ''family glitch,'' would increase the number of individuals with PTC-subsidized Exchange coverage by approximately 1 million per year for the next 10 years.[86]

These recent and projected enrollment trends and the availability of the enhanced subsidies lessen the accessibility and affordability concerns expressed by the Departments in the preamble to the 2018 final rules regarding the availability of affordable options for comprehensive coverage, and offer further support for the provisions in these final rules, which are aimed at helping consumers differentiate between comprehensive coverage and other forms of more limited health coverage to decide which option is best for them.

Although access to affordable comprehensive coverage has improved in recent years, the Departments recognize that affordability concerns continue to persist among consumers, including among consumers who are enrolled in comprehensive coverage. A 2022 national survey conducted by the Commonwealth Fund found that 29 percent of people with employer-sponsored coverage and 44 percent of those with coverage purchased in the individual market (including coverage purchased through an Exchange) were underinsured, meaning that their coverage did not provide them with affordable access to health care.[87] As benchmarks for affordability, the study considered whether out-of-pocket costs over the prior 12 months, excluding premiums, were equal to 10 percent or more of household income; out-of-pocket costs over the prior 12 months, excluding premiums, were equal to 5 percent or more of household income for individuals living under 200 percent of the FPL ($27,180 for an individual or $55,500 for a family of four in 2022); or the deductible constituted 5 percent or more of household income. The performance of STLDI products along these affordability dimensions has been proven worse, often to striking degree, as discussed in section II.B of this preamble.

The Departments also recognize that these affordability concerns could be exacerbated when the expanded PTC subsidies under the IRA end in 2025 or if health expenditures (and therefore premiums) continue to grow at a relatively high rate.[88] The Departments are of the view that it is important to ensure consumers have access to a wide range of products that can support access to affordable health care. However, neither STLDI nor fixed indemnity excepted benefits coverage represent a complete solution to larger issues of affordable access to health care and health coverage, and current marketing practices and benefit designs that mimic comprehensive coverage exacerbates affordability and accessibility concerns. Consumers who enroll in these plans as a substitute for comprehensive coverage or under the misapprehension that STLDI and fixed indemnity excepted benefits coverage are a lower-cost equivalent to comprehensive coverage are at risk of being exposed to significant financial liability in the event of a costly or unexpected health event, often without knowledge of the risk associated with such coverage.

B. Risks to Consumers

As noted in the introduction to this section II of this preamble, the limitations on benefits and coverage under STLDI or fixed indemnity excepted benefits coverage may allow some issuers to offer such coverage at lower monthly premiums than comprehensive coverage. The Departments are concerned about additional costs to consumers who enroll in STLDI or fixed indemnity excepted benefits coverage and incur medical expenses that are not covered by such coverage. The typical limits on coverage provided by STLDI and fixed indemnity excepted benefits coverage can lead to more and higher uncovered medical bills than consumers enrolled

[79] McDermott, Daniel and Cynthia Cox (2020). ''Insurer Participation on the ACA Marketplaces, 2014–2021,'' KFF, available at: *https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021.*

[80] *See* KFF (2024). ''Number of Issuers Participating in the Individual Health Insurance Marketplaces, 2014–2024,'' available at: *https://www.kff.org/other/state-indicator/number-of-issuers-participating-in-the-individual-health-insurance-marketplace.*

[81] *See* CMS (2024). ''Marketplace 2024 Open Enrollment Period Report: Final National Snapshot,'' available at: *https://www.cms.gov/newsroom/fact-sheets/marketplace-2024-open-enrollment-period-report-final-national-snapshot.*

[82] *See* CMS (2023). ''Health Insurance Marketplaces, 2023 Open Enrollment Report,'' available at: *https://www.cms.gov/files/document/health-insurance-exchanges-2023-open-enrollment-report-final.pdf.*

[83] Although unsubsidized premiums for 2023 increased on average between 2.2 percent and 4.7 percent compared to the previous year, after 4 years of declines, the expanded PTC subsidies under the IRA largely shielded many consumers from these premium increases. *See* Ortaliza, Jared, Justin Lo, Krutika Amin, and Cynthia Cox (2022). ''How ACA Marketplace Premiums Are Changing By County in 2023,'' KFF, available at: *https://www.kff.org/private-insurance/issue-brief/how-aca-marketplace-premiums-are-changing-by-county-in-2023.*

[84] Congressional Budget Office (2022). ''Letter from Phillip L. Swagel to Rep. Mike Crapo, ''Re: Health Insurance Policies,'' available at: *https://www.cbo.gov/system/files?file=2022-07/58313-Crapo_letter.pdf.*

[85] 87 FR 61979 (October 13, 2022).

[86] *Id.* at 61999.

[87] Collins, Sara, Lauren Haynes, and Relebohile Masitha (2022). ''The State of U.S. Health Insurance in 2022: Findings from the Commonwealth Fund Biennial Health Insurance Survey,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/publications/issue-briefs/2022/sep/state-us-health-insurance-2022-biennial-survey.*

[88] Regarding trends in national health expenditure, *see* CMS (2023). ''NHE Fact Sheet,'' available at: *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

in comprehensive coverage would incur, exposing consumers with STLDI or fixed indemnity excepted benefits coverage to greater financial risk.[89] Healthy consumers who enroll in STLDI or fixed indemnity excepted benefits coverage as an alternative to comprehensive coverage may not realize their STLDI or fixed indemnity excepted benefits coverage excludes or limits coverage for preexisting conditions (including conditions the consumer did not know about when they enrolled), or conditions contracted after enrollment,[90] such as COVID–19, as discussed in this section and in section V.B.2.a.

Additionally, a consumer enrolled in STLDI may discover that a newly-diagnosed medical condition is categorized as a preexisting condition, and related medical expenses will not be covered by, or will be only partially covered by, their STLDI policy.[91] For example, a consumer in Illinois who was diagnosed with Stage IV cancer a month *after* enrolling in STLDI was denied coverage for treatment by the STLDI issuer, both for treatments that led to his successful remission and for a potentially life-saving bone marrow transplant. In his case, the issuer of his STLDI policy determined that his cancer was a preexisting condition because he had disclosed experiencing back pain of undiagnosed cause to the broker who sold him his STLDI policy—leaving him with $800,000 of medical debt and without meaningful health coverage as he continued to fight his illness.[92]

The financial risk for consumers enrolled in STLDI increases with the length of their policy, as the longer consumers are enrolled in STLDI, the more likely they are to incur costs that are not covered. This is especially the case for consumers who encounter newly diagnosed conditions or have a significant medical event while enrolled in STLDI. Researchers found that the maximum out-of-pocket health care spending limit for STLDI was on average nearly three times that of comprehensive coverage in 2020.[93] A 2020 report found that over 60 percent of the STLDI policies surveyed had a maximum out-of-pocket limit greater than the $7,900 limit that was permitted for self-only comprehensive coverage in 2019, and 15 percent had limits in excess of $15,000; as is typical for STLDI, these limits apply only to the coverage period, which in some cases was only 6 months, compared to the annual limits required under the ACA for comprehensive coverage.[94] Consumers enrolled in STLDI who ultimately require medical care are more likely to incur higher out-of-pocket costs than if they had enrolled in comprehensive coverage.[95] Refer to section V.B.2.c of this preamble for additional discussion of the financial risks to consumers.

As noted in section I.D of this preamble, consumers who enroll in fixed indemnity excepted benefits coverage as an alternative to comprehensive coverage bear similar risk and exposure to significant out-of-pocket expenses due to their health care costs exceeding the fixed cash benefit to which they may be entitled, if benefits are even provided at all for their illness or injury. Comments received in response to the 2023 proposed rules affirmed the Departments' concerns by offering several examples of consumer risk and exposure resulting from enrollment in fixed indemnity insurance. For example, one commenter described a fixed indemnity plan that advertised that it would pay $25 for a doctor visit, $100 for a diagnostic exam, and $300 for neonatal intensive care, and contrasted those benefits to one hospital's pricing schedule for NICU service, Level 4. The commenter observed that a consumer with such fixed indemnity insurance alone could still face $8,500 daily for NICU services. Another commenter stated that indemnity plans that are structured to pay various dollar amounts for different services appear very similar to comprehensive insurance, even though they offer much less coverage.

Consumers who enroll in STLDI and fixed indemnity excepted benefits coverage and do not also have comprehensive coverage may experience financial hardship when their medical bills are unaffordable.[96] Notably, the protections against balance billing and out-of-network cost sharing for certain out-of-network services established under the No Surprises Act, which are intended to shield consumers from surprise bills that can result in medical debt,[97] do not apply to STLDI or fixed indemnity excepted benefits coverage.[98] Because STLDI is typically subject to medical underwriting and is not guaranteed renewable, consumers enrolled in STLDI in lieu of comprehensive coverage may be unable to renew their STLDI policy at the end of the coverage period. These consumers therefore face the risk of being uninsured until they are eligible to purchase comprehensive coverage in the individual market during an open

[89] Palanker, Dania, JoAnn Volk, and Kevin Lucia (2018). ''Short-Term Health Plan Gaps and Limits Leave People at Risk,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2018/short-term-health-plan-gaps-and-limits-leave-people-risk.* (Describing STLDI marketing materials that list coverage limits that would fall far short of typical costs to a consumer, including $1,000 a day for hospital room and board coverage, $1,250 a day for the intensive care unit, $50 a day for doctor visits while in the hospital, $100 a day for inpatient substance abuse treatment, and $250 for ambulance transport).

[90] *See* Williams, Jackson (2022). ''Addressing Low-Value Insurance Products With Improved Consumer Information: The Case of Ancillary Health Products,'' National Association of Insurance Commissioners, *Journal of Insurance Regulation,* available at: *https://content.naic.org/sites/default/files/cipr-jir-2022-9.pdf.*

[91] *See* Lueck, Sarah (2018). ''Key Flaws of Short-Term Health Plans Pose Risks to Consumers,'' Center on Budget and Policy Priorities, available at: *https://www.cbpp.org/research/health/key-flaws-of-short-term-health-plans-pose-risks-to-consumers. See also* Hall, Mark and Michael McCue (2022). ''Short-Term Health Insurance and the ACA Market,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2022/short-term-health-insurance-and-aca-market. See also* Partnership to Protect Coverage (2021). ''Under-Covered: How 'Insurance-Like' Products are Leaving Patients Exposed,'' available at: *https://www.nami.org/NAMI/media/NAMI-Media/Public%20Policy/Undercovered_Report_03252021.pdf.*

[92] Partnership to Protect Coverage (2021). ''Under-Covered: How 'Insurance-Like' Products are Leaving Patients Exposed,'' available at: *https://www.nami.org/NAMI/media/NAMIMedia/Public%20Policy/Undercovered_Report_03252021.pdf.*

[93] Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-term Limited-duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[94] *Id. See also* Palanker, Dania, Kevin Lucia, and Emily Curran (2017). ''New Executive Order: Expanding Access to Short-Term Health Plans Is Bad for Consumers and the Individual Market,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2017/new-executive-order-expanding-access-short-term-health-plans-bad-consumers-and-individual.* (''When considering the deductible, the best-selling plans have out-of-pocket maximums ranging from $7,000 to $20,000 for just three months of coverage. In comparison, the ACA limits out-of-pocket maximums to $7,150 for the entire [2017 calendar] year.'').

[95] *Id.*

[96] Unaffordable medical debt increasingly impacts members of disadvantaged and marginalized communities. *See* Lopes, Lunna, Audrey Kearney, Alex Montero, Liz Hamel, and Mollyann Brodie (2022). ''Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills,'' KFF, available at: *https://www.kff.org/health-costs/report/kff-health-care-debt-survey. See also* Himmelstein, David, Samuel Dickman, Danny McCormick, David Bor, Adam Gaffney, and Steffie Woolhandler (2022). ''Prevalence and Risk Factors for Medical Debt and Subsequent Changes in Social Determinants of Health in the US,'' *JAMA Network Open,* Volume 5, Issue 9, available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796358.*

[97] Families USA (2019). ''Surprise Medical Bills, Results from a National Survey,'' available at: *https://familiesusa.org/wp-content/uploads/2019/11/Surprise-Billing-National-Poll-Report-FINAL.pdf.*

[98] *See* 26 CFR 54.9816–2T, 29 CFR 2590.716–2(b), and 45 CFR 149.20(b).

enrollment or when a special enrollment period occurs. It is therefore critical for consumers to understand, prior to purchase, that STLDI serves better as a bridge between different sources of comprehensive coverage than as an alternative to comprehensive coverage, and that choosing to substitute STLDI for comprehensive coverage may reduce access to coverage. Similarly, as noted in section I.D of this preamble, consumers need to understand, prior to purchase, that fixed indemnity excepted benefit coverage serves best as an income replacement policy [99] that supplements comprehensive coverage by providing financial assistance, rather than serving as an alternative to comprehensive coverage.

In the preamble to the 2018 final rules, the Departments stated that individuals who purchased STLDI would potentially experience improved health outcomes and have greater protection from catastrophic health care expenses than if those individuals were uninsured.[100] However, experience with the COVID–19 public health emergency (PHE) [101] has prompted the Departments to reassess the degree of protection generally afforded by STLDI and fixed indemnity excepted benefits coverage, and to reassess the value of a framework that instead encourages uninsured individuals to purchase comprehensive coverage. Enrollees in STLDI with COVID–19 typically face significant limitations on coverage for COVID–19 related treatments, and high out-of-pocket expenses.[102] In addition, neither STLDI nor fixed indemnity excepted benefits coverage was subject to requirements under section 6001 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020), as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to cover COVID–19 diagnostic testing, without cost sharing, furnished during the COVID–19 PHE; or the requirement under section 3203 of the CARES Act to cover qualifying coronavirus preventive services, including COVID–19 vaccines, without cost sharing.[103] Instead, both of these important coverage expansions enacted by Congress as part of the nation's response to the COVID–19 PHE applied only to comprehensive coverage. Any coverage by STLDI of (or, with respect to fixed indemnity excepted benefits coverage, benefits provided related to) COVID–19 diagnostic testing or vaccines was subject to the discretion of individual issuers of these policies and applicable State law. Notably, the Health Resources and Services Administration's COVID–19 Coverage Assistance Fund, which reimbursed eligible health care providers for providing COVID–19 vaccines to underinsured individuals, included enrollees in STLDI and excepted benefits coverage within the definition of underinsured.[104] The CARES Act also amended the definition of ''uninsured individual'' in Social Security Act section 1902(ss) to include individuals enrolled only in STLDI. Even individuals enrolled in STLDI or fixed indemnity excepted benefits coverage who are generally healthy are at risk of needing health care, and thus at risk of incurring unaffordable medical bills at any time. The COVID–19 PHE underscored the unpredictability of when the need for medical care will arise, and the importance of encouraging individuals to enroll in comprehensive coverage.

The Departments have also become aware of potentially deceptive or aggressive marketing of STLDI and fixed indemnity excepted benefits coverage to consumers who may be unaware of the coverage limits of these plans or the availability of Federal subsidies that could reduce the costs of premiums and out-of-pocket health care expenditures for comprehensive coverage purchased

[99] As an income replacement policy, the policyholder of a fixed indemnity excepted benefits coverage plan typically has broad discretion in how to use the fixed cash benefits provided, including but not limited to payment for medical expenses not covered by comprehensive coverage (for example, deductibles, coinsurance, copays) or to defray non-medical costs (for example, mortgage or rent).

[100] 83 FR 38212, 38229 (October 2, 2018).

[101] On January 31, 2020, HHS Secretary Alex M. Azar II declared that as of January 27, 2020, a nationwide public health emergency exists as a result of the 2019 novel coronavirus (COVID–19). *See* HHS Administration for Strategic Preparedness and Response (January 31, 2020). ''Determination That A Public Health Emergency Exists,'' available at: *https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx.* This declaration was last renewed by HHS Secretary Xavier Becerra on October 13, 2022, following previous renewals on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 20, 2021, October 18, 2021, January 14, 2022, April 12, 2022, and July 15, 2022. *See* ''HHS Administration for Strategic Preparedness and Response, Renewal of Determination That A Public Health Emergency Exists,'' available at: *https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx.* On January 30, 2023, and February 9, 2023, the Biden-Harris Administration announced that it intended to end the PHE at the end of the day on May 11, 2023. *See* Executive Office of the President, Office of Management and Budget (January 30, 2023). ''Statement of Administration Policy: H.R. 382 and H.J. Res. 7,'' available at: *https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf;* HHS Secretary Xavier Becerra (February 9, 2023). ''Letter to U.S. Governors from HHS Secretary Xavier Becerra on renewing COVID–19 Public Health Emergency (PHE),'' available at: *https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html.* The PHE ended at the end of the day on May 11, 2023.

[102] *See, for example,* Curran, Emily, Kevin Lucia, JoAnn Volk, and Dania Palanker (2020). ''In the Age of COVID–19, Short-Term Plans Fall Short for Consumers,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2020/age-covid-19-short-term-plans-fall-short-consumers.* This study found that STLDI policies provide less financial protection than comprehensive coverage if an enrollee needs treatment for COVID–19. The study found that among the 12 brochures reviewed for STLDI policies being sold in Georgia, Louisiana, and Ohio, 11 excluded nearly all coverage for prescription drugs, with some providing limited coverage of inpatient drugs. The study further found that STLDI imposed high cost sharing, with deductibles ranging from $10,000 to $12,500 (which did not count toward the enrollees' maximum out-of-pocket costs) and that enrollees may be required to meet separate deductibles for emergency room treatment, forcing some enrollees to face out-of-pocket costs of more than $30,000 over a 6-month period. Additionally, the study found that STLDI did not cover services related to pre-existing conditions.

[103] Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 71142, 71173 (Nov. 6, 2020); *See also* Departments of the Treasury, Labor, and Health and Human Services. ''FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, Q1,'' (April 11, 2020), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf* and *https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf* (FAQs Part 42); ''FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 50,'' (October 4, 2021), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-50.pdf* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-50.pdf* (FAQs Part 50); ''FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation,'' (Jan. 10, 2022), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf* (FAQs Part 51); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52'' (February 4, 2022), available at: *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-52.pdf* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-52.pdf* (FAQs Part 52); and ''FAQs about Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act and Health Insurance Portability and Accountability Act Implementation Part 58'' (March 29, 2023), available at: *https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-58* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf* (FAQs Part 58). Note that the COVID–19 PHE ended on May 11, 2023.

[104] Underinsured individuals are defined for this purpose as having a health plan that either does not include COVID–19 vaccine administration as a covered benefit or covers COVID–19 vaccine administration but with cost sharing. *See* Health Resources and Services Administration. ''FAQs for The HRSA COVID–19 Coverage Assistance Fund,'' available at: *https://www.hrsa.gov/provider-relief/about/covid-19-coverage-assistance/faq.*

through an Exchange.[105] A recent study that engaged in covert testing of health insurance sales representatives found evidence of deceptive marketing practices by agents and brokers who omitted or misrepresented information about the products they were selling.[106] For example, during a phone transaction, a sales representative told the consumer that they were purchasing a comprehensive health insurance plan, but instead sold the consumer two limited benefit insurance plans. During the exchange, the consumer repeatedly informed the sales representative that they had diabetes and had recently been seeking treatment for the condition. However, the application filled out by the sales representative on the consumer's behalf stated that consumer had not been treated for or diagnosed with diabetes for the past 5 years. In another phone transaction, the sales representative enrolled the consumer in a benefit association offering a limited benefit indemnity insurance plan. The representative would not provide the consumer with documentation describing the plan prior to enrollment and stated that the consumer had to purchase the plan on the day of the call if they wanted to be guaranteed the quoted price. The Departments note that these concerns are not limited to individual market consumers considering STLDI or fixed indemnity excepted benefits coverage. Reports that employers are increasingly offering fixed indemnity coverage alongside a plan that offers only a very limited set of primary or preventive care benefits (or in some cases, as the only form of health coverage) have also raised concerns with respect to consumers who obtain this health coverage through their employers.[107]

Consumers who are unaware of the coverage limitations of these arrangements, or who are employed by employers who are similarly unaware, can face overwhelming medical costs if they require items and services that are not covered by the very limited group health plan. This is because the fixed indemnity excepted benefits coverage generally provides only fixed cash benefits that may be far lower than the costs of medical services, rather than coverage intended to cover most of the costs of the medical services themselves. For example, a Texas consumer who was enrolled in two forms of health insurance through his employer received a $67,000 hospital bill after he experienced a heart attack. Although he believed he had comprehensive coverage, he learned that his coverage was provided through a group health plan that covered only preventive services and prescription drugs and a fixed indemnity excepted benefits coverage policy that provided a cash benefit of less than $200 per day of hospitalization.[108] Additionally, employers may incur penalties if they erroneously treat fixed indemnity policies as excepted benefits when the policies do not meet the requirements for excepted benefits (for example, when they are not offered as independent, noncoordinated benefits) and fail to comply with applicable group market Federal consumer protections and requirements for comprehensive coverage, such as the requirement to provide participants, beneficiaries, and enrollees with a summary of benefits and coverage that meets applicable content requirements or the prohibition on lifetime and annual dollar limits on essential health benefits.[109]

In light of research revealing significant disparities in health insurance literacy among certain underserved racial and ethnic groups and people with incomes below the FPL,[110] and as further discussed in sections III.A.1 and V.B.2.g of this preamble, the Departments are also concerned that underserved populations may be particularly vulnerable to misleading or aggressive sales and marketing tactics that obscure the differences between comprehensive coverage and STLDI or fixed indemnity excepted benefits coverage, exposing these populations to higher levels of health and financial risks. As noted in Executive Order 13995, the COVID–19 pandemic has ''exposed and exacerbated severe and pervasive health and social inequities in America,'' highlighting the urgency with which such inequities must be addressed.[111] These concerns continue during the time frame when States are unwinding from the Medicaid continuous enrollment condition under the Families First Coronavirus Response Act (FFCRA), which expired on March 31, 2023, under amendments made by the Consolidated Appropriations Act, 2023. Across the country, State agencies are currently in the process of resuming regular eligibility and enrollment operations, which includes conducting full Medicaid and CHIP renewals and terminating coverage for individuals who are no longer eligible.[112] As a result, individuals may have to transition between coverage programs, leaving them vulnerable.[113] The Departments are concerned that those transitioning out of Medicaid coverage may be susceptible to aggressive or deceptive marketing and sales tactics,

[105] Palanker, Dania and Kevin Lucia (2021). ''Limited Plans with Minimal Coverage Are Being Sold as Primary Coverage, Leaving Consumers at Risk,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2021/limited-plans-minimal-coverage-are-being-sold-primary-coverage-leaving-consumers-risk.* (Noting that fixed indemnity insurance may be ''bundled'' with other non-comprehensive insurance products in such a way that ''the plans look like comprehensive coverage'' while still offering limited benefits). *See also* Palanker, Dania, JoAnn Volk, and Maanasa Kona (2019). ''Seeing Fraud and Misleading Marketing, States Warn Consumers About Alternative Health Insurance Products,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/seeing-fraud-and-misleading-marketing-states-warn-consumers-about-alternative-health.*

[106] Government Accountability Office (2020). ''Private Health Coverage: Results of Covert Testing for Selected Offerings,'' available at: *https://www.gao.gov/products/gao-20-634r.*

[107] Young, Christen Linke and Kathleen Hannick (2020). ''Fixed Indemnity Coverage is a Problematic Form of ''Junk'' Insurance,'' U.S.C.-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance.*

[108] Avila, Jaie (2019). ''Show Me Your Bill Helps Wipe Out $70K in Charges After Heart Attack,'' News 4 San Antonio, available at: *https://news4sanantonio.com/news/trouble-shooters/show-me-your-bill-helps-wipe-out-70k-in-charges-after-heart-attack.*

[109] *See* 26 CFR 54.9815–2715(e); 29 CFR 2590.715–2715(e); 45 CFR 147.200(e). *See also* section 2711 of the PHS Act and section 4980D of the Code.

[110] Edward, Jean, Amanda Wiggins, Malea Hoepf Young, Mary Kay Rayens (2019). ''Significant Disparities Exist in Consumer Health Insurance Literacy: Implications for Health Care Reform,'' *Health Literacy Research and Practice,* available at: *https://pubmed.ncbi.nlm.nih.gov/31768496. See also* Villagra, Victor and Bhumika Bhuva (2019). ''Health Insurance Literacy: Disparities by Race, Ethnicity, and Language Preference,'' *The American Journal of Managed Care,* available at: *https://www.ajmc.com/view/health-insurance-literacy-disparities-by-race-ethnicity-and-language-preference.*

[111] 86 FR 7193 (January 26, 2021).

[112] *See* CMS, Center for Medicaid & CHIP Services (January 5, 2023). Key Dates Related to the Medicaid Continuous Enrollment Condition Provisions in the Consolidated Appropriations Act, 2023, available at: *https://www.medicaid.gov/sites/default/files/2023-01/cib010523_1.pdf.* As a condition of receiving a temporary Federal Medical Assistance Percentage (FMAP) increase under section 6008 of the FFCRA, States were required to maintain enrollment of nearly all Medicaid enrollees. This ''continuous enrollment condition'' expired on March 31, 2023, under amendments made by the Consolidated Appropriations Act, 2023. States adopted other flexibilities in CHIP and BHP that impacted renewals in those programs during this time.

[113] *See* CMS, Center for Medicaid & CHIP Services (January 27, 2023). ''Letter to State Health Officials from Deputy Administrator and Director Daniel Tsai RE: Medicaid Continuous Enrollment Condition Changes, Conditions for Receiving the FFCRA Temporary FMAP Increase, Reporting Requirements, and Enforcement Provisions in the Consolidated Appropriations Act, 2023,'' available at: *https://www.medicaid.gov/sites/default/files/2023-08/sho23002.pdf.*

and might therefore mistakenly enroll in STLDI or fixed indemnity excepted benefits coverage in lieu of comprehensive coverage.

C. Impact on Risk Pools

At the time the 2018 final rules were issued, the Departments acknowledged that expanding access to STLDI could have potential negative effects on the risk pools for individual health insurance coverage and on individuals who find themselves insufficiently protected by the typically limited benefits of an STLDI policy.[114] However, the Departments were of the view that the affordability and access challenges facing consumers at that time outweighed those potential negative effects and necessitated action to increase access to STLDI to provide an alternative option for individuals who were unable or disinclined to purchase comprehensive coverage.

As discussed earlier in section II.A of this preamble, access to affordable comprehensive coverage has significantly improved since the 2018 final rules were published. However, research based on individual market data for plan year 2020 has substantiated concerns about the negative impact that the shift of healthier individuals from comprehensive coverage to STLDI has on individuals remaining in the risk pools for individual health insurance coverage.[115] Because healthier individuals are more likely to enroll in STLDI than individuals with known medical needs, the extended contract terms and renewal periods of STLDI under the current Federal regulations result in healthier consumers leaving (or opting out of) the risk pools for individual health insurance coverage for extended periods of time. This has resulted in increased premiums for individuals seeking to purchase individual health insurance coverage.[116] For unsubsidized individuals, the costs are borne directly by the consumer, and for subsidized individuals, the costs are borne largely by the Federal Government in the form of increased per capita PTC spending associated with increased individual health insurance coverage premiums. Likewise, reports of fixed indemnity excepted benefits coverage being marketed and sold as an alternative to comprehensive coverage, as discussed in section V.B.2.a of this preamble, raise concerns about the potential for such practices having a similar impact on the risk pools for individual health insurance coverage.

Another study looking at States that have adopted policies that restrict STLDI to shorter durations than allowed under the current Federal regulations found that, from 2018 to 2020, States that restricted or prohibited the sale of STLDI saw fewer consumers enroll in such insurance, were able to keep more healthy people in the individual health insurance coverage market risk pool, and saw a greater decline in average medical costs for enrollees in individual health insurance coverage.[117] The study reported that, as a result, the risk score—a measurement of the relative medical costs expected for the populations covered by comprehensive coverage in each State, both on- and off-Exchange—decreased by 40 percent more in States with more regulation of STLDI than States with less regulation.[118]

In addition to ensuring that consumers can clearly distinguish STLDI from comprehensive coverage, this new evidence provides an additional basis for the Departments' conclusion that it is important to amend the Federal definition of STLDI.

D. Need for Rulemaking

For the reasons described in this section II of this preamble, the Departments are of the view that it is necessary and appropriate to amend the Federal definition of STLDI to ensure that consumers can clearly distinguish STLDI from comprehensive coverage, protect the risk pools and stabilize premiums for individual health insurance coverage, and promote access to affordable comprehensive coverage.

With respect to individual market fixed indemnity excepted benefits coverage, the decision in *Central United Life Ins. Co.* v. *Burwell,* which invalidated the requirement that an individual must attest to having MEC prior to purchasing fixed indemnity excepted benefits coverage in the individual market, and the passage of the Tax Cuts and Jobs Act, which reduced the individual shared responsibility payment to $0 for months beginning after December 31, 2018, increase the likelihood that individuals would purchase fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage. HHS is of the view that these changes necessitate rulemaking with respect to individual market fixed indemnity excepted benefits coverage. Further, while the Departments did not finalize the proposed amendments to the group market fixed indemnity excepted benefits coverage regulations outlined in the 2016 proposed rules, the Departments noted their intention to address fixed indemnity excepted benefits coverage in future rulemaking.[119] The Departments have continued to monitor the impact of these coverage options and remain concerned about the negative impacts of fixed indemnity excepted benefits coverage on consumers when such products are sold as an alternative to comprehensive coverage.

In light of the Departments' ongoing concerns about the numerous negative impacts of STLDI and fixed indemnity excepted benefits coverage being offered as an alternative to comprehensive coverage, as well as the significant changes in market conditions and in the legal landscape since the Departments' last regulatory actions addressing these products, and in consideration of the comments on the 2023 proposed rules received by the Departments, the Departments are finalizing changes to the Federal regulations governing STLDI and addressing notice requirements in the individual and group market regulations related to fixed indemnity excepted benefits coverage. HHS is also finalizing the technical amendments to the individual market fixed indemnity excepted benefits coverage regulation to remove the MEC attestation requirement currently codified at 45 CFR 148.220(b)(4)(i). As further explained in section III.B of this preamble, the Departments are not finalizing the proposed payment standards and noncoordination provisions regarding

[114] 83 FR 38212 at 38218 (August 3, 2018).

[115] *See* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-term Limited-duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[116] *Id.* (''Carrier expectations for the impact of [regulatory actions including the expansion of short-term, limited-duration insurance policies and other loosely regulated insurance and the repeal of the Federal individual shared responsibility payment being reduced to $0] on premiums in the ACA individual market for 2020 are approximately 4 percent in [S]tates that have not restricted the sale or duration of STLD policies . . . Among the [S]tates that have limited the impact of loosely regulated insurance through reinstating an individual mandate or by restricting STLD expansion, carriers have assumed an average premium impact in 2020 due to regulatory actions that is about 5 percent lower than other [S]tates.'') As noted in section V.B.2.e of this preamble, this study also found that the few issuers that explicitly included a premium adjustment because of the adoption of the revised Federal definition of STLDI in the 2018 final rules increased premiums by between 0.5 percent and 2 percent in 2020.

[117] *See* Hall, Mark and Michael McCue (2022). ''Short-Term Health Insurance and the ACA Market,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2022/short-term-health-insurance-and-aca-market.*

[118] *Id.*

[119] 81 FR 75316 at 75317 (October 31, 2016).

fixed indemnity excepted benefits coverage at this time. The Departments remain concerned about the issues addressed by these proposals, and intend to address these issues in future rulemaking, after additional study and consideration of the concerns raised in comments.

III. Overview of the Final Regulations—The Departments of the Treasury, Labor, and Health and Human Services

A. Short-Term, Limited-Duration Insurance

After considering the public comments, the Departments are finalizing the proposed amendments to the Federal definition of STLDI with some modifications. Under the definition in these final rules, STLDI means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance that has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this definition, a renewal or extension includes the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance. As explained in section III.A.2 of this preamble, in response to comments, the Departments are specifying that for purposes of this definition, if the issuer is a member of a controlled group, a renewal or extension also includes the term of a new STLDI policy, certificate, or contract of insurance issued by any other issuer that is a member of such controlled group. As used in this context, the term ''controlled group'' means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code, as amended.

These final rules also retain the requirement that STLDI issuers display a notice on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font. As finalized in these final rules, STLDI issuers must use the following updated language for the STLDI consumer disclosure notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

As explained in section III.A.4 of this preamble, in response to comments, the notice adopted in these final rules contains additional specificity, including that STLDI does not have to meet Federal standards for comprehensive coverage and information about finding contact information for State departments of insurance on the NAIC website (*naic.org*).

In response to comments, the Departments are finalizing modified applicability dates. These final rules apply to new STLDI policies sold or issued on or after September 1, 2024. The provisions of the 2018 final rules

continue to apply to STLDI policies sold or issued before September 1, 2024, except that the updated notice provision adopted in these final rules applies to such policies for coverage periods beginning on or after September 1, 2024. As was proposed in the 2023 proposed rules, these final rules are effective 75 days after publication in the **Federal Register**.

1. In General

The Departments received comments generally in support of and generally opposed to the adoption of the STLDI proposals in the 2023 proposed rules. The Departments summarize and respond to comments about the STLDI proposals in the 2023 proposed rules later in this section of the preamble.

Some commenters stated that the 2023 proposed rules were an overreach of the Departments' authority because Congress did not provide an explicit delegation of authority to define the terms ''short-term'' and ''limited-duration.'' Some commenters expressed concern that the 2023 proposed rules are contrary to congressional intent because Congress specifically determined that certain types of insurance would not be subject to the requirements of the ACA, including STLDI, which is excepted from the definition of individual health insurance coverage. Commenters suggested that the Departments' interpretation is unreasonable because it conflicts with and undermines Congress's express goals for consumers to have access to STLDI plans that are exempt from Federal regulation, to reduce gaps in health insurance and the number of uninsured. One commenter also expressed concern that the Departments' interpretation will increase medical underwriting frequency to every 3 to 4 months leading to more consumers losing coverage. One commenter stated that the Departments' interpretation is unreasonable because it pressures consumers into enrolling in comprehensive coverage to avoid greater financial exposure. Several commenters stated that there is no statutory basis for the Departments to regulate consumer behavior and the Departments have no legal authority to impose burdens or limitations on STLDI, such as a consumer notice. One commenter argued that the Departments lack the authority to implement a shorter maximum allowed length because the proposals are overly broad and will unduly harm consumers. Several commenters stated that the proposed rules are arbitrary, capricious, and not in accordance with law because the Departments rely on factors to justify the new definition that were not relevant to Congress's considerations.

The Departments are not persuaded by these comments. As explained in greater detail in this section III.A.1 of this preamble, these final rules revise the definition for the term ''short-term, limited-duration insurance,'' and set standards to more clearly distinguish STLDI from individual health insurance coverage. These final rules do not regulate consumer behavior. Consumers will continue to have access to STLDI plans that are generally exempt from the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage.[120] As detailed later in this section of this preamble, the Departments have clear authority to promulgate regulations to define STLDI and to pursue the current amendments. The Departments also disagree that the definition in the proposed rules, and as finalized in these rules, is unreasonable, inconsistent with the law, or arbitrary and capricious.

Other commenters stated that the Departments have clear statutory authority under the PHS Act to interpret undefined terms in the PHS Act, ERISA, and the Code,[121] and to promulgate regulations that interpret (or reinterpret) the meaning of ''short-term, limited-duration,'' so long as their interpretation is reasonable. These commenters observed that Congress did not define the term ''short-term, limited-duration insurance,'' and primarily only included a reference to STLDI as an exclusion from individual health insurance coverage.[122] [123] These commenters explained that the Departments must give meaning to the term short-term, limited-duration insurance to distinguish it from individual health insurance coverage.

The Departments disagree with the commenters who questioned the Departments' legal authority to promulgate Federal regulations to define STLDI and distinguish it from individual health insurance coverage. As explained in the preamble to the 2018 final rules,[124] the Departments have clear statutory authority under the Code, ERISA, and the PHS Act to implement those statutes.[125] To determine what is and is not individual health insurance coverage, which is essential to ensure that the Code, ERISA, and the PHS Act function as Congress intended, and to allow enforcement of the rules that apply to individual health insurance coverage, the Departments must give meaning to the term STLDI.[126]

The 2023 proposed rules are faithful to Congress's intent because Congress wanted STLDI to be an option but did not intend STLDI to be a substitute for comprehensive coverage or to pass as comprehensive coverage while avoiding ACA requirements and other Federal consumer protections applicable to comprehensive coverage. Finally, the 2023 proposed rules and these final rules are not designed to limit access to STLDI or pressure consumers into enrolling in comprehensive coverage. Rather, they are designed to, among other things, ensure that consumers can distinguish between STLDI and comprehensive coverage. Congress provided the Secretaries of the Treasury, Labor, and HHS with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act.[127] This includes the authority to issue regulations on STLDI to define it and set standards to distinguish it from individual health insurance coverage.

The Departments' authority to issue regulations that define STLDI and set standards to distinguish it from individual health insurance coverage was also recently affirmed in the D.C.

[120] Neither the proposed rules nor these final rules seek to extend the Federal consumer protections and requirements for comprehensive individual health insurance coverage to STLDI.

[121] *See* section 715 of ERISA and section 9815 of the Code, which incorporate provisions of part A of title XXVII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into ERISA and the Code. *See also* section 104 of HIPAA. *See also* sections 505 and 734 of ERISA, sections 2761 and 2792 of the PHS Act, section 1321(a)(1) and (c) of ACA and section 7805 of the Code.

[122] *See* section 2791(b)(5) of the PHS Act (defining ''individual health insurance coverage'').

[123] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

[124] 83 FR 38212 at 38215 (August 3, 2018).

[125] *See* section 9815 of the Code and section 715 of ERISA, which incorporate provisions of Part A of title XVIII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into the Code and ERISA. *See also* section 104 of HIPAA. *See also* section 7805 of the Code, sections 505 and 734 of ERISA, sections 2761 and 2792 of the PHS Act, and section 1321(a)(1) and (c) of the ACA. *See also Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury,* 966 F.3d 782 (D.C. Cir. 2020).

[126] As discussed in footnote 13, the definition of STLDI also has some relevance with respect to certain provisions that apply to group health plans and group health insurance issuers over which the Departments of Labor and the Treasury have jurisdiction.

[127] *See* section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Circuit.[128] In 2020, the D.C. Circuit explicitly considered the Departments' authority to define STLDI as finalized in the 2018 final rules and affirmed the Departments' authority to promulgate such regulations.[129] The D.C. Circuit stated:

> Without further guidance from Congress, we will not place amorphous restrictions on the Departments' authority to define such an open-ended term. It suffices to say that the Departments have the discretion to define STLDI to include policies shorter than the standard policy term.[130]

Furthermore, the decision made clear that Congress gave the Departments ''wide latitude'' to define STLDI, which includes the flexibility to narrow the definition of STLDI in the future, provided the Departments provide a reasoned explanation for the change.[131] Both the 2023 proposed rules and these final rules provide the Departments' reasoned explanations for the changes to the Federal definition of STLDI. These final rules adopt a revised Federal definition of the term STLDI and set standards to more clearly distinguish STLDI from individual health insurance coverage without placing unreasonable burdens on issuers of STLDI.

The Departments acknowledge that the final rules may be associated with some consumers being subject to medical underwriting more frequently. For example, a consumer who prefers STLDI coverage and chooses to reenroll in STLDI coverage with a different issuer every 4 months may be subject to medical underwriting each time they enroll or renew coverage, whereas under the current rules they could stay in one STLDI policy for a longer duration. However, in the Departments' view, this possibility does not outweigh other potential benefits to consumers of the revised definition of STLDI, in part because consumers face a similar risk under the current rules. Even when enrolled in STLDI coverage that complies with the 2018 final rules, a consumer can be subject to post-claims underwriting and their STLDI coverage may not cover certain health conditions that develop unexpectedly or over time. Yet because the STLDI coverage has a longer maximum duration under current rules, a consumer who remains in STLDI coverage might go without necessary benefits for a longer period of time, forcing the consumer to choose between necessary medical care and high out-of-pocket expenses. Consumers may avoid the potential consequences of more frequent medical underwriting by enrolling in comprehensive coverage subject to Federal consumer protections and requirements.

The definition and standards, as proposed and finalized, apply to health insurance issuers that elect to offer STLDI, and they do not regulate consumer behavior. Issuers will not be prohibited from selling STLDI and consumers may continue to choose to purchase it. The changes to the Federal definition and standards for STLDI will help consumers make more informed purchasing decisions and mitigate the risk that consumers will mistakenly enroll in STLDI as a substitute for comprehensive coverage.

The Departments disagree that the revised Federal definition of STLDI is unreasonable or arbitrary and capricious. As explained in the preamble to the 2023 proposed rules[132] and in the introduction to this section III.A of this preamble, the Federal definition established in these final rules clearly distinguishes STLDI from individual health insurance coverage that is subject to the Federal consumer protections and requirements for comprehensive coverage. Further, the statute does not explicitly denote a required length for STLDI or to what extent the definition of STLDI must vary from the definition of individual health insurance coverage, so the Departments are interpreting and implementing the statute in a manner that distinguishes between STLDI and individual health insurance coverage. Over the last two decades, the Departments have used this discretion to both shorten and lengthen the duration of STLDI as the Departments have deemed appropriate and necessary given the market conditions and legal landscape they were then facing. Beginning in 1997, the Departments defined STLDI as coverage of less than 12 months to accommodate 12-month preexisting condition exclusion periods imposed by group health plans and group health insurance issuers when a new hire did not have 12 months of creditable coverage that ended no more than 63 days prior to the enrollment date in the plan or coverage.[133] Once preexisting condition exclusions were prohibited and the Departments implemented a limit on employee waiting periods of up to 90 days plus a 1-month reasonable and bona fide employment-based orientation period (as defined in section 9801(b)(4) of the Code, section 701(b)(4) of ERISA, and 2704(b)(4) of the PHS Act),[134] and comprehensive coverage in the individual market was guaranteed available to individuals through or outside of the Exchanges, the Departments determined that a shorter duration for STLDI was more appropriate and revised the definition in the 2016 final rules.[135] Subsequently, when the Departments were concerned about the availability of affordable health insurance options, the Departments lengthened the initial contract term to less than 12 months with a maximum allowed duration of 36 months (including renewals and extensions) in the 2018 final rules.[136] [137]

The definition of STLDI in the 2023 proposed rules, and that the Departments are finalizing in these final rules, is consistent with applicable Federal law (for example, the Code, ERISA, and the PHS Act). The 2023 proposed rules proposed a revised Federal definition that set standards for STLDI that clearly distinguish it from individual health insurance coverage that is subject to the Federal consumer protections and requirements. This proposal and the definition finalized in these rules is consistent with Congress maintaining the exclusion of STLDI from the PHS Act definition of individual health insurance coverage. Further, as noted by commenters and discussed in section III.A.2 of this preamble, the new definition gives reasonable meaning to the terms ''short-term'' and ''limited-duration'' since they reflect periods of time that are brief in comparison to the length of comprehensive coverage sold with an initial term of 12 months, on a guaranteed renewable basis.[138] The

[128] *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury,* 966 F.3d 782 (D.C. Cir. 2020), *aff'd* 966 F.3d 782 (D.C. Cir. 2020).

[129] *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury,* 966 F.3d 782 (D.C. Cir. 2020).

[130] *Id.* at 789.

[131] *Id.* at 789 and 792 (citing to *Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016)).

[132] *See, for example,* 88 FR 44596 at 44610, 44612, 44614–44618 (July 12, 2023) (discussing how the proposed changes to definitions of ''short-term'' and ''limited-duration'' and the proposed modifications to the required consumer notice would allow consumers to better distinguish between STLDI and comprehensive coverage).

[133] 62 FR 16894 (April 8, 1997). *See also* 69 FR 78,720 (December 30, 2004) (finalizing the definition of STLDI in the 1997 HIPAA interim final rules).

[134] 26 CFR 54.9815–2708, 29 CFR 2590.715–2708, and 45 CFR 147.116.

[135] 81 FR 75316 at 75317, 75318 (October 31, 2016).

[136] As noted previously, the Departments' authority to issue the 2018 final rules was challenged and upheld in *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury,* 966 F.3d 782 (D.C. Cir. 2020). *See also Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury,* 392 F.Supp.3d 22 (D.D.C. 2019).

[137] 83 FR 38212 at 38218 (August 3, 2018).

[138] As the court noted in *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*

Continued

definition of STLDI in the 2023 proposed rules and these final rules is consistent with the original intent of HIPAA, as reinforced by the ACA, to provide temporary, stopgap coverage for individuals transitioning between comprehensive coverage.

Some commenters suggested that the Departments failed to provide sufficient justification, or lacked sufficient data or analysis, to support the proposed changes to the Federal definition of STLDI, particularly with respect to the changes to limit the initial duration of STLDI policies to 3 months, and the maximum duration to 4 months including renewals and extensions. In addition, one commenter expressed concern that an abrupt change to the maximum duration of STLDI may have unintended consequences on overall health care coverage and consumer choices, as occurred when the Departments increased the maximum duration of STLDI from less than 3 months to less than 12 months in the 2018 final rules. Some commenters suggested that the 2023 proposed rules would impose a market-disrupting change in the duration of STLDI without providing evidence to support this change.

As the Supreme Court stated in *Encino Motorcars* v. *Navarro,*[139] and the D.C. Circuit Court repeated in *Association for Community Affiliated Plans* v. *U.S. Department of the Treasury,*[140] ''[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change.'' The Departments satisfy this requirement; the proposed rules and these final rules provide a reasoned explanation of the changes to the Federal definition of STLDI. As explained in section III.A.2 of this preamble, the Departments determined that it is necessary and appropriate to amend the Federal definition of STLDI to ensure that consumers can clearly distinguish STLDI from individual health insurance coverage, protect the risk pools and stabilize premiums for individual health insurance coverage, and promote access to affordable comprehensive coverage. While the Departments acknowledge that they have limited data on enrollment in STLDI, the Departments have sufficient information and evidence to conclude that the changes to the definition finalized in these rules are appropriate and justified. The Departments are of the view that these final rules are necessary and appropriate to combat deceptive marketing practices, distinguish STLDI from individual health insurance coverage, and address the changes in the legal landscape and market conditions from 2018 to 2024. Further, as discussed in section II.A of this preamble, since the publication of the 2018 final rules, comprehensive coverage for individuals has generally become more accessible and affordable, and while affordability concerns persist among consumers, STLDI is an inadequate substitute for comprehensive coverage.

Aggressive, deceptive marketing practices are an ongoing challenge for consumers shopping for coverage. As discussed in section II.B and section III.A.3 of this preamble, recent secret shopper studies have detailed ongoing practices by sellers of STLDI that do not inform consumers of eligibility for less expensive Exchange plans or that provide misleading information about STLDI with limited benefits.[141] Deceptive marketing practices can have devastating financial implications for consumers that purchased STLDI without fully understanding its limitations and later encounter unexpected and expensive medical events that are not covered by their insurance.[142] In addition, as explained in section III.A.2 of this preamble and the preamble to the 2023 proposed rules, the Federal definition for STLDI in these final rules is consistent with the group market rules regarding the 90-day waiting period provision under the ACA and with STLDI's traditional role of serving as temporary coverage for individuals transitioning between other types of comprehensive coverage. The definition is also similar to the less-than-3-month maximum term for STLDI under the 2016 final rules and under a number of State laws and aligns with the goal of Executive Order 14009 to support protections for people with preexisting conditions. The Departments have weighed the potential benefits and costs to consumers when developing the proposed rules and these final rules and concluded the changes will not unduly harm consumers.[143]

While the Departments are of the view that the changes to the Federal definition of STLDI finalized in these rules are critical, these final rules take steps to limit the potential of the rules having an abrupt, disruptive effect, particularly with respect to consumers currently enrolled in STLDI coverage, and to address the potential reliance interests of both issuers offering STLDI and consumers enrolled in STLDI under the 2018 final rules. As discussed in section III.A.6 of this preamble, with the exception of the notice provision, these final rules will not be applicable to STLDI policies sold or issued before September 1, 2024. This will result in a phased-in approach that limits the potential for market disrupting impact by allowing individuals currently enrolled in STLDI to maintain coverage that meets the standards in the 2018 final rules through the duration of their current policy. In addition, this phased-in approach does not require issuers who have relied on the current rules to modify contracts for STLDI policies that are currently in place. Further, the proposed changes that are finalized in these rules will not result in an abrupt change in the maximum permitted duration of STLDI in many States. Of the States that currently permit STLDI, seven States and the District of Columbia already have a maximum permitted length of less than 3 months for STLDI while four additional States prohibit the sale of STLDI entirely, notwithstanding the longer duration permitted under the 2018 final rules.[144] Finally, as these final rules intend to protect against misleading marketing practices that harm consumers, the benefits of further differentiating STLDI from comprehensive coverage outweigh any potential unintended consequences of changing the maximum allowable duration of STLDI. As outlined in this section and elsewhere in these rules, the definition is well reasoned, is clearly

regarding the STLDI definition adopted in the 2018 final rules, ''(u)nder the Departments' definition, 'short-term' refers to the initial contract term, while 'limited-duration' refers to the policy's total length, including renewals. This reasonable reading gives independent meaning to each term.'' 966 F.3d at 789. The Departments are applying the same general framework to establish the new definition adopted in these final rules, with ''short-term'' referring to the initial contract term and the term ''limited-duration'' referring to the policy's total length, including extensions and renewals.

[139] 136 S. Ct. 2117, 2125 (2016).

[140] 966 F. 3d at 792.

[141] Schwab, R., & Volk, J. (August 28, 2023). ''The Perfect Storm: Misleading Marketing of Limited Benefit Products Continues as Millions Losing Medicaid Search for New Coverage,'' Center on Health Insurance Reforms, available at: *https://chirblog.org/the-perfect-storm-misleading-marketing-of-limited-benefit-products-continues-as-millions-losing-medicaid-search-for-new-coverage.*

[142] Deam, Jenny (2021). ''He Bought Health Insurance for Emergencies. Then He Fell Into a $33,601 Trap,'' ProPublica, available at: *https://www.propublica.org/article/junk-insurance.*

[143] *See* the Regulatory Impact Analysis in section V of this preamble.

[144] *See Healthinsurance.org* (2023). ''Duration and Renewals of 2023 Short-Term Medical Plans by State,'' available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf; see also* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-term Limited-duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

within the Departments' authority, and is consistent with other applicable Federal law, and is therefore not arbitrary and capricious.

Some commenters expressed concern that the proposed definition of STLDI would interfere with the authority of States to regulate insurance pursuant to the McCarran-Ferguson Act and PHS Act. These commenters stated that the McCarran-Ferguson Act reserves the regulation of insurance to States so that States can tailor their health insurance policies to the needs of their residents. They stated that State regulators are better positioned to understand the unique characteristics and requirements of each State's respective insurance markets and are more responsive to the needs of their insurance markets. Another commenter stated that under the PHS Act, Federal authority to regulate insurance is secondary to the primary authority of the States, and any Federal intrusion on State authority must be based on information that a State may not be substantially enforcing PHS Act requirements. A commenter noted that States have demonstrated their willingness and capacity to regulate STLDI coverage because half of States have regulations in place. For example, the commenter noted that the sale of STLDI is prohibited in some States [145] and other States have restricted the maximum allowed term of STLDI to 3, 6, or 12 months or coverage that terminates at the end of the calendar year.[146] Other commenters stated that some States only allow limited renewals of STLDI. Another State regulates STLDI by requiring that STLDI policies sold in the State provide certain consumer protections, implementing a separate risk pool, and creating a special enrollment period for consumers that exhaust the 36-month period of STLDI coverage, while setting minimum benefit and coverage requirements to meet the needs of seasonal employees that desire flexibility and low-cost health care coverage.[147] A commenter noted that 12 States currently prohibit health status underwriting for STLDI, which effectively bans STLDI in those States. The commenter stated that the proposed rules fail to balance States' interest in regulating health insurance issuers and their health insurance markets with Congress's intent to provide protections to consumers. On the other hand, a few commenters noted that variation in State oversight of STLDI has resulted in a patchwork of consumer protections across States, and one commenter stated that consumers would benefit from national-level STLDI regulation.

These final rules establish the Federal definition of STLDI with respect to the maximum length of the initial contract term, the maximum allowable duration (including renewals and extensions), and a consumer notice. The Departments acknowledge and respect States' authority to regulate the business of insurance. The Departments generally agree that States retain the authority to regulate STLDI and further note that these final rules do not change or otherwise modify the existing ERISA or PHS Act preemption standard.[148] As such, States may impose requirements tailored to the needs of their populations, and may adopt limitations on stacking, as well as limitations on sales and marketing practices. Relatedly, in section III. B of this preamble, in these final rules, the Departments added language to the notice to alert consumers as to how the coverage they are purchasing might vary from individual health insurance coverage. States may impose additional language requirements for a consumer notice and remain free to regulate STLDI.

The Departments agree that the States play an important role in regulating STLDI and recognize the federalism implications of the proposed rules and these final rules.[149] As noted by commenters, the McCarran-Ferguson Act generally affirms the preeminence of State regulation, and also explicitly allows for Federal regulation when an act of Congress specifically relates to the business of insurance.[150] However, the commenters' argument that Federal authority to regulate insurance is secondary to the primary authority of the States conflates Federal authority to regulate insurance under section 1012 of the McCarran-Ferguson Act with HHS's authority under section 2723 of the PHS Act to enforce requirements in part A and D of title XXVII of the PHS Act against issuers.[151] Under section 2723 of the PHS Act, States have authority to enforce the requirements of part A and D of title XXVII of the PHS Act, and where the State fails to substantially enforce a provision (or provisions) of part A or D with respect to health insurance issuers in the State, HHS shall enforce such provision (or provisions) in the State. In contrast, the McCarran-Ferguson Act balances State and Federal interests in regulating the business of insurance. Section 1012(a) of the McCarran-Ferguson Act maintained State regulatory authority by enabling State preemption of some Federal law, and section 1012(b) of the McCarran-Ferguson Act limited Federal regulatory authority by generally exempting the ''business of insurance'' from Federal law.[152] Although Congress allowed an exception for State preemption of Federal law in this way, Congress also preserved Federal authority to regulate insurance provided that, to overcome the State preemption, congressional action must specifically relate to the

[145] The commenter noted that STLDI is not for sale in a number of States including California, Colorado, Connecticut, Hawaii, Maine, Massachusetts, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington. *See also Healthinsurance.org* (2023). ''Duration and Renewals of 2023 Short-Term Medical Plans by State,'' available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf* (As of September 6, 2023, STLDI is not for sale in 14 States—California, Colorado, Connecticut, Hawaii, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington—and the District of Columbia.)

[146] The commenter stated that Illinois allows the sale of STLDI that lasts for up to 180 days, and in New Hampshire, STLDI contracts can last for up to 6 months with a renewal or extension of up to a total of 18 months.

[147] The commenter stated that Iowa imposed minimum benefit and coverage requirements on short-term plans above Federal standards.

[148] Section 731 of ERISA and sections 2724 and 2762 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a) and 148.210(b)).

[149] *See* 88 FR at 44648–44649. *See also* the federalism discussion in section V.H of this preamble.

[150] *Compare* ''The business of insurance, and every person engaged therein, shall be subject to the laws of the several States which relate to the regulation or taxation of such business . . .'' 15 U.S.C. 1012(a), *with* ''No Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, or which imposes a fee or tax upon such business, unless such Act specifically relates to the business of insurance: Provided, that after June 30, 1948, the Act of July 2, 1890, as amended, known as the Sherman Act, and the Act of October 15, 1914, as amended, known as the Clayton Act, and the Act of September 26, 1914, known as the Federal Trade Commission Act, as amended [15 U.S.C. 41 *et seq.*], shall be applicable to the business of insurance to the extent that such business is not regulated by State Law. . . .'' 15 U.S.C. 1012(b).

[151] HHS also has authority under section 2761 of the PHS Act to enforce the requirements in part B of title XXVII of the PHS Act against issuers in situations where a State fails to substantially enforce one or more provisions of part B with respect to health insurance issuers in the State.

[152] *See* Steffen, Peter B. (2000) ''After Fabe: Applying the *Pireno* Definition of Business of Insurance in First-Clause McCarran-Ferguson Act Cases,'' University of Chicago Legal Forum: Vol. 2000, available at: *https://chicagounbound.uchicago.edu/uclf/vol2000/iss1/15* (''The first clause enabled [S]tate law to supersede [F]ederal law; the second clause provided a [F]ederal antitrust exemption for the 'business of insurance' . . . The Act gave [S]tates some powers they did not have before, by stating in the first clause that only a [F]ederal law that 'specifically relates to the business of insurance' can preempt a [S]tate law dealing with insurance. Congressional legislation merely affecting insurance would not meet the first-clause test and thus would not, be exempt from the general prohibition on preemption. Rather, in order to apply, [F]ederal law must specifically relate to the 'business of insurance' . . .'').

business of insurance.[153] It is without question that HIPAA, the ACA, and the other Acts of Congress that added Federal consumer protections and requirements applicable to health insurance issuers offering group and individual health insurance coverage specifically relate to the business of insurance. In addition, as discussed earlier, the Departments have clear legal authority to define STLDI and set standards to distinguish it from individual health insurance coverage. This includes authority to adjust the interpretations for and implementation of the terms ''short-term'' and ''limited-duration'' that set the length of the initial contract term and the maximum duration (including renewals and extensions) for STLDI, as well as to update the consumer notice. As outlined previously, Congress provided the Departments with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act. The Departments are of the view that the Federal regulatory definition of STLDI in these final rules is necessary and appropriate to carry out the provisions of the Code, ERISA, and the PHS Act. Further, the Departments must give meaning to the undefined statutory term STLDI, and the meaning must distinguish it from individual health insurance coverage. This is because the PHS Act imposes certain requirements on individual health insurance coverage and does not impose those same requirements on STLDI. The Departments are also of the view that it is necessary and appropriate for consumers considering the purchase of STLDI, and those purchasing such insurance, to be aware that such coverage is not subject to the Federal consumer protections and requirements for comprehensive coverage. Defining STLDI in a way that requires a short, standard description of how the coverage might vary from individual health insurance coverage allows for a clear determination by regulators that the policy is STLDI, and promotes ease of understanding by consumers. As explained previously and detailed in the 2023 proposed rules, the changes to the Federal definition of STLDI, including the updates to the consumer disclosure notice, are reflective and responsive to changes observed by the Departments in market conditions and the legal landscape.

These final rules define STLDI for purposes of the Code, ERISA, and the PHS Act. Insurance coverage that meets the definition of STLDI in these final rules will qualify for the exception to the Federal definition of individual health insurance coverage and be exempt from the Federal consumer protections and requirements applicable to comprehensive coverage. Nothing in these final rules prevents regulation of STLDI for purposes of State law. For example, States may determine whether to permit the sale of STLDI in their insurance markets. If a State law permits or requires an action that is inconsistent with the Federal definition of STLDI, any coverage offered pursuant to that State law that does not meet the standards set forth in these final rules would not qualify as STLDI under these final rules and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. For example, if a State were to prohibit policies issued in that State from including the Federal consumer notice, then coverage in that State that did not include the Federal consumer notice language would not qualify for the exclusion from the PHS Act definition of individual health insurance coverage and thus would be subject to the Federal consumer protections and requirements applicable to individual health insurance coverage.

Amending the Federal regulation defining STLDI protects the distinctively Federal role and interest in ensuring that the Federal definition for STLDI clearly distinguishes STLDI from individual health insurance coverage for consumers in every State. As discussed in the preamble to the 2023 proposed rules, many STLDI policies that are sold through associations are sold across numerous States. Often consumers are purchasing STLDI policies in a different State from the State in which the policy is regulated. This can create challenges for both consumers and State regulators. The Departments are of the view that establishing a shorter Federal maximum duration for STLDI may reduce the incentives for issuers to offer STLDI through associations to the extent that they are using associations as a way to avoid State limits on duration. This, in turn, will help minimize consumer confusion related to coverage offered through associations. In addition, STLDI with a shorter maximum allowable duration would decrease the impact of STLDI on Federal Government spending. As discussed in section III.A.6 of this preamble, STLDI that has a maximum allowable duration of up to 36 months, including renewals and extensions, has an annual impact on Federal PTC spending due to selection-induced effects.

The Departments are of the view that these final rules appropriately balance States' interests in regulating health insurance issuers and their health insurance markets with Congress' intent to establish a general Federal framework for health insurance coverage, including the provision of certain key protections to consumers enrolled in comprehensive coverage.

Some commenters expressed general support for the proposed definition of STLDI. Commenters in favor of the proposed definition noted that it would return STLDI to its traditional and intended purpose of providing temporary, stopgap coverage between periods of comprehensive coverage, and not serve as a long-term substitute for comprehensive coverage. Some of these commenters highlighted that low health literacy rates, a long maximum allowed term of STLDI that mimics the duration of comprehensive coverage, and deceptive marketing practices cause many consumers to confuse STLDI with comprehensive coverage. These commenters also stated that STLDI lacks Federal consumer protections and is inadequate to serve patients grappling with complex medical needs such as those that require maternity care or habilitative care; behavioral health problems; or chronic diseases such as cancer and cardiovascular disease. These commenters further stated that unwary consumers unexpectedly are underinsured when they enroll in STLDI and may end up forgoing needed, routine medical treatment and exacerbating chronic medical conditions because of limited benefits or high cost-sharing responsibilities. Consequently, consumers may then be sicker when they finally seek care in the emergency room for untreated medical conditions, which can increase costs absorbed by providers and facilities, costing the health care system more in the long run. Commenters who supported the STLDI definition in the proposed rules warned that some consumers who enroll in STLDI as an alternative to comprehensive coverage can become subject to unexpected medical debt leading to unforeseen long-term financial consequences. Other commenters that supported the revised Federal definition for STLDI stated that while STLDI is highly profitable for health insurance issuers, agents, and brokers, the impact of STLDI on the risk pools for individual health insurance coverage indicates that it is necessary to clarify the distinctions between STLDI

[153] *Id.,* citing Lee R. Russ, 3 Couch on Insurance sec. 2:4 at 2–12 (Clark 1994) (''McCarran-Ferguson turns the traditional rule of [F]ederal preemption of [S]tate law on its head.'').

and comprehensive coverage. Other commenters expressed general opposition to the STLDI definition proposed in the 2023 proposed rules. These commenters stated that while STLDI is not adequate coverage for everyone, STLDI provides a useful, short-term, affordable option, particularly for consumers who do not have access to PTC subsidies, and provides access to specialists that are not in-network with many comprehensive coverage options.

The Departments acknowledge that the changes to the Federal definition of STLDI that are finalized in these rules may result in individuals who prefer STLDI losing access to such coverage as a long-term coverage option. However, as explained previously and in the 2023 proposed rules, the Departments have concluded that these concerns are now outweighed by the negative financial and health consequences that some individuals who enroll in STLDI in lieu of comprehensive coverage experience; consumer challenges in differentiating STLDI from individual health insurance coverage, particularly in light of low health literacy rates and aggressive marketing; and the negative impact on the risk pools for individual health insurance coverage when healthier individuals enroll in STLDI in lieu of individual health insurance coverage.[154]

As the availability of affordable comprehensive coverage options has increased since the 2018 final rules were finalized, the Departments are of the view that STLDI is no longer needed to provide a year-round coverage option for individuals and should be limited to a temporary coverage option for shorter periods when an individual experiences gaps between comprehensive coverage. The Departments agree with commenters that the definition of STLDI under the 2018 final rules heightened the risk that uninformed consumers will mistakenly purchase STLDI as a substitute for comprehensive coverage, and under current market conditions, unnecessarily expose themselves to severe financial risks if they have complex medical needs or conditions. The Departments agree with commenters that the lack of key Federal consumer protections and requirements that apply to benefits offered by STLDI [155] results in STLDI being an inadequate substitute for comprehensive coverage, especially for those with complex medical needs. Some consumers with complex health conditions may enroll in STLDI because a preferred provider may be in-network with an STLDI policy but out-of-network with comprehensive coverage plans.[156] However, STLDI plans are typically associated with higher overall financial risk due to high premium increases that may be imposed upon an individual whose health condition worsens. For example, a study that examined the potential impacts of STLDI and associated State policies on cancer diagnoses found that individuals in States that prohibited STLDI were associated with an increase in early-stage cancer diagnoses when compared to States that did not regulate STLDI.[157] In addition, because issuers of STLDI can engage in medical underwriting, individuals can be charged higher premiums based on health status, gender, age and other factors.[158] Enrolling in comprehensive coverage instead of STLDI prior to when a consumer is diagnosed with a complex medical condition or incurs major medical expenses will promote access to care and improve overall health outcomes.

In addition, the Departments share commenters' concerns that low health literacy rates can have a detrimental impact on health insurance decision-making, putting some consumers at increased risk for purchasing STLDI when they are looking to purchase comprehensive coverage. Low health literacy rates combined with potentially erroneous assumptions about minimum standards for coverage makes the average consumer vulnerable to deceptive marketing practices and creates barriers to accessing health care and comprehensive coverage. As discussed in the preamble to the 2023 proposed rules, consumers may not understand that while some STLDI policies may have lower premiums than comprehensive coverage, consumers may incur steep and potentially debt-inducing health care bills once enrolled in STLDI due to limited benefits provided by such coverage, limited Federal consumer protections, and high-cost sharing requirements.[159] A qualitative study cited by commenters examined consumer comprehension of marketing materials for STLDI and found that not only did participants have low health insurance literacy rates, but they struggled to understand the plan's limitations because the ACA has shaped their expectations about what ''typical'' health plans cover.[160] As a result, consumers often expect that all health insurance provides the same benefits and protections even absent deceptive marketing practices, increasing the importance of guardrails to distinguish comprehensive coverage from STLDI. These concerns are exacerbated in underserved communities, given their low rates of health literacy.[161] As discussed in the 2023 proposed rule, in addition to systemic and social structures that impact access to health care,[162] health literacy can make it more difficult for historically underserved and marginalized groups to navigate high deductibles, expanded cost sharing, coverage exclusions and narrow formularies found in STLDI.[163] These barriers can lead to consumers rationing their medicine or not taking it at all or delaying necessary health care services, causing devastating consequences to

[154] *See* section V of this preamble for the regulatory impact analysis; *see also* 88 FR 44596 at 44608 (2023).

[155] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[156] In some circumstances, even accounting for the expense of using an out-of-network provider, comprehensive coverage still may be the less expensive choice overall because of lower out-of-pocket spending a consumer would enjoy when enrolled in comprehensive coverage. In many cases, expenses for premiums and cost sharing for comprehensive coverage enrollees are still lower than the uncovered costs associated with STLDI, particularly when an individual undergoes costly medical treatment.

[157] Barnes, Justin, Anne Kirchhoff, Robin Yabroff, and Fumiko Chino (2023). ''State Policies Regulating Short-Term Limited Duration Insurance Plans and Cancer Stage at Diagnosis,'' *JNCI Cancer Spectrum,* Volume 7, Issue 5, available at: *https://doi.org/10.1093/jncics/pkad060.*

[158] *See* Pollitz, Karen, Michelle Long, Ashley Semanskee, and Rabah Kamal (2018). ''Understanding Short-Term Limited Duration Health Insurance,'' KFF, available at: *https://www.kff.org/affordable-care-act/issue-brief/understanding-short-term-limited-duration-health-insurance. See also* Lueck, Sarah (2018). ''Key Flaws of Short-Term Health Plans Pose Risks to Consumers,'' Center on Budget and Policy Priorities, available at: *https://www.cbpp.org/research/health/key-flaws-of-short-term-health-plans-pose-risks-to-consumers.*

[159] *See, for example,* 88 FR 44596 at 44608, 44612, 44613, 44615–44617, 44646 (July 12, 2023).

[160] Georgians for a Healthy Future (2019). ''Report on Testing Consumer Understanding of a Short-Term Health Insurance Plan,'' available at: *https://healthyfuturega.org/wp-content/uploads/2019/04/Consumer-Testing-Report_NAIC-Consumer-Reps.pdf.*

[161] Kutner M, Greenberg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006–483). Washington, DC: U.S. Department of Education, National Center for Education Statistics; 2006.

[162] Muvuka, B., *et al* (2020). ''Health Literacy in African-American Communities: Barriers and Strategies,'' *Health Literacy Research and Practice,* available at: *https://journals.healio.com/doi/full/10.3928/24748307-20200617-01.*

[163] 88 FR 44596 at 44608, 44613, 44615 (July 12, 2023).

their health.[164] Shortening the maximum allowable term and duration of STLDI will serve as a clear indicator to consumers about the nature of each coverage option and instill more confidence in their coverage decisions. The Departments are also concerned about the prevalence of deceptive marketing practices, as noted by commenters who referenced secret shopper studies and anecdotes about negative consumer experiences, including when deceptive marketing practices were used to encourage consumers to enroll in STLDI instead of receiving education about their eligibility for low-cost comprehensive coverage or to inhibit consumers from choosing the coverage they need to access health care and protect themselves from financial burdens.

Finally, the Departments agree that it is necessary and appropriate to revisit the Federal STLDI definition to further distinguish between these types of coverage given concerns about the impact on risk pools. As discussed in section II.C of this preamble, STLDI siphons off healthier individuals from the risk pools for individual health insurance coverage, thereby raising premiums for such coverage.

Some commenters expressed particular concern about the impact of deceptive and aggressive marketing practices for STLDI given the increase in consumers currently looking for health coverage options as States resume Medicaid eligibility redeterminations due to the expiration of the FFCRA Medicaid continuous enrollment condition, as discussed in section II.B of this preamble. These commenters explained that many consumers who lose Medicaid coverage and are seeking new coverage at a low cost will be vulnerable to misleading or aggressive sales and marketing tactics that obscure the differences between comprehensive coverage and STLDI, and might therefore mistakenly enroll in STLDI in lieu of comprehensive coverage. These commenters noted that underserved populations with low health literacy and incomes below the FPL may be particularly vulnerable.

The Departments recognize that more individuals may be considering new coverage options as a result of an increased volume of Medicaid eligibility redeterminations, and therefore may be particularly susceptible to this type of misleading or aggressive sales and marketing tactics even though affordable options for comprehensive coverage may be available to them. CMS has made it a priority to ensure that as many people as possible maintain continuous comprehensive coverage during this ''unwinding period.'' [165] CMS has a robust plan in place to reach people with Medicaid or CHIP coverage, so that they are aware of the steps they need to take to maintain their Medicaid or CHIP coverage, or, if no longer eligible, to smoothly transition to other forms of coverage, such as individual health insurance coverage purchased through an Exchange.[166] This plan includes new policy and operational flexibilities, such as a temporary exceptional circumstances special enrollment period available through *HealthCare.gov* for qualified individuals and their families who lose Medicaid or CHIP coverage following the end of the continuous enrollment condition; multi-pronged, large-scale national and local outreach and stakeholder engagement efforts; and investments and innovations in enrollment assistance.[167] State-based Exchanges have taken similar steps to update or implement new special enrollment period policies, as well as conduct outreach and stakeholder engagement, to support qualified individuals and their families who lose Medicaid or CHIP coverage following the end of the continuous enrollment condition. Despite these efforts, current data shows that a substantial number of people have lost coverage and may want to enroll in coverage.[168]

Commenters requested that the Departments clarify whether any of the existing special enrollment periods would allow a consumer to access comprehensive coverage if their STLDI coverage ends outside of an open enrollment period. Some commenters recommended that the Departments create a new special enrollment period for individuals to enroll in comprehensive coverage after their STLDI coverage ends, or that allows an individual to enroll in coverage through an Exchange upon the termination of STLDI coverage specifically for situations where a consumer elected STLDI following a loss of employment-based coverage due to a job transition or to provide temporary coverage during an employer's waiting period. Some commenters expressed concern about the potential for consumers to experience gaps in coverage in the absence of access to a special enrollment period, explaining that those consumers purchasing a 3-month STLDI plan mid-calendar year would become financially vulnerable with no continued coverage options until the next open enrollment period.

The Departments affirm that individuals who lose eligibility for STLDI coverage, such as when their STLDI policy ends, are already eligible for a special enrollment period and have 60 days to enroll in group health plan coverage, either insured or self-funded.[169] HHS did not propose to create a new individual market special enrollment period for individuals to enroll in individual health insurance coverage (on- or off-Exchange) at the expiration of their STLDI coverage and declines to do so in these final rules. Providing consumers with an individual market special enrollment period to purchase off-Exchange or on-Exchange coverage when they lose eligibility for STLDI or their STLDI policy ends could confuse or mislead consumers who are considering their health coverage options. Consumers may delay enrolling in comprehensive coverage when first available, on the expectation that such coverage would be available at any time, even if STLDI coverage does not renew or is otherwise terminated. Also, as explained previously, inflating the fraction of low-risk individuals who enroll in STLDI rather than individual health insurance coverage will have negative consequences for the risk pools for individual health insurance coverage.

Furthermore, there are other options for individuals who anticipate experiencing longer gaps between comprehensive coverage. For example, an individual who loses comprehensive

[164] Schumacher, Jessica R. *et al.* (2013). ''Potentially Preventable Use of Emergency Services: The Role of Low Health Literacy,'' *Medical Care* 51(8), August 2013, available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756810.*

[165] *See* Temporary Special Enrollment Period (SEP) for Consumers Losing Medicaid or the Children's Health Insurance Program (CHIP) Coverage Due to Unwinding of the Medicaid Continuous Enrollment Condition—Frequently Asked Questions (FAQ) (January 27, 2023), available at: *https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf.*

[166] *See* CMS (2023). ''Unwinding and Returning to Regular Operations after COVID, Medicaid and CHIP Renewals Outreach and Educational Resources,'' available at: *https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/medicaid-and-chip-renewals-outreach-and-educational-resources/index.html.*

[167] *See* CMS (August 26, 2022). ''Biden-Harris Administration Makes Largest Investment Ever in Navigators Ahead of *HealthCare.gov* Open Enrollment Period,'' available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-makes-largest-investment-ever-navigators-ahead-healthcaregov-open.*

[168] *See* Corallo, Bradley, Jennifer Tolbert, Patrick Drake, Sophia Moreno, and Robin Rudowitz, (2024). ''Halfway Through the Medicaid Unwinding: What Do the Data Show?'' KFF, available at: *https://www.kff.org/policy-watch/halfway-through-the-medicaid-unwinding-what-do-the-data-show.*

[169] *See* 26 CFR 54.9801–6, 29 CFR 2590.701–6, 45 CFR 146.117.

coverage may be eligible for a special enrollment period that allows them to enroll in group coverage sponsored by their employer, the employer of their parent, spouse or partner, or individual health insurance coverage, either directly with the issuer, or through the Exchanges, where they may be eligible for APTC.[170] [171] In some circumstances, they may be eligible for other coverage such as government-based assistance for qualified individuals under Medicaid, CHIP, or BHP.[172] In addition, if a consumer experiences a reduction in benefits or termination of employment and is uncertain as to when they will be eligible for other comprehensive coverage, the consumer in many cases has the option of electing coverage under the Consolidated Omnibus Budget Reconciliation Act (COBRA) [173] (18, 29, or 36 months depending on the nature of the COBRA qualifying event) or State mini-COBRA continuation coverage laws. Also, as discussed in section III.A.2 of this preamble, an individual who enrolls in STLDI coverage from one issuer and wishes to purchase another STLDI policy maintains the option of enrolling in STLDI coverage with another issuer that is not a member of the same controlled group.

One commenter suggested that the Departments require that certain consumer protection provisions apply to STLDI. Other commenters urged the Departments to extend the prohibition on rescissions to STLDI. One of these commenters explained that STLDI issuers can rescind the patient's coverage following post-claims underwriting,[174] leaving patients without any financial or medical protection and at high risk of incurring medical debt.

The Departments appreciate commenters' suggestions regarding ways in which to ensure STLDI provides key Federal consumer protections. The Departments agree that STLDI can place a consumer's health and financial well-being at risk if they experience a significant medical event or have a complex medical condition. As discussed in this preamble at section II.B, consumers may be susceptible to deceptive marketing and sales practices that often mask post-claims underwriting practices by STLDI issuers and the exclusion of key essential health benefits and Federal consumer protections under STLDI plans. Consumers may be unaware of the limitations of their STLDI coverage until they need care or have incurred significant medical expenses, particularly those with low health literacy. However, the Departments did not propose to apply Federal consumer protections to STLDI and are not finalizing in these final rules the extension of any of the individual health insurance coverage Federal consumer protections and requirements to STLDI.[175] The Departments further note it would be inconsistent with the statute to extend the Federal prohibition on rescissions to STLDI, as Congress limited its applicability to group health plans and health insurance issuers offering group or individual health insurance coverage.[176] In addition, as discussed in section III.A.2 of this preamble, the Departments have determined that limiting extensions and renewals of STLDI instead of applying guaranteed renewability to STLDI appropriately distinguishes STLDI from individual health insurance coverage.

Other commenters suggested that the Departments collect data on key elements, including, for example, compensation paid by issuers to brokers or agents; plan-level enrollment/disenrollment and claims data that is disaggregated by age, income, race/ethnicity, and geographic locations; coverage limits; and other data to enable regulators and stakeholders to assess whether and how children and families are being served by STLDI.

The Departments agree with commenters that it would be useful to have access to more data on STLDI. HHS is committed to collecting information from issuers offering STLDI regarding any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in STLDI, as authorized under section 2746 of the PHS Act.[177] However, beyond this requirement, the Departments do not currently have authority to collect data from issuers of STLDI. States, in contrast, can survey and collect data on STLDI under State authority and the NAIC Market Analysis and Procedures Working Group annually collects data from issuers of STLDI.[178] The Departments encourage States that do not already collect such data to consider the collection of data from STLDI issuers, as suggested by commenters, to assist with Federal and State oversight of STLDI.

2. Definitions of ''Short-term'' and ''Limited-duration''

The 2023 proposed rules proposed to amend the Federal definition of ''short-term, limited-duration insurance'' in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103 to reflect a new interpretation of the phrase ''short-term'' to mean a policy, certificate, or contract of insurance with an issuer that has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance.[179] The 2023 proposed rules also proposed to interpret ''limited-duration'' to mean a maximum coverage period that is no longer than 4 months in total, including renewals and extensions.[180] For this purpose, the Departments proposed that a renewal or extension would include the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer to the same policyholder within the 12-month period, beginning on the original effective date of the initial policy, certificate, or contract of insurance. As proposed, in this context, the phrase ''same issuer'' would refer to the entity licensed to sell the policy, consistent with the definition of health insurance issuer in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103. Under this proposal, the duration of coverage would be calculated based on the total number of days of coverage (either consecutive or non-consecutive) that a policyholder is enrolled in an STLDI policy with the same issuer within the prior 12-month period, regardless of whether the

[170] 45 CFR 155.420.

[171] 45 CFR 147.104(b)(2).

[172] Medicaid eligibility requirements vary by State.

[173] Public Law 99–272, April 7, 1986.

[174] Post-claims underwriting refers to the practice of engaging in an underwriting review after a claim is made rather than going through the time and expense of doing such a review to assess the consumer's actuarial risk and medical conditions at the time the policy is purchased.

[175] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI. Those requirements will be addressed by HHS in a separate rulemaking. *See* Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement; Proposed Rules, 86 FR 51730 at 51740–51744 and 51770–51771 (Sept. 16, 2021).

[176] *See* PHS Act section 2712.

[177] *See* Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement; Proposed Rules, 86 FR 51730 at 51740–51744 and 51770–51771 (Sept. 16, 2021).

[178] The NAIC is currently collecting additional data on STLDI as part of its Market Conduct Annual Statement data call for STLDI offered in 2023. *See https://content.naic.org/mcas-2023.htm.*

[179] 88 FR 44596 at 44610–44611 (July 12, 2023).

[180] *Id.* at 44611–44614 (July 12, 2023).

coverage issued to the policyholder is under the same or a new policy, certificate, or contract of insurance.

The calculation for the duration of coverage, however, would not include days of coverage under an STLDI policy, certificate, or contract of insurance sold to the same policyholder by a *different* issuer. As the Departments explained in the preamble to the 2023 proposed rules, this proposed distinction would effectively limit stacking of policies sold by the same issuer, would be easier for issuers to track and comply with than if applied across different issuers, and would allow consumers to purchase subsequent STLDI policies from other issuers within a 12-month period.[181]

As explained in the preamble to the 2023 proposed rules, the new proposed definition for STLDI is consistent with the group market rules regarding the 90-day waiting period provision under the ACA and with STLDI's traditional role of serving as a temporary coverage for individuals transitioning between other types of comprehensive coverage. The proposed definition is also similar to the less-than-3-month maximum term for STLDI under the 2016 final rules and under a number of State laws,[182] and aligns with the goal of Executive Order 14009 to support protections for people with preexisting conditions.

The Departments requested comments on the proposed new interpretations of the phrases ''short-term'' and ''limited-duration.'' The Departments also requested comments on whether the interpretation of ''short-term'' in the proposed definition of STLDI should be some other length, such as no longer than 4 months, and why, and whether there are circumstances under which issuers should be allowed to renew or extend STLDI for periods of time beyond what would be permitted in the proposed rules. The Departments also requested comments on whether there are additional ways to differentiate STLDI from comprehensive coverage options, including information on State approaches or limits on the sale of STLDI by a different issuer, and how the subsequent issuer would determine whether or not an applicant had previous STLDI with another issuer. The Departments also solicited comments on whether to broaden the limits on stacking to include issuers that are members of the same controlled group.

Given that the majority of comments addressed the definitions of ''short-term'' and ''limited-duration'' together, the Departments are addressing comments related to the maximum allowed length and the definitions for these two terms together, along with the comments related to the practice of stringing together multiple or consecutive policies, a practice known as ''stacking.''

Commenters suggested various options for the allowable maximum duration. Some commenters supported finalizing the maximum duration as proposed. These commenters agreed that STLDI serves as an adequate gap filler for consumers that need a bridge between comprehensive forms of coverage, and a 3-month initial term makes it easier for a consumer to distinguish between STLDI and comprehensive coverage. In addition, some of these commenters supported a short initial term to protect consumers from the inherent risks of enrolling in coverage that does not provide Federal consumer protections or comprehensive health benefits, and to curb negative impacts on the risk pools for individual health insurance coverage. Some commenters were of the view that the proposed definitions of the terms ''short-term'' and ''limited-duration'' better align with the plain language of the statute than the current definitions. Others supported shortening the initial maximum allowable period to a period less than allowed under the current rules, but longer than the proposed 3-month period, for example a period of less than 6 months, to strike a balance between the drawbacks of STLDI with consumers' need for gap-coverage when coverage is needed for a short period of time, they have no other insurance options, or comprehensive coverage is otherwise unaffordable. Other commenters stated that STLDI policies should be permitted to have longer durations as long as they end by December 31 of the calendar year in which the policy period commences, at which point individuals can enroll in comprehensive coverage during the annual individual market open enrollment period. One commenter, who supported the proposed maximum duration, suggested that the Departments require that all initial contract terms end by December 31 of the policy year in which the policy commences (even when the STLDI policy is purchased late in the year), to minimize situations where consumers miss the annual individual market open enrollment period. The commenter suggested that requiring STLDI policies to end by December 31 would cause consumers to look for new coverage during the individual market open enrollment period and increase the likelihood that they would enroll in comprehensive coverage. The commenter further suggested that, for alignment with the proposed maximum duration, the Departments could allow renewal for up to 4 months (past December 31), but only if the full 4-month period of coverage is not sold at the same time and that an additional notice is sent to consumers about the annual individual market open enrollment period.

Other commenters opposed modifying the initial maximum allowed length of ''short-term'' and instead recommended keeping the 2018 final rule's maximum allowed length for an initial contract term of less than 12 months. With respect to the definition of ''limited-duration,'' some commenters suggested the Departments redefine the standard to allow a longer maximum length than proposed. One commenter requested that the Departments define ''limited-duration'' as up to 12 to 18 months. Another commenter suggested that the Departments define ''limited-duration'' as up to 9 months in a 12-month period to allow consumers who do not have a qualifying event for a special enrollment period to purchase comprehensive coverage to use STLDI to bridge the gap between annual open enrollment periods in the individual market.

Commenters who supported a longer allowable maximum duration than the proposed period stated that limiting the maximum allowed length to no more than 3 months and a 1-month extension fails to account for all circumstances for which a consumer may need access to STLDI. Commenters gave examples of consumers who may benefit from being able to purchase longer-duration STLDI coverage, such as workers experiencing a change in employment, or unemployment; contract workers who do not have coverage through their employer; self-employed individuals or owners of a small business; college students who are not on their parent's insurance; workers in industries that require frequent travel, such as nurses and truckers; consumers with varying and unpredictable incomes; or consumers eligible for little or no APTC who would encounter a substantial premium expense if they enrolled in comprehensive coverage. In advocating for a longer maximum allowed duration, one commenter also noted that the average length of unemployment is 20.6 weeks, while according to a group of

[181] *Id.* at 44612 (July 12, 2023).

[182] *See, for example,* D.C. Code § 31–3303.13d; 18 Del. Admin. Code 1320–4.0; Haw. Rev. Stat. § 431:10A–605; Md. Code Ann., Insurance § 15–1301(s); N.M. Stat. § 13.10.3.8; Or. Rev. Stat. § 743B.005; and Ver. Stat. Ann. tit. 8 § 4084a(c). *See also Healthinsurance.org* (2023). ''Duration and Renewals of 2023 Short-Term Medical Plans by State,'' available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf.*

issuers and marketers of STLDI the average length of enrollment in STLDI is only 7 months. Other commenters stated that the maximum allowable length of STLDI should be left to the States. Some commenters suggested the Departments require issuers offering STLDI with renewals and extensions of up to 4 months to guarantee that the renewal or extension be available to the consumer without additional underwriting if the consumer chooses to renew or extend their coverage.

Although the Departments acknowledge that there will be times when consumers may experience gaps in comprehensive coverage that exceed the maximum allowable duration for STLDI finalized in these rules, the Departments are not persuaded that a longer maximum initial contract term or longer maximum duration, taking into account renewals or extensions, is appropriate. Maintaining the definition that permits a longer initial length of up to 1 year would not alleviate the challenges consumers currently face in distinguishing STLDI from individual health insurance coverage, would continue to place consumers who enroll in STLDI at financial risk, and would not mitigate the impact on the risk pools for individual health insurance coverage or those consumers purchasing individual health insurance coverage. Because of low health literacy, consumers face the risk of inadvertently enrolling in STLDI coverage that does not sufficiently provide coverage for unexpected or significant medical events that arise during the coverage period.

The Departments are not persuaded by comments that urged the Departments to align the maximum duration with a time frame that reflects average periods of unemployment, such as 6 to 9 months, rather than the proposed limit. The limit of no-more-than 3 months with a 1-month extension aligns with the 90-day waiting period limitation and 1-month additional reasonable and bona fide employment-based orientation period that is permitted under the ACA. The Departments are of the view that aligning the maximum duration of an STLDI policy with the period Federal law expressly permits as an ''orientation'' period in employment-based coverage most appropriately reflects STLDI's traditional role to fill temporary gaps in coverage. Consumers who purchase STLDI during a 90-day waiting period have a predictable end to their gap in coverage. Their gap is defined, and generally temporary, and thus is exactly the type of gap that STLDI traditionally serves to fill. In contrast, a loss in coverage due to a loss of employment is not the type of gap that STLDI traditionally is intended to fill because consumers that experience a loss of employment do not have certainty regarding how long their gap in comprehensive coverage will be, and for some that gap will not be temporary and may extend beyond the average length of unemployment. By enrolling in STLDI in lieu of COBRA continuation coverage or individual health insurance coverage during the 60-day period for which they are eligible for a special enrollment period for loss of qualifying coverage, these consumers may lose access to comprehensive coverage until the next individual market open enrollment period. While STLDI may be an appropriate choice for some individuals during a period of unemployment, the Departments concluded that aligning the maximum duration with the 90-day waiting period limitation and 1-month additional reasonable and bona fide employment-based orientation period better captures the traditional role of STLDI. In addition, consumers are more likely to face an unexpected health issue during a longer coverage period—such as 6, 9, or 12 months—and may find themselves insufficiently protected by the typically limited benefits of an STLDI policy and potential resulting financial burdens.

By allowing an initial term of no more than 3 months, the interpretation of ''short-term'' for purposes of the revised Federal definition of STLDI finalized in these rules provides a clear demarcation from the 1-year length of a policy year for individual health insurance coverage. In addition, as discussed earlier, STLDI's traditional role is to provide coverage for temporary gaps for consumers transitioning between comprehensive coverage. A maximum period of no more than 3 months and 1-month extension (for a total maximum duration of 4 months, including renewals or extensions) is more appropriate for coverage intended to fill a temporary gap in comprehensive coverage. As explained in the preamble to the 2016 final rules, for longer gaps in coverage, guaranteed availability of coverage and special enrollment period requirements in the individual market under the ACA ensure that individuals can purchase individual health insurance coverage through or outside of the Exchange that is minimum essential coverage and includes the Federal consumer protections and requirements for comprehensive coverage.[183] Many consumers will also have the opportunity to enroll in comprehensive coverage offered by an employer and some may be eligible for other coverage, such Medicaid, CHIP or BHP.

The Departments are similarly not persuaded by the recommendation that STLDI be permitted to have a longer maximum duration, provided that coverage ends by December 31. Although the Departments appreciate that this approach would minimize gaps in coverage between when an individual's STLDI ends and when they can enroll in comprehensive individual health insurance coverage during the annual individual market open enrollment period, the Departments are concerned that such an approach would not sufficiently distinguish STLDI from individual health insurance coverage, which also ends on December 31. Finally, as mentioned in the 2023 proposed rules, the maximum allowable length of no more than 3 months and a 1-month extension represents a balance between providing a flexible standard that captures many of the circumstances for which an individual would want to enroll in STLDI, responds to the significant changes in the legal landscape and market conditions since the Departments last addressed STLDI, and addresses the low value that STLDI provides to consumers when used as a substitute for comprehensive coverage.

Some commenters requested that the Departments impose a guaranteed renewability requirement on STLDI to prevent additional underwriting if a consumer chooses to renew or extend their coverage. The Departments have determined that limiting extensions and renewals of STLDI instead of applying guaranteed renewability to STLDI appropriately distinguishes STLDI from individual health insurance coverage. As such, these final rules do not impose a guaranteed renewability requirement on STLDI. Underwriting practices, including post-claims underwriting are outside the scope of these final rules.

Many commenters supported the new proposed interpretation of ''limited-duration'' and accompanying proposed definition of renewal or extension to address stacking of STLDI policies by the same issuer to the same policyholder within a 12-month period. These commenters stated that issuers have exploited this loophole to sell consumers consecutive STLDI policies that collectively sidestep the maximum duration limits, deliberately misleading consumers about differences between STLDI and comprehensive coverage. According to some of these commenters, addressing the stacking loophole would reduce the risk of consumers unknowingly enrolling in coverage with

[183] 81 FR 75318 (Oct. 31, 2016).

inadequate benefits for an extended period of time. Commenters further stated stacking practices provide consumers with a false sense of security that they purchased a viable long-term substitute for comprehensive coverage and make it more challenging for consumers to distinguish STLDI from individual health insurance coverage. Commenters expressed concern about the exposure to financial risk that consumers face when purchasing stacked STLDI policies, explaining that a consumer typically faces new deductibles, new annual out-of-pocket limitations, and new preexisting condition limitations with each new STLDI policy term. A commenter noted that consumers may not understand that a health event experienced when covered under one STLDI policy could serve as the basis to impose a preexisting exclusion under a subsequent STLDI policy to deny benefits for the same condition.

Other commenters questioned the basis for the Departments to adopt this part of the definition of ''limited-duration'' to address stacking of policies sold by the same issuer, members of the same controlled group, and/or by unrelated issuers, stating that the Departments do not have authority to constrain consumer choice. A commenter argued that preventing consumers from purchasing subsequent STLDI policies from an issuer of their choice is contrary to the statute, which looks at the issuer's conduct rather than the consumer's conduct, and would run afoul of the decision in *Central United Life Ins. Co.* v. *Burwell*.[184] The commenter further stated that Congress unambiguously specified in the ACA and HIPAA the types of insurance and actors Congress intended to regulate, and Congress consistently chose to exempt STLDI from the definition of individual health insurance coverage and to regulate issuer behavior instead of consumer behavior. Another commenter encouraged the Departments to defer to States on whether and to what extent an issuer could sell consecutive or multiple STLDI policies to consumers within a 12-month period. Other commenters stated that addressing the stacking loophole would leave consumers financially vulnerable, as some will not understand that their STLDI coverage cannot be renewed or extended with the same issuer and will have limited coverage options outside the annual individual market open enrollment period.[185]

Some commenters who supported addressing the stacking loophole encouraged the Departments to extend the new interpretation of ''limited-duration'' and the accompanying definition of renewal or extension to include all issuers that are a part of the same controlled group. These commenters stated that issuers with shared ownership should not be able to exploit their corporate structure to avoid consumer protections and effectively circumvent the otherwise applicable maximum duration limits for STLDI coverage. Some commenters suggested that extending the limitation to include all issuers in the same controlled group could help address concerns regarding STLDI sold through associations,[186] as associations might be positioned to facilitate the issuance of stacked STLDI policies from different subsidiaries of the same controlled group. One commenter stated that members of the same controlled group should have the data and member-tracking capabilities to know if a consumer has purchased an STLDI policy within the 12 months from another issuer within the same controlled group.

The Departments agree with commenters that supported the Departments' authority to address the stacking loophole as part of the definition of renewal or extension for purposes of the new interpretation of ''limited-duration.'' As stated in the preamble to the 2023 proposed rules, the Departments are concerned that stacking practices lengthen the duration of STLDI coverage without offering the benefits of comprehensive coverage that is subject to Federal consumer protections and requirements for comprehensive coverage, including limitations on medical underwriting, the prohibition of preexisting condition exclusions, and the prohibition on coverage rescissions. Using the stacking loophole, issuers could enroll consumers in multiple consecutive STLDI policies that together provide coverage for 12 months (or longer), in effect circumventing the rules related to maximum duration and making it more challenging for consumers to distinguish STLDI from comprehensive coverage.[187]

As discussed in section III.A.1 of this preamble, the Departments have clear authority to interpret and implement the Code, ERISA, and the PHS Act as they do here. This includes the authority to issue regulations on STLDI to define it and set standards that distinguish it from individual health insurance coverage. Providing a definition for what a renewal or extension means in the context of the new interpretation of ''limited-duration'' is included within this authority and is not a constraint on consumer behavior. Instead, the definition and standards, as proposed and finalized, apply to health insurance issuers that elect to offer STLDI. Further, consumers will continue to have access to STLDI plans that are generally exempt from the Federal consumer protections and requirements for comprehensive coverage.[188] Neither the proposed rules nor these final rules sought to extend to STLDI or otherwise make changes with respect to the applicability of those consumer protections and requirements.

After considering comments, the Departments are finalizing as proposed that a renewal or extension, for purposes of applying the interpretation of ''limited-duration'' under the new STLDI definition adopted in these final rules, includes the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance. Subsequent sales to the same policyholder by the same issuer within the same 12-month period will be treated comparably to renewals for purposes of calculating and applying the limited-duration standard.

The Departments also agree that extending the definition of renewal or extension for purposes of applying the new interpretation of ''limited-duration'' to limit stacking of STLDI policies sold by issuers that are members of the same controlled group is appropriate and necessary. This prevents issuers from circumventing the maximum duration standards in the revised Federal STLDI definition adopted in these final rules by marketing policies of one member of a controlled group to policyholders enrolled in STLDI coverage of another member of the controlled group, keeping that policyholder enrolled in STLDI coverage for more than the maximum allowed coverage period. The final rules therefore provide that for purposes of applying the new interpretation of ''limited-duration,'' a

[184] 827 F.3d 70, 74 (D.C. Cir. 2016).

[185] *See* section III.A.4 of this preamble.

[186] For further discussion on STLDI sold through associations, *see* section III.A.5 of this preamble.

[187] 88 FR 44596 at 44612–44613 (July 12, 2023).

[188] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

renewal or extension includes the term of a new STLDI policy, certificate, or contract of insurance offered by either the same issuer or, if the issuer is a member of a controlled group, any other issuer that is a member of the same controlled group. For these purposes, a ''controlled group'' means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code. HHS uses a similar definition of ''controlled group'' for purposes of the guaranteed renewability rules and QHP issuer standards, and the Departments anticipate the usage is familiar to health insurance issuers.[189]

The relevant metric to calculate whether the duration of coverage sold by the same issuer or any other issuer that is a member of the same controlled group to the same policyholder satisfies the revised Federal interpretation of ''limited-duration'' in these final rules is the total number of days of coverage (either consecutive or non-consecutive) that the policyholder is enrolled in an STLDI policy with the same issuer or any other issuer that is a member of the same controlled group. That calculation applies regardless of whether the coverage is a renewal or extension under the same policy, certificate, or contract of insurance, or if it involves the issuance of a new STLDI policy, certificate, or contract of insurance to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance.

Several commenters requested that the Departments expand the approach to address the stacking loophole to also include the sale of STLDI policies by unaffiliated issuers. These commenters were concerned that stacking will continue through policies sold by multiple issuers. Some commenters questioned whether focusing only on stacking policies sold by the same issuer achieves the goals described in the proposed rules because consumers could still stack STLDI purchased from different issuers. One commenter expressed concern that the proposed limitation on stacking by only the same issuer would harm consumers because seeking STLDI policies from multiple issuers would result in the coverage offering different networks and benefits. A commenter that supported extending the approach to address the stacking loophole to also apply to STLDI policies sold by unaffiliated issuers shared that some States prohibit consumers from enrolling in STLDI for more than 3 months in a 12-month period, regardless of issuer. Another commenter, who was supportive of the general concept of limiting stacking across issuers, cautioned that it would be exceedingly difficult for issuers to implement a limit on the sale of multiple STLDI policies by different issuers within the same year at this time. Some commenters who supported the extension of the approach to unaffiliated issuers explained that such an approach could be implemented by issuers certifying, by consumer attestation, or by another similar mechanism, that the policyholder has not purchased STLDI coverage from any issuer within the previous 12-month period, while others suggested that the Departments create a safe harbor for issuers that require consumers to sign attestations regarding previous STLDI coverage.

While the Departments appreciate these comments and recommendations, the Departments decline to extend the definition of renewal or extension for purposes of applying the revised interpretation of ''limited-duration'' to limit stacking of policies issued by unaffiliated issuers. As explained in the proposed rules, the Departments are cognizant of the administrative burden for issuers of tracking and ensuring compliance with such a prohibition.[190] However, States may choose to further address issuer stacking practices, such as by prohibiting stacking across issuers not within the same controlled group.

One commenter suggested the Departments limit an issuer's ability to issue subsequent STLDI policies to members of the same household. The Departments did not propose to limit an issuer's ability to sell subsequent STLDI policies to members of the same household and decline to adopt such a limitation in these final rules. Members of the same household may need temporary, stopgap coverage at different times over a 12-month period. Limiting the ability of members of the same household to purchase STLDI coverage would remove flexibility for consumers and unnecessarily complicate their health insurance enrollment process because issuers would have to determine whether members of the same household have enrolled in any STLDI coverage during the previous 12-month period each time any member of the household enrolls in STLDI, which could create an administrative burden on issuers. Furthermore, whereas limiting stacking across affiliated issuers in the same controlled group will prevent issuers from using their corporate structure to circumvent the rules related to maximum duration, it is not apparent to the Departments that limiting stacking across unaffiliated issuers or different members of the same household accomplishes any similar goal. Finally, the administrative burden of tracking members of the same household may outweigh any potential benefit of restricting the sale of multiple STLDI policies to individuals who reside in the same household.

Some commenters requested that the Departments affirm that consumers are entitled to renewal guarantees that might be offered by an STLDI issuer. As explained in the preamble to the 2018 final rules, renewal guarantees generally permit a policyholder, when purchasing their initial insurance contract, to pay an additional amount in exchange for a guarantee that the policyholder can elect to purchase, for periods of time following the expiration of the initial contract, another policy or policies at some future date, at a specific premium that would not require any additional underwriting.[191] The Departments affirm that the final rules do not address renewal guarantees. However, the Departments acknowledge that the revisions to the Federal definition—including the provision that requires counting the term of a new STLDI contract issued by the same issuer or, if the issuer is a member of a controlled group, any other issuer that is a member of the same controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, contract, or certificate of insurance toward the total maximum duration of STLDI—would limit the guarantees that such instruments may be able to provide.[192]

3. Sales and Marketing Practices

In the 2023 proposed rules, the Departments expressed concerns about reports of aggressive and deceptive sales and marketing practices related to STLDI where STLDI is marketed as a substitute for comprehensive coverage, despite being exempt from most of the Federal individual market consumer protections and requirements for comprehensive coverage.[193] [194] The

[189] *See* 45 CFR 147.106(d)(3) and (4) (providing an exception to market withdrawal under guaranteed renewability regulations) and 156.20 (defining an ''issuer group'' for purposes of QHP issuer standards).

[190] 88 FR 44596 at 44646 (July 12, 2023).

[191] *See* 83 FR 38219, 38220 (Aug. 3, 2018).

[192] While the Departments may be limited in their ability to take an enforcement action with respect to transactions involving products or instruments that are not health insurance coverage, the Departments may have the authority to regulate the coverage issued pursuant to such a product or instrument.

[193] *See* 88 FR 44596 at 44613 (July 12, 2023).

[194] The agent and broker compensation disclosure and reporting requirements in section 2746 of the

Continued

Departments solicited comments on additional ways to help consumers distinguish between comprehensive coverage and STLDI. In particular, the Departments requested comments on ways to prevent or otherwise mitigate the potential for direct competition between comprehensive coverage and STLDI during the open enrollment period for comprehensive individual health insurance coverage.[195]

Many commenters agreed that STLDI deceptive marketing practices have caused many consumers to confuse STLDI with comprehensive coverage. These commenters stated that these misleading marketing practices often attract younger, healthier consumers who may not realize how limited STLDI coverage is until faced with out-of-pocket costs. Commenters observed that studies indicate that STLDI has been aggressively and deceptively marketed to consumers especially during the open enrollment period for comprehensive individual health insurance coverage,[196] which has left consumers at increased risk of purchasing plans that do not meet their medical needs. Commenters also noted that the population of individuals affected by States resuming Medicaid eligibility redeterminations due to the end of the FFCRA's Medicaid continuous enrollment condition has been vulnerable to these practices. Commenters highlighted evidence of salespeople neglecting to tell consumers that they may be eligible for subsidized ACA plans, asserting that an individual's health needs would be covered by an STLDI plan despite plan documents contradicting these assertions, or misstating an STLDI plan's coverage of certain preexisting conditions. Commenters also included examples of deceptive marketing practices (some of which were identified during secret shopper studies), such as marketing materials with images of activities for which coverage of associated injuries are excluded, marketing materials with logos of well-known issuers that are not affiliated with the STLDI being sold, or websites selling STLDI that include the words ''Obamacare'' or ''ACA.''

One commenter suggested that the Departments should monitor and limit marketing of STLDI that is conducted in a manner that may lead consumers to unwittingly enroll in STLDI. The commenter stated that multiple States have already implemented prohibitions against aggressive and deceptive marketing of STLDI products to protect individuals. The commenter stated that a Federal prohibition on such marketing tactics would ensure that people are aware of the most affordable and comprehensive health coverage options available to them, are not exposed to deceptive marketing practices, and are able to avoid potentially catastrophic gaps in coverage.

Other commenters expressed concern regarding the sale of STLDI over the telephone and internet. The commenters cited studies showing an increase in sales over the telephone and internet since the 2018 final rules. Commenters stated that although telephone and internet sales are convenient for consumers, the incentives to provide reliable customer service are low. Commenters noted that such sales methods are prone to abuse and make it hard for consumers to get concrete, verifiable answers about the product they are being sold before they buy it. Other commenters suggest that sellers of STLDI be reviewed for compliance with laws enforced by the Federal Trade Commission that prohibit deceptive marketing practices. Some commenters suggested that marketers of STLDI sold over the telephone or internet should be required to provide a clear warning to consumers about the true coverage terms prior to the conclusion of a sale.

Some commenters encouraged the Departments to collaborate with State departments of insurance to combat misleading marketing practices. Commenters noted that the expansion of STLDI following the 2018 final rules has presented challenges for State regulators attempting to monitor the applicable State market and protect potential consumers against deceptive marketing practices. Commenters suggested that the Departments, in collaboration with the Federal Trade Commission and the Federal Bureau of Investigation, should investigate and stop lead generators and sales agents who use deceptive marketing techniques through websites, social media, phone calls, and other means.

Several commenters urged the Departments to establish a Federal prohibition on the sale of STLDI during the annual open enrollment period for comprehensive individual health insurance coverage. Commenters cautioned that when STLDI is marketed and sold during the annual individual market open enrollment period, the potential for consumer confusion is particularly acute. Commenters explained that sellers take advantage of the annual open enrollment period when more consumers are shopping for comprehensive individual health insurance coverage to push them into products that are not comprehensive and argued that halting sales of STLDI during this period would decrease consumer confusion and facilitate access to comprehensive coverage. Another commenter stated that legitimate needs for STLDI coverage may arise at any time of year and recommended that if the Departments place restrictions on the sale of STLDI during the annual individual market open enrollment period, those restrictions should be limited to the sale of products with a January 1 effective date.

Another commenter suggested that the Departments explicitly prohibit Federal and State Exchanges from linking to or advertising STLDI. The commenter stated that HHS should also impose a similar requirement on agents and brokers to prohibit side-by-side advertising of STLDI or other non-compliant plans on the same web page as individual health insurance coverage that is subject to the Federal consumer protections and requirements for comprehensive coverage.

One commenter suggested that the Departments consider prohibiting the offering of higher broker commissions for the sale of STLDI than commissions for the sale of comprehensive coverage, arguing that this type of prohibition could significantly decrease the financial incentive for agents and brokers to encourage consumers to purchase STLDI over comprehensive coverage and help reduce direct competition between these two types of products.

Some commenters encouraged the Departments to invest in and take steps to increase consumer education and enrollment assistance activities that could improve consumer understanding of the differences between comprehensive coverage and STLDI.

Other commenters suggested placing requirements on agents and brokers or the consumer to better ensure consumers understand the differences between STLDI and comprehensive coverage. For example, one commenter suggested that the Departments require agents and brokers to sign an attestation that the information given to the consumer by the agent or broker spells out in plain language the terms of the STLDI coverage and acknowledges that the consumer understands the limitations. The commenter asserted this would help ensure that underserved communities and patients with chronic medical conditions who struggle to find

PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

[195] *See* 88 FR 44596 at 44613–44614 (July 12, 2023).

[196] Government Accountability Office (2020). ''Private Health Coverage: Results of Covert Testing for Selected Offerings,'' available at: *https://www.gao.gov/products/gao-20-634r.*

affordable health insurance options are not targeted by unscrupulous sales and marketing tactics. Another commenter urged the Departments to adopt the same disclosure and consent requirements applicable to agents, brokers, and web-brokers assisting consumers in a Federally-facilitated Exchange or State Exchange using the Federal platform for agents, brokers, and web-brokers assisting consumers purchasing STLDI.[197] One commenter suggested that the Departments require a statement for consumers to sign acknowledging that the coverage does not meet the minimum standards required under the ACA and does not provide equivalent Federal consumer protections.

The Departments appreciate these comments and suggestions and will take them into consideration in any future regulations or guidance defining STLDI. In addition, the Departments appreciate the recommendations regarding steps that the Departments can take outside of rulemaking to educate consumers about their health coverage options and limit the possibility that consumers inadvertently purchase STLDI when shopping for comprehensive coverage. HHS has already taken steps separate from these final rules to limit the potential for individuals to inadvertently purchase an STLDI plan when shopping for a qualified health plan and will consider additional opportunities to do so. *HealthCare.gov,* the platform for the Federally-facilitated Exchanges and State Exchanges using the Federal platform, neither links to nor advertises STLDI.[198] In addition, for the Federally-facilitated Exchanges and State Exchanges using the Federal platform, direct enrollment entities [199] are generally required to use three different website pages to display and market coverage—one for qualified health plans offered through the Exchange, one for individual health insurance coverage offered outside the Exchange, and one for any other products, including STLDI.[200] Direct enrollment entities participating in the Federally-facilitated Exchanges and State Exchanges using the Federal platform must also limit marketing of non-QHPs, such as STLDI, during the Exchange eligibility application and QHP selection process.[201] In its proposed rule entitled ''Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO–OP) Program; and Basic Health Program,'' HHS proposed to apply these requirements to direct enrollment entities operating in State Exchanges and to web-brokers that assist with or facilitate enrollment in coverage in a manner that constitutes enrollment through the State-based Exchanges.[202]

4. Notice

In the preamble to the 2023 proposed rules, the Departments explained that the notice is important to help consumers distinguish between comprehensive coverage and STLDI and ensure that consumers are aware of the limitations of STLDI.[203] The Departments proposed to amend the existing STLDI notice to further clarify the differences between STLDI and comprehensive coverage and identify options for consumers to obtain comprehensive coverage in concise, understandable language that would be meaningful to them.[204] The Departments proposed to apply the amendments to the notice to all STLDI policies sold or issued on or after the effective date of the final rules and to existing STLDI policies for notices provided upon renewal or extension on or after the effective date of the final rules.[205]

In the 2023 proposed rules, the Departments proposed that the notice must be displayed (in either paper or electronic form) prominently in at least 14-point font, on the first page of the policy, certificate, or contract of insurance (including for renewals or extensions), in any marketing and application materials provided in connection with enrollment in such coverage, including on websites that advertise or enroll individuals in STLDI, and in any enrollment and reenrollment materials that are provided at or before the time an individual has the opportunity to enroll or reenroll in coverage (including on any website used to facilitate reenrollment in STLDI).[206]

In these final rules, the Departments are finalizing the revised notice with modifications to implement feedback from comments and consumer testing, improve consumer comprehension of the notice, and further distinguish between STLDI and comprehensive coverage. As discussed in section III.A.6 of this preamble, the revised notice must be provided with respect to both new and existing STLDI for coverage periods (including renewals or extensions) beginning on or after September 1, 2024.

Some commenters were generally opposed to revisions to the notice standard. These commenters expressed concern that the Federal revised notice may not comport with notices that State legislatures and regulators create, often in consultation with consumer advocates and State insurance experts. A commenter expressed concern that the information about ACA coverage in the proposed notice would confuse the average person shopping for health coverage. Another commenter suggested that the Departments defer to the NAIC

[197] *See* 45 CFR 155.220 for standards applicable to agents and brokers and web-brokers who assist qualified individuals, qualified employers, or qualified employees enrolling in qualified health plans.

[198] *See* section 1311(d)(2) of the ACA, which generally prohibits an Exchange from making available any health plan that is not a qualified health plan. *See also* CMS, Frequently Asked Questions on Reuse of Exchange for Ancillary Products (March 29, 2013), available at: *https://www.cms.gov/cciio/resources/files/downloads/ancillary-product-faq-03-29-2013.pdf.*

[199] ''Direct enrollment entity'' means an entity that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by 45 CFR 155.220(c)(3), 45 CFR 155.221, or 45 CFR 156.1230. 45 CFR 155.20.

[200] 45 CFR 155.221(b)(1).

[201] 45 CFR 155.221(b)(3).

[202] 88 FR 82510, 82568 and 82562 (Nov. 24, 2023) (''Consistent with §§ 156.1230(b)(1) and (2), to directly enroll consumers in a manner that is considered to be through the Exchange, QHP issuer DE entities are required to comply with the applicable requirements in § 155.221 . . . In this rulemaking, we propose to extend these FFE requirements to also apply them to QHP issuer DE entities in State Exchanges. As proposed to be applied in these State Exchanges, QHP issuer DE entities would similarly be required to provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the Exchanges, and insurance affordability programs. In addition, QHP issuer DE entities in State Exchanges would also be required to refrain from marketing or conduct that is misleading (including by having a DE website that the State Exchange determines could mislead a consumer into believing they are visiting the Exchange's website), coercive, or discriminates based on race, color, national origin, disability, age, or sex . . . Finally, we propose . . . to extend the current web-broker FFE standard of conduct established at § 155.220(j)(2)(i) to also apply to web-brokers assisting consumers in State Exchanges, and consequently to these State Exchanges. Section 155.220(j)(2)(i) requires agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE, or assist individuals in applying for APTCs and CSRs for QHPs sold through an FFE, must provide consumers with correct information, without omission of material fact, regarding the FFEs, QHPs offered through the FFEs, and insurance affordability programs . . . and refrain from marketing or conduct that is misleading (including by having a DE website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex.'')

[203] 88 FR 44596 at 44614 (July 12, 2023).

[204] *Id.* at 44614–44618.

[205] *Id.* at 44618–44619.

[206] *Id.* at 44614–44616.

and State regulatory experts who are currently drafting minimum standards for STLDI products. A commenter suggested that States should have the option to substitute their own required disclosure language in place of the Federal mandated language and that notice provisions should only be applicable if a State has no comparable notice provisions.

Another commenter shared a study asserting that the revised notice did not substantially improve consumer understanding of STLDI and that any notice should be of short length because most consumers have trouble understanding lengthy explanations that tend to present multiple concepts in the same notice. Other commenters supported the proposed revisions to the notice standard and agreed that the revisions would help educate consumers about the differences between comprehensive coverage and STLDI before a decision is finalized about health coverage in a way that would alleviate downstream concerns about applicable benefits and costs.

The Departments agree that it is important to provide consumers with concise, accurate information to evaluate insurance products so that consumers may make informed decisions about health insurance coverage. The Departments sought to address potential confusion caused by the notice by requesting comments on the proposed notice standard and conducting consumer testing. Based on current research highlighting deceptive marketing practices and consumer confusion, [207] [208] [209] the Departments are of the view that it is necessary and appropriate for issuers of STLDI to disclose key differences between comprehensive coverage and STLDI before completing the sale or renewal so consumers can make informed decisions. The revised notice standard under these final rules will help clarify the differences between STLDI and comprehensive coverage. As the Departments agree that the revisions to the notice standard alone will not protect consumers from deceptive marketing practices, revisions to the notice standard are being finalized in tandem with revisions to the definitions of the terms ''short-term'' and ''limited-duration.'' The Departments disagree with and decline to adopt the suggestion that the notice should not be part of the Federal definition of STLDI.

With respect to concerns about the lack of State input in the revisions to the notice standard, the Departments consulted plain language experts, conducted consumer testing, and considered comments on the 2023 proposed rules from State regulators, consumer advocates, and other interested parties. The Departments therefore disagree that there was a lack of State input. The Departments concluded that a uniform Federal notice best furthers the Departments' interest in ensuring that information is communicated to consumers to enable them to identify and distinguish STLDI from comprehensive coverage. Therefore, the Departments decided not to specify that the revised notice would be applicable only if a State has no comparable notice provision. In addition, these final rules do not prevent States from requiring additional language be included with the notice for purposes of State law or prohibit issuers from including additional language in their notices. Policies that do not include the language in the revised notice under these final rules will not be considered STLDI coverage, and therefore will not qualify for the exception for STLDI from the definition of individual health insurance coverage for purposes of Federal law.

One commenter alleged that the revised notice standard raised First Amendment concerns because the notice violates the First Amendment's prohibition on compelled speech. The commenter argued that the revised notice standard constitutes a content-based restriction and is not justified because it is not narrowly tailored to serve a compelling government interest.

The Departments disagree with this commenter. The rules do not require the provision of a notice, but instead simply provide that coverage offered without such a notice would not qualify as STLDI and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. Moreover, as discussed in section III.B.1 of this preamble, required disclosures of factual, uncontroversial information in commercial speech are subject to more deferential First Amendment scrutiny and have been upheld where the disclosure requirement reasonably relates to a government interest, and is not unjustified or unduly burdensome.[210] Regardless, the Departments believe that the revised notice standard would pass muster under any form of First Amendment scrutiny.

The Departments have a substantial, and even compelling, government interest in combatting deceptive marketing practices by ensuring consumers are informed about the key differences between STLDI and comprehensive coverage, are aware of their option to purchase comprehensive coverage, and have access to resources for additional information about the range of available health coverage options so consumers can make informed choices. As discussed in section II.B of this preamble, this is currently of particular importance due to significant changes in market conditions and in the legal landscape and low health literacy amid widespread deceptive marketing practices that play on consumer confusion about the benefits and limitations of STLDI. The revised notice communicates factual information to consumers about the differences between STLDI and comprehensive coverage and explains how consumers can find resources when consumers have questions about the different coverage options. Finally, the revised notice is reasonably related to, and narrowly tailored to, the government's interest in informing consumers about STLDI coverage, and combating deceptive marketing practices and potential sources of misinformation, by directing consumers to appropriate resources to learn more about the range of available health coverage options. The notices do not include irrelevant or superfluous information unrelated to these interests. Accordingly, these final rules serve substantial government interests.

[207] For one example of deceptive marketing practices, *see* Federal Trade Commission (2022). ''FTC Action Against Benefytt Results in $100 Million in Refunds for Consumers Tricked into Sham Health Plans and Charged Exorbitant Junk Fees,'' available at: *https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-action-against-benefytt-results-100-million-refunds-consumers-tricked-sham-health-plans-charged.*

[208] Palanker, Dania and Kevin Lucia (2021). ''Limited Plans with Minimal Coverage Are Being Sold as Primary Coverage, Leaving Consumers at Risk,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2021/limited-plans-minimal-coverage-are-being-sold-primary-coverage-leaving-consumers-risk.* (Noting that fixed indemnity insurance may be ''bundled'' with other non-comprehensive insurance products in such a way that ''the plans look like comprehensive coverage'' while still offering limited benefits). *See also* Palanker, Dania, JoAnn Volk, and Maanasa Kona (2019). ''Seeing Fraud and Misleading Marketing, States Warn Consumers About Alternative Health Insurance Products,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/seeing-fraud-and-misleading-marketing-states-warn-consumers-about-alternative-health.*

[209] Government Accountability Office (2020). ''Private Health Coverage: Results of Covert Testing for Selected Offerings,'' available at: *https://www.gao.gov/products/gao-20-634r.*

[210] The U.S. Supreme Court recognized this standard of scrutiny in *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626 (1985) (''*Zauderer*'') and later confirmed it in *National Institute of Family and Life Advocates* v. *Becerra,* 138 S. Ct. 2361, 2372, 2376 (2018) (''*NIFLA*'').

In addition, the revised notice standard is not unjustified, unduly burdensome, or insufficiently tailored to the interests described previously. As stated in the preamble to the 2023 proposed rules, the Departments are concerned about consumers who are at risk of significant financial liability if they enroll in STLDI that exposes consumers to high health care costs that are not covered by their STLDI policy. The language on the Federal revised notice includes factual, uncontroversial information. The Departments consulted plain language experts, conducted consumer testing, and considered comments on the proposed revised notice to ensure the language was factual, easy to read, and understandable. Furthermore, the revised notice standard does not unduly burden issuer speech because issuers remain free to communicate with consumers about their coverage using any methods of communication they choose. As discussed in section V.B.2.d of this preamble, the Departments estimate that the cost to issuers of displaying the revised notice will be relatively low, because the Departments have adopted static language that issuers do not have to tailor to the policy or State of sale. For the reasons discussed previously, the Departments are of the view that requiring STLDI issuers to provide a notice that provides factual information to consumers prior to when the consumers purchase coverage is reasonably related to the government's stated interests in ensuring consumers can distinguish STLDI and comprehensive coverage and are informed of options to purchase comprehensive coverage, should the consumer wish to obtain such coverage. The information required to be disclosed is clearly identified and has a direct nexus to that legitimate government interest. Finally, the revised notice standard is narrowly tailored to inform consumers about the limitations of STLDI and to combat deceptive marketing practices and potential sources of misinformation by directing consumers to appropriate resources to learn more about their health coverage options. The notice does not include irrelevant or superfluous information unrelated to informing and directing consumers to appropriate resources.

The Departments sought comments on whether the proposed placement for the notice substantially improves the likelihood that consumers have a meaningful opportunity to review the notice and their health coverage options before applying for, enrolling in, or reenrolling in STLDI, as well as any practical or logistical barriers to providing this notice as proposed. In particular, the Departments sought comments from members of underserved communities, and organizations that serve such communities, on whether the language accessibility, formatting, and content of the notice sufficiently mitigate barriers that exist to ensuring all individuals can read, understand, and consider the full range of their health coverage options.[211]

Most commenters supported the proposed placement of the notice on the first page of any policy, certificate, or contract of insurance (including for renewals and extensions), website used to facilitate enrollment (or reenrollment) in STLDI, and marketing and application materials provided in connection with enrollment in STLDI, because the benefits of simplifying access to the notice far outweighs any associated burden of including the information in these locations. One commenter suggested that issuers should have the flexibility to put the notice for renewals on a separate document and not on the face page of the policy, certificate, or contract of insurance because some States require pre-approval of notice provisions. Another commenter supported the notice being provided in the same format that sales of STLDI are conducted, since misleading marketing often occurs when STLDI is not sold in person and consumers are given limited time to contemplate their insurance choices before being pressured to choose a product. For example, if enrollment occurs over the telephone, the commenter suggested the seller should be required to read the notice to the consumer and record their acknowledgement, or if the enrollment occurs via the internet, a prominent notice should be featured during the accompanying online sign-up process. Other commenters recommended that the Departments require audio and video advertisements to include an audio version of the notice within the first 10 seconds of any advertisement of STLDI coverage. Another commenter suggested that telephone solicitors, brokers or agents making sales calls, or in-person sales should be required to inquire as to the consumer's preferred language through a qualified language translator or language telephone line. Commenters also suggested that the notice be provided in multiple common languages other than English that are spoken in the United States in a manner that is culturally appropriate, readable, and clear so that consumers can make appropriate coverage decisions. Commenters highlighted the importance of the notice being accessible to individuals with disabilities.

The Departments are finalizing the standard for the notices to be prominently displayed on the first page of applicable materials[212] in at least 14-point font, as proposed. Because ensuring that consumers understand any limitations of what they are purchasing is of utmost importance, provision of the notice should not be saved until the time of enrollment when consumers may feel pressured to sign up and effectuate coverage instead of restarting their search for a different insurance product. The Departments agree with commenters that the need for consumers to have easy access to the notice during enrollment and reenrollment outweighs the burden associated with placement of the notice on the first page of applicable materials. The Departments further agree with commenters that if the STLDI policy is sold online or electronically then the notice should be communicated in the same format as the sale. Further, consistent with the proposal in the 2023 proposed rules, the placement standard under these final rules extends the notice to websites that advertise or offer the opportunity to enroll (or reenroll) in STLDI. Although these final rules provide that the notice must be prominently displayed in any marketing materials provided in connection with enrollment (or reenrollment) in STLDI, the Departments decline to require audio and video advertisements include an audio version of the notice within the first 10 seconds of any advertisement of STLDI coverage. The Departments did not include a proposal on audio and video advertisements in the 2023 proposed rules and therefore decline to address such other types of communication formats in these final rules.

The Departments agree that it is important that the notice be accessible and understandable to individuals with limited English proficiency. While the Departments did not propose and are not finalizing language access standards

[211] 88 FR 44596 at 44617 (July 12, 2023).

[212] The applicable materials on which the STLDI notice must be prominently displayed (in either paper or electronic form) are the first page of the policy, certificate, or contract of insurance (including for renewals or extensions), any marketing and application materials provided in connection with enrollment in such coverage, including on websites that advertise or enroll individuals in STLDI, and in any enrollment and reenrollment materials provided at or before the time an individual has the opportunity to enroll or reenroll in coverage (including on any website used to facilitate reenrollment in STLDI).

specific to these notices as part of this rulemaking, the Departments remind plans and issuers that they are required to comply with other State and Federal laws establishing accessibility and language access standards to the extent applicable. For example, recipients of Federal financial assistance must comply with Federal civil rights laws that prohibit discrimination. These laws may include section 1557 of the Affordable Care Act,[213] title VI of the Civil Rights Act of 1964,[214] section 504 of the Rehabilitation Act of 1973,[215] and the Americans with Disabilities Act of 1990.[216] Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as written translation of written content in paper or electronic form into languages other than English. Sections 1557 and 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Additionally, section 508 of the Rehabilitation Act of 1973 requires that information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply.

In the 2023 proposed rules, the Departments requested comment on two potential formats for the revised notice standard [217] (Notice A and Notice B).

The proposed STLDI notice (Notice A) was as follows:

BILLING CODE 4830–01–P

Notice to Consumers About Short-Term, Limited-Duration Insurance

IMPORTANT: This is short-term, limited-duration insurance. This is temporary insurance. **It isn't comprehensive health insurance.** Review your policy carefully to make sure you understand what is covered and any limitations on coverage.

- This insurance might not cover or might limit coverage for:
  - preexisting conditions; or
  - essential health benefits (such as pediatric, hospital, emergency, maternity, mental health, and substance use services, prescription drugs, or preventive care).
- You won't qualify for Federal financial help to pay for premiums or out-of-pocket costs.
- You aren't protected from surprise medical bills.
- When this policy ends, you might have to wait until an open enrollment period to get comprehensive health insurance.

Visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325) to review your options for comprehensive health insurance. If you're eligible for coverage through your employer or a family member's employer, contact the employer for more information. Contact your State department of insurance if you have questions or complaints about this policy.

An alternative proposed STLDI notice (Notice B) was as follows:

[213] 42 U.S.C. 18116.
[214] 42 U.S.C. 2000d *et seq.*
[215] 29 U.S.C. 794.
[216] 42 U.S.C. 12101 *et seq.*
[217] 88 FR 44596 at 44616–44617 (July 12, 2023).

WARNING

This is not comprehensive insurance. This is short-term, limited-duration insurance.

This plan has fewer protections than comprehensive insurance options you can find on HealthCare.gov.

This Insurance	Insurance on HealthCare.gov
• May deny you coverage if you have a preexisting condition	• You cannot be denied coverage because of a preexisting condition
• There may be no limit to the amount you have to pay out-of-pocket for care	• The most you have to pay out-of-pocket for essential health benefits in a year is limited
• You will not qualify for Federal financial help to pay your premiums and out-of-pocket costs	• You may qualify for Federal financial help to pay your premiums and out-of-pocket costs
• You may not have access to all essential health benefits, including: pediatric, hospital, emergency, maternity, mental health, and substance use disorder services, prescription drugs, and preventive care	• You will have access to all essential health benefits, including: pediatric, hospital, emergency, maternity, mental health, and substance use disorder services, prescription drugs, and preventive care

Questions?

- For more info about comprehensive coverage, visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325).
- For more info about your employer's coverage, or a family member's employer coverage, contact the employer.

For questions or complaints about this policy, contact your State department of insurance.

The Departments received comments in support of both notice formats. Some commenters supported implementing the format of Notice A because they found the bulleted format easier to read and more understandable than a chart. Other commenters supported implementing the format of Notice B because they were of the view that the format is easier to follow and has more concise language. A commenter stated that consumers understand information better that is presented in charts. Another commenter suggested that the Departments design a notice format that would allow issuers to check boxes next to relevant provisions. Other commenters recommended that the Departments conduct consumer testing of the content and presentation of the notices through focus groups or surveys to ensure the notices are understandable. These commenters stated that notices should be tested with multiple audiences, particularly given current disparities in health insurance literacy rates and concerns for individuals with limited English proficiency and with disabilities.

HHS consulted plain language experts and engaged in consumer testing as part of the consideration of comments on the revised notice. Based on the testing of Notice A and Notice B, feedback from plain-language experts, along with consideration of comments on the revised notice, the Departments are finalizing the table format used in Notice B, with content modifications that are discussed in detail this section. Consumer testing revealed that the table format, comparing key features of STLDI and insurance offered through *HealthCare.gov,* helped consumers best distinguish between STLDI coverage and comprehensive coverage, and understand the differences between such coverage types.

After taking into account feedback from the comments, consulting with plain-language experts, and conducting consumer testing, the Departments are finalizing the following language for the notice to improve readability and effectiveness of the notice:

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

The Departments took into consideration all comments received on the notice. As mentioned in this section, following an initial review of the comments, HHS performed consumer testing to evaluate the effectiveness and readability of different messages and notice formats, including messages or changes to the proposed revised notice recommended by commenters. These final rules revise the content of the proposed notice to better inform consumers considering purchasing STLDI about the differences between STLDI and comprehensive coverage, support informed coverage purchasing decisions, and promote readability. The

revised notice balances including information about STLDI with readability and length so that consumers will be more likely to read and understand the notice.

The Departments sought comments on whether additional changes to the notice language would improve readability or further help individuals distinguish STLDI from comprehensive coverage, and whether there are practical or logistical barriers that would present challenges to compliance with the new proposed notice standard. The Departments solicited comments on all aspects of the proposed revisions to the notice standard, including whether to add a website link and telephone number for *HealthCare.gov*, and the proposed placement of the notice in the marketing, application, and enrollment (or reenrollment) materials, including the extension of the notice provision to websites that advertise or offer the opportunity to enroll (or reenroll) in STLDI and on the associated administrative burden for issuers, agents, brokers, or others who will be involved in providing the notice to consumers.

Many commenters suggested specific changes to the content of the revised notice standard. A commenter requested that the notice be displayed in highly readable fonts such as a Sans Serif font in a 14-point font to improve the readability of the notice. Some commenters suggested that the notice include additional information to explain what it means that STLDI is exempt from most Federal consumer protection laws. Some commenters recommended that the notice include a statement that STLDI coverage commonly conducts post-claims underwriting and may deny claims for chronic health conditions, surgeries, and other common services. A commenter recommended that the Departments add language warning consumers about the possibility of recissions because STLDI issuers often engage in post-claims chart review to search for signs of an undisclosed preexisting condition and thereby rescind coverage. The commenter recommended that the notice state: ''This insurance may rescind or retroactively cancel your coverage and not pay claims based on your medical history.'' The Departments are finalizing the requirement that the notice be in 14-point font size. While the final rules do not include a requirement that the notice be displayed in a specific font, the Departments would not consider the notice to be prominently displayed unless the font used is clear and readable. The revised notice standard will give issuers the flexibility to use a font that aligns with the format of their policies. In addition, the Departments revised the content of the chart based on comments and consumer testing. As a result, the chart clarifies that STLDI is not required to meet the Federal standards for comprehensive coverage and might not cover chronic health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health and substance use. In contrast, the notice does not specifically caution consumers that STLDI might conduct post-claims underwriting, or post-claims recissions. The Departments had to balance providing useful information that clarifies the differences between STLDI and comprehensive coverage and the readability, length, and effectiveness of the notice. The differences highlighted in the notice were selected primarily because consumer testing showed they were more effective at helping consumers distinguish between STLDI and comprehensive coverage than other options considered.

Some commenters suggested the notice address the 10 categories of essential health benefits [218] and state explicitly which essential benefits are not covered. Other commenters requested that the notice address coverage for certain types of items or services, such as maternity services, habilitative and rehabilitative services, and devices, so that consumers fully understand what coverage could be missing when purchasing STLDI. While the Departments agree that it is important to highlight for consumers that essential health benefits might not be covered by an STLDI policy, the notice only highlights a few categories of essential health benefits, including prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, and physical therapy. The Departments had to balance the importance of notifying consumers of the types of benefits that might not be covered, with the importance of not overcrowding the notice so that the notice is easy to read and understand.

Some commenters supported the notice including information about where consumers can access additional information about comprehensive coverage options, including referencing *HealthCare.gov* or the State Exchange website where the consumer resides, including when the coverage is sold by associations. Some commenters requested that the notice explain what subsidies may be available for consumers that enroll in coverage on the Exchanges instead of STLDI to increase transparency of the costs to consumers. Some commenters suggested adding information on the timing of the annual individual market open enrollment period to underscore the differences between STLDI and comprehensive individual health insurance coverage and help consumers plan their transition to Exchange coverage. Commenters also suggested that providing information on special enrollment periods for those losing Medicaid or employer coverage would further clarify consumers' coverage options. Additionally, given the potential for varied open enrollment or special enrollment periods across different States, a commenter recommended adding language saying, ''Because State Based Exchanges may have different enrollment timelines, if you lose coverage always check your eligibility on *Healthcare.gov* or your State Based Exchange for possible enrollment options.''

The Departments agree with commenters that it is important for the notice to include information about where consumers can access additional information about comprehensive coverage options, and are finalizing a notice standard that includes information about *HealthCare.gov*. Through this website, consumers in States with a Federally-facilitated Exchange or State Exchange using the Federal platform can purchase comprehensive coverage, and consumers in States with a State Exchange can get directed to the State Exchange. In addition, *HealthCare.gov* provides additional information about comprehensive coverage that might help consumers further distinguish STLDI coverage from comprehensive coverage, and may help consumers better understand the notice. The Departments considered including in the revised notice standard additional details, as suggested by commenters, about open enrollment, special enrollment periods, and subsidies. However, the Departments are concerned about the length these topics could add to the notice, and the burden associated with customizing the notices to include enrollment time frames which can vary slightly from State to State. After consideration of the comments, the Departments are finalizing the revised notice standard without information on these topics. However, the Departments note that information on each of these topics is available on *HealthCare.gov*, and the notice directs consumers to

[218] *See* section 1302 of the ACA, and 45 CFR 156 subpart B (defining essential health benefits).

HealthCare.gov for additional information on health coverage options.

Some commenters suggested additional or alternative language to focus consumers' attention or to convey key points. A commenter suggested using the phrase ''Important Notice—Please Read Carefully'' as the title to better catch the attention of consumers and inform them that this is important information they should consider prior to purchase. Another commenter supported the use of the word ''WARNING'' in capital letters as a heading in the notice for clarity. A commenter suggested adding to the introductory notice language, ''This plan has fewer protections, provides fewer benefits, and has higher out of pocket costs than comprehensive insurance options you can find on *HealthCare.gov*.'' A commenter suggested that the Departments replace the last sentence of the introductory paragraph with something very close to the following in bold text, ''You may be able to get much better coverage for less money (with tax credits) through a health insurance exchange even outside of open enrollment.'' A commenter suggested that the Department should change the heading of the second column of the comparison table from ''Insurance on *HealthCare.gov*'' to ''Comprehensive Insurance on *Healthcare.gov*.'' One commenter encouraged the Departments to remove the statement that STLDI is not comprehensive coverage because of a study that indicated that 95 percent of STLDI plans provide comprehensive coverage. A commenter suggested that the Departments revise ''You won't qualify for [F]ederal help to pay for premiums or out-of-pocket costs,'' to ''Most people qualify for tax credits that will lower out of pocket costs if they purchase coverage that meets certain [F]ederal requirements. For more information, visit [this website].'' In addition, the Departments could create a website to link consumers to clear information, the commenter stated.

The Departments took into consideration comments that suggested alternative language to include in the introductory paragraph. Based on consumer testing, the Departments are finalizing the revised notice standard with the heading, ''IMPORTANT,'' instead of ''WARNING.'' The Departments are of the view that ''IMPORTANT'' is sufficient to draw attention to the notice. In addition, the Departments revised the introductory paragraph to clarify that STLDI and insurance options on *HealthCare.gov* are not the only insurance options that might provide comprehensive coverage. While employer coverage is not included in the table, the Departments finalized the revised notice standard with a bullet point reminding consumers that have access to employer coverage to contact that employer about coverage options. The Departments are of the view that suggested additions to the introductory paragraph add content that is already accounted for in the table section of the notice. The Departments are not revising the notice heading for the second column. The heading, ''Insurance on *HealthCare.gov*,'' effectively communicates that the column applies to insurance options available on *HealthCare.gov*.

Some commenters provided recommendations for ways to enhance consumers' understanding of the notice. One commenter suggested that the Departments define key terms used in the notice and use alternate language to indicate that the coverage is ''comprehensive'' because some consumers believe that it means the best or most expensive coverage that most consumers do not need. A commenter discouraged the use of terms ''may'' and ''might'' because they fall short of conveying how STLDI does not meet Federal standards.

The Departments considered comments and worked with plain language experts to ensure that the revised notice standard is written in plain language that maximizes readability for the average consumer. While consumer testing revealed that consumers did not always understand terms used in the notice (including the term ''comprehensive''), the testing showed that consumers were still able to distinguish between STLDI and comprehensive coverage, based on the notice. Therefore, the Departments are of the view that defining key terms is not critical to the effectiveness of the notice and are finalizing the revised notice standard without defining key terms. In addition, the Departments will use the term ''might'' to preface certain rows in the table. It is important to include the term ''might'' to ensure that the content in the table accurately describes all STLDI coverage, as some STLDI might voluntarily, or under State law, provide the consumer protections listed in the notice.

Some commenters were in support of including the name and State of domicile of the issuer, name and State of domicile of the association (if applicable), website, and telephone number for the State department of insurance tailored to each STLDI policy in the notices included in marketing, application, and renewal materials to help consumers access regulators and consumer advocacy resources that can assist consumers regarding questions or concerns about their policies. Commenters stated that STLDI coverage filed in another State or sold through an out-of-State association should be required to include in the notice both the contact information of the insurance regulator in the State in which the consumer resides and the State in which the plan is filed, to aid in maintaining accountability for issuers and associations selling these insurance products. Commenters stated that access to such information will assist consumers in receiving accurate information about insurance products to make informed decisions about coverage and should be made available in the preferred language of individuals and families. Commenters argued that State regulators often have difficulty monitoring and regulating STLDI sold through out-of-State associations, the associations may attempt to operate outside the reach of the State in which the STLDI is sold, and consumers may be unaware of what State has regulatory authority over the product they are purchasing.

Other commenters were opposed to including State-specific information in the notices because the information would be of limited benefit to consumers and unnecessarily increase the administrative burden and costs for issuers. Another commenter suggested that the Departments provide a link to the directory of State insurance departments that the NAIC maintains.

In developing the proposed revised notice language, the Departments sought to balance the goals of distinguishing STLDI from comprehensive coverage and combatting deceptive marketing practices, as well as reducing misinformation by directing consumers to appropriate resources, with the need to provide a concise, understandable notice that would be meaningful and useful to consumers.[219] The Departments understand commenters' concerns regarding the burden associated with customizing notices to include State-specific information. However, the Departments also recognize the value of including State-specific information, such as appropriate contact information. After consideration of comments and the results of consumer testing, the Departments are finalizing changes to the notice to incorporate uniform language as part of the required content for the revised notice standard that directs individuals to an NAIC web page

[219] *See* 88 FR 44596 at 44614–44615 (July 12, 2023).

where they can find the contact information for the applicable State regulatory agency. This approach avoids adding an administrative burden on issuers to tailor the notice for each plan depending on the domicile of each consumer. In the case of STLDI sold by out-of-State associations, the link to the NAIC web page would provide consumers with access to contact information for State regulators in the State where the consumer purchased the STLDI coverage as well as the State where the STLDI is issued. Although this is a link to a non-United States Government website, the Departments are including this link in the notice because it allows consumers to access State-specific contact information, without requiring plans and issuers to customize the notice. The Departments cannot attest to the accuracy of information provided on the NAIC web page or any other linked third-party site. The NAIC link is provided for reference only and the inclusion in the notice of a link to a non-United States Government website does not constitute an endorsement by the Departments. Also, the privacy protections generally provided by United States Government websites do not apply to third-party sites.

In addition, as described earlier in this section, the Departments incorporated static language as part of the content for the revised notice standard finalized in these final rules that direct individuals to *HealthCare.gov* where individuals can navigate to their State's Exchange or get information about different types of health coverage options. This approach is intended to balance the desire to ensure individuals can access State-specific information with not increasing the burden on issuers associated with the development of customized notices that provide State-specific contact information. Since the Departments are not including State-specific or association-specific contact information as part of the revised notice standard, the Departments decline to specify a certain agency's contact information that should be included for products that are filed in multiple States.

The preamble to the 2023 proposed rules explained that the Departments were considering whether to add a statement to the notice describing the maximum permitted length of STLDI under the Federal definition, explaining that coverage cannot be renewed or extended beyond the maximum allowable duration, and explaining that the length of STLDI may be shorter subject to State law. The Departments sought comments on this approach, including how best to clearly and concisely communicate such information to consumers, including how to address the bifurcated applicability dates with respect to the proposals around the maximum allowed length; whether such information is already included elsewhere in the plan documents; and on the associated administrative burden for issuers, agents, brokers, or others who would be involved in providing the notice to consumers. The Departments also sought comments on whether information about the maximum allowed length of new or existing STLDI and options regarding renewal and extensions would be included in enrollment materials (or reenrollment materials) provided to enrollees as part of the normal course of business.

Commenters generally supported adding a statement to the notice describing the maximum allowed length of STLDI under Federal and State rules, where applicable. One commenter requested that the Departments add, ''coverage is intended to last for 3 months, if you enroll in the plan you may have to wait until the next open enrollment period to enroll in comprehensive coverage.'' A commenter suggested adding a sentence to the notice after the second sentence of the introductory paragraph that says, ''Coverage cannot last beyond 4 months or even less depending on the State in which you live.'' This minimally increases the length of the notice while informing the consumer that the policy cannot be renewed beyond 4 months or a shorter period depending on the State in which the consumer resides, the commenter stated.

While the Departments appreciate that information on maximum duration may be useful to consumers, the Departments remain concerned about how to clearly and concisely communicate such information to consumers using static language, without creating confusion for consumers if the duration of their policy differs from the maximum duration standards in the notice—for example, because of the bifurcated applicability dates,[220] shorter maximum durations allowed under State law, or the specifics of their policy. Given these concerns and based on consumer testing and consultation with plain language experts, the Departments are finalizing the notice without adding information on the maximum permitted length of STLDI. Since States have the flexibility to enact a different maximum permitted length of STLDI, including a standardized maximum permitted length in the revised notice standard may confuse consumers. The Departments are also mindful of limiting the amount of information provided on the notice for readability and comprehension and are of the view that the burden on issuers of requiring issuers to tailor their notices to each State outweighs the potential benefits of adding more language to the notice to capture State-specific information on the maximum permitted length for the STLDI policy. In addition, the Departments anticipate that information on the maximum allowed length of the STLDI coverage is included in the policy, certificate, or contract of insurance, and that options for renewal and extensions are typically included in enrollment materials (or reenrollment materials) provided to enrollees as part of the normal course of business.

The Departments solicited comments on whether it would be beneficial to consumers to require issuers to include language in the notice that clearly informs consumers that the notice is an officially required document, such as ''This notice is required by Federal law.'' One commenter suggested that including such a statement would further validate the importance of the notice and accentuate the caution warranted when considering purchasing STLDI, while another commenter argued that the statement would add length to the notice and is not critical for consumers' understanding of their rights. Consumer testing revealed that some testers found the inclusion of that phrase at the bottom of the notice helpful and reported that it made the information on the notice seem more legitimate, other consumers stated this statement suggested that the STLDI policy was endorsed by the Federal Government. After consideration of the comments and results from consumer testing, the Departments are finalizing the notice without the inclusion of a statement that the notice is required by Federal law. The Departments are of the view that any potential benefit of including the language is outweighed by the risk that some consumers will interpret the statement as a Federal endorsement of the policy.

5. Short-Term, Limited-Duration Insurance Sold Through Associations

In section III.A.5 of the preamble to the 2023 proposed rules, the Departments explained that they understand most sales of STLDI occur through group trusts or associations that are not related to employment

[220] *See* section III.A.6 of this preamble for discussion of the STLDI applicability dates finalized in these final rules.

(sometimes referred to as individual membership associations) [221] and solicited comments on what steps, if any, can be taken to support State oversight of STLDI sold to or through associations.[222] Under these arrangements, out-of-State issuers file STLDI products for approval in one State and then sell the same policies in other States through an association, many times with few requirements on consumers to participate in the association, other than payment of association dues. State regulators have reported that they often lack the authority to track sales of policies made through out-of-State associations and are unable to approve or regulate such policies when offered for sale by issuers that are not licensed by their State. Further, as explained in section III.A.V of the preamble to the 2023 proposed rules, the Departments have received feedback that many issuers take advantage of the ambiguity about which State's jurisdiction applies to the STLDI they sell to avoid State regulation.[223] For example, one study found that in a review of 34 policy brochures for STLDI, 28 of the brochures included references to associations.[224] Consumers may not understand that some STLDI marketed in their States are not regulated by their State and do not include State-specific consumer protections.

The Departments received comments agreeing that association-based STLDI coverage is often used as a vehicle to avoid local State regulation, with one commenter stating that such coverage is increasing in prevalence for employers with 10 or fewer employees. Commenters explained that because these association products are sold in States in which they are not registered, States have limited ability to protect their consumers from hidden fees and limited benefits. Nevertheless, some commenters asserted that States are best positioned to oversee the marketing of association-based STLDI coverage. Some commenters encouraged the Departments to work with States and the NAIC to improve oversight of products sold through out-of-State associations including collecting and sharing data and clarifying State authority to regulate these arrangements on behalf of their residents. Another commenter urged the Departments to consider additional enforcement mechanisms to ensure that STLDI issuers are not selling STLDI products in States in which they are not approved and ensure that consumers have recourse to file complaints when necessary.

As with the current regulatory definition of STLDI, the provisions of these final rules apply to STLDI sold to or through associations. As explained in the preamble to the 2023 proposed rules, coverage that is provided to or through associations, but not related to employment, and is sold to individuals, either as certificate holders or policyholders, is not group coverage under section 9832 of the Code, section 733(b)(4) of ERISA, and section 2791(b)(4) of the PHS Act.[225] If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered coverage in the individual market under Federal law, regardless of whether it is considered group coverage under State law. Thus, any health insurance sold to individuals through a group trust or association, other than in connection with a group health plan, or sold to a group trust or association to the extent the insurance is intended to cover association members who are individuals, must meet the definition of STLDI at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, or else be considered individual health insurance coverage that is subject to all the Federal individual market consumer protections and requirements for comprehensive coverage.

The Departments are aware that some group trusts and associations have also marketed STLDI policies to employers as a form of employer-sponsored coverage. As explained in section I.C of this preamble, there is no provision excluding STLDI from the Federal definition of group health insurance coverage.[226] Thus, any health insurance that is sold to or through a group trust or association in connection with a group health plan and which purports to be STLDI would in fact be group health insurance coverage and must comply with the Federal consumer protections and requirements for comprehensive coverage applicable to the group market. Failure to meet those requirements could result in penalties for employers offering such coverage.[227]

The Departments did not propose changes specific to association-based STLDI coverage and are not finalizing any such changes in these final rules. The Departments will continue to work closely with States, both individually and through the NAIC, to support State oversight and enforcement efforts of STLDI offered through associations.

6. Applicability Dates

In the 2023 proposed rules, the Departments proposed applicability dates for the proposed amendments to the Federal definition of STLDI that distinguish between new and existing STLDI under 26 CFR 54.9833–1, 29 CFR 2590.736, and 45 CFR 146.125 and 148.102. The Departments also proposed a technical amendment to 26 CFR 54.9833–1, 29 CFR 2590.736, and 45 CFR 146.125 (regarding applicability dates) to remove outdated language. The Departments proposed the technical amendment would apply to all coverage (that is, both new and existing STLDI) as of the effective date of the final rules.

The Departments did not receive any comments on the proposed applicability dates for the technical amendments and are finalizing them as proposed.

For new STLDI sold or issued on or after the effective date of the final rules, the Departments proposed that the amendments to the definition of STLDI would apply for coverage periods beginning on or after such date. For STLDI sold or issued before the effective date of the final rules (including any subsequent renewal or extension consistent with applicable law), the Departments proposed that the current Federal definition of such coverage would continue to apply with respect to the maximum allowable duration. Therefore, under the proposed rules, existing STLDI could continue to have an initial contract term of less than 12 months and a maximum duration of up to 36 months (taking into account any renewals or extensions), subject to any limits under applicable State law.

The Departments proposed that the amendments to the notice provision at paragraph (2) of the proposed definition of ''short-term, limited-duration insurance'' in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103 would apply for coverage periods beginning on or after the effective date of the final rules, regardless of whether the coverage was sold or issued before, on, or after the effective date of the final rules.

[221] *See* 88 FR 44596 at 44618 (July 12, 2023).

[222] *Id.*

[223] *Id.*

[224] *Id.* (citing Curran, Emily, Dania Palanker, and Sabrina Corlette (2019). ''Short-term Plans Sold Through Out-of-State Associations Threaten Consumer Protections,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/short-term-health-plans-sold-through-out-state-associations-threaten-consumer-protections*.)

[225] 88 FR 44596 at 44618 (July 12, 2023) (citing 45 CFR 144.102(c)).

[226] *See* section 2791(b)(5) of the PHS Act, which excludes STLDI from the definition of ''individual health insurance coverage''.

[227] Section 4980D of the Code.

The Departments sought comments on whether the proposed revised notice standard should apply only to new STLDI or should apply to both new STLDI and existing coverage upon renewal or extension, and whether the application of the proposed revised notice standard to existing STLDI should instead be delayed until January 1, 2025, or some other date. The Departments sought comments on whether all STLDI policies and any renewals or extensions of such coverage, including existing coverage sold or issued prior to the effective date of the final rules, should instead end upon the effective date of the final rules or some other date. The Departments also sought comments on whether an applicability date that would provide a longer transition period for consumers with policies, certificates, or contracts of STLDI sold or issued before the effective date of the final rules could help alleviate any potential market disruption. In addition, the Departments sought comments on whether it would be more reasonable for all STLDI policies, and any renewals or extensions of such coverage in effect before the date the final rules are published, to end before January 1, 2025, or some other date.

Only a few commenters commented on the applicability date for new STLDI policies. One commenter stated that it is critically important for consumers that the proposed amendments to the Federal definition of STLDI take effect as soon as possible for new STLDI policies to better inform consumers about the differences between STLDI and comprehensive coverage and protect consumers from deceptive marketing practices. A few commenters suggested that the Departments delay the applicability date for new STLDI policies, with recommended dates ranging from between 90 days and 12 months after the effective date of the final rules. Commenters recommended providing this additional time because STLDI products have already been filed and approved for 2024 and issuers need more time to evaluate plan designs, update system processes, re-file policy forms with State regulators and complete other administrative tasks.

The Departments agree that an applicability date of 75 days following publication of these final rules might cause challenges for some States and issuers as they move to revise plan designs and file new policy forms that comply with the Federal definition of SLTDI under these final rules. The Departments are mindful of the administrative obstacles identified by commenters and are of the view that providing more time to comply with the revised Federal definition of STLDI will be beneficial both to issuers and States. However, the Departments are also mindful of the caution from commenters that the potential for consumer confusion is particularly acute when STLDI is marketed and sold during the annual individual market open enrollment period. Although these final rules do not prohibit the sale or marketing of STLDI during the individual market open enrollment period, the Departments are of the view that the potential for consumer confusion about whether they are considering purchasing an STLDI plan or comprehensive coverage will be substantially lessened if the final rules go into effect for new STLDI policies before the beginning of the next individual market open enrollment period.[228] Therefore, after consideration of comments, these final rules provide that the new definition of STLDI will apply to new STLDI policies, certificates, or contracts of insurance for coverage periods beginning on or after September 1, 2024.[229] This applicability date will provide issuers and States with more time to come into compliance with these final rules for new STLDI policies. It will also allow uninsured consumers who enroll in a new STLDI policy on or after September 1, 2024, to bridge the gap to when new comprehensive coverage purchased during the next individual market open enrollment period would begin. The Departments decline to extend the applicability for new STLDI policies further to ensure an end to the marketing of STLDI with a longer maximum allowed length prior to the beginning of open enrollment for the 2025 individual market plan year.[230]

The Departments received some comments on the applicability date with respect to the maximum allowable duration for existing STLDI (including renewals and extensions). A few commenters requested that the revised maximum allowable duration apply to existing policies as soon as possible. These commenters stated that agents and brokers may attempt to steer as many consumers as possible into policies that are subject to the 2018 final rules prior to the applicability date for new policies, locking consumers into less protective coverage with a longer duration, and potentially destabilizing the risk pools for individual health insurance coverage. Commenters stated that this is particularly concerning as more consumers are shopping for health coverage as States resume Medicaid eligibility redeterminations due to the end of the FFCRA's Medicaid continuous enrollment condition. Another commenter stated that the Departments should apply the same applicability date for the maximum duration to new and existing policies because having a different applicability date for new and existing STLDI could create confusion for consumers and issuers. However, a different commenter suggested that the proposed applicability date for the revised maximum duration to apply to existing coverage would minimize confusion for currently enrolled consumers. One commenter supported the proposed applicability date for the revised maximum duration to apply to existing STLDI, as the dates allow issuers to honor their contractual obligations while avoiding unnecessary disruptions in coverage. Another commenter suggested aligning the applicability date for the revised maximum duration to apply to existing STLDI with the existing term or the start of the subsequent plan year for Exchange coverage, whichever comes first, and providing a 60-day special enrollment period to consumers whose coverage ends after the individual market open enrollment period. Other commenters recommended that the Departments postpone the applicability date for the revised maximum duration for STLDI to apply to existing policies to accommodate the end of the initial contract term, but prevent renewals or extensions to strike a balance between avoiding disruption of current plans and prolonging the harms of the maximum permitted duration under the current Federal definition of STLDI. These commenters also suggested this alternative approach would simplify the application of the revised maximum duration for STLDI coverage under the final rules. Other commenters suggested setting a different fixed applicability date for the revised maximum duration for SLTDI to apply to existing policies that aligns with the start of the individual market open enrollment period for plan years 2025 or 2026.[231]

[228] The next individual market open enrollment period begins on November 1, 2024. *See* 45 CFR 155.410(e)(4)(i).

[229] For new STLDI policies, the new maximum duration standards and the revised notice established in these final rules will apply for coverage periods beginning on or after September 1, 2024.

[230] The individual market open enrollment period for plan year 2025 begins on November 1, 2024. *See* 45 CFR 155.410(e)(4)(i).

[231] The individual market open enrollment periods for plan years 2025 and 2026 begins on November 1, 2024, and November 1, 2025, respectively. *See* 45 CFR 155.410(e)(4)(i).

The Departments appreciate the need to implement the changes to the revised maximum duration for STLDI as soon as practical to mitigate the risk of consumers mistakenly enrolling in STLDI in lieu of comprehensive coverage. At the same time, the Departments recognize that some consumers who are already enrolled in STLDI purchased such coverage with the understanding it would continue for a given period of time, consistent with the current Federal definition of STLDI and applicable State law. Such individuals may also have purchased coverage with the expectation that they could renew coverage, consistent with the current Federal definition and applicable State law. While the Departments want to balance avoiding prolonging the harms of a longer maximum permitted duration, to minimize disruption and confusion for individuals who purchased or were enrolled in STLDI prior to the effective date of the final rules, the Departments are finalizing the proposal to permit such individuals to remain covered under STLDI for the maximum initial contract term, as well as for renewals and extensions, to the extent permitted under the 2018 final rules, subject to any limits under applicable State law. Although the Departments are not applying the revised maximum duration for STLDI to renewals or extensions of existing coverage, consumers can opt not to renew or extend their coverage prior to reaching the maximum duration permitted for such coverage. The Departments are not persuaded by the concern that having different applicability dates for the revised maximum duration for new and existing coverage will create confusion for consumers and issuers. As noted by one commenter, allowing individuals with existing coverage to continue their coverage for the maximum duration allowed when they purchased STLDI may instead minimize confusion and align with the consumer's expectations when they purchased the coverage. Confusion for consumers who newly enroll in STLDI coverage on or after September 1, 2024, is likely to be minimal since they would not be eligible to purchase, renew, or extend an STLDI policy for the longer maximum duration permitted under the 2018 final rules. The Departments are of the view that the different applicability dates will also create minimal confusion and burden for issuers, which already need to track which STLDI policies are eligible for renewal or extension and for how long. The Departments are finalizing the applicability date for existing STLDI policies with respect to the maximum allowable duration for such coverage as proposed.

As discussed in section III.A.1 of this preamble, HHS declines to create a special enrollment period for individuals to enroll in individual health insurance coverage at the expiration of their STLDI coverage. However, nothing in Federal law would prevent an individual from discontinuing their STLDI coverage prior to its expiration date to align the end of their STLDI coverage with the start of individual health insurance coverage or other comprehensive coverage.

Some commenters supported applying the proposed revised notice to new STLDI sold or issued on or after the effective date of the final rules and to existing coverage upon renewal or extension. Another commenter recommended that the Departments apply the proposed amendments to the notice only to new STLDI sold or issued on or after the effective date of the final rules and to existing coverage starting 12 months after the publication of these final rules. Some commenters expressed concern that the proposed applicability dates for the revised STLDI notice did not provide enough time for implementation in States that require notices be submitted to the State department of insurance for review or approval.

The Departments agree with commenters that the revised notice should promptly apply to both new and existing (upon renewal or extension) STLDI coverage to alert all consumers who are considering purchasing or renewing STLDI to the differences between comprehensive coverage and STLDI. The notice is key to providing consumers with the information necessary to make an informed decision about the range of available coverage options. However, the Departments recognize that it would be burdensome on issuers to finalize three separate applicability dates (that is, for the notice provisions, for the maximum duration standards applicable to new policies, and for the maximum duration standards applicable to existing policies). In addition, the Departments acknowledge that issuers in some States may need to engage with their State regulator prior to implementing the new notice. After consideration of comments, the Departments are finalizing a delayed applicability date for the revised notice to align with the delayed applicability date finalized in these final rules for new STLDI coverage. Specifically, the revised notice specified in these final rules must be provided for new STLDI policies sold or issued on or after September 1, 2024, and with respect to existing coverage, upon renewal or extension that occurs on or after September 1, 2024.

B. Independent, Noncoordinated Excepted Benefits Coverage

In the group market, for hospital indemnity or other fixed indemnity insurance to qualify as an excepted benefit, among other criteria, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day), regardless of the amount of expenses incurred. In contrast, under the current individual market regulations, fixed indemnity insurance can pay on a per-period and/or per-service basis and be considered an excepted benefit. In the 2023 proposed rules, HHS proposed to realign the individual market regulations with the group market regulations, which would require hospital indemnity or other fixed indemnity insurance to pay a fixed dollar amount per day (or per other period) of hospitalization or illness to be considered an excepted benefit in the individual market, consistent with the group market rules.

The Departments also proposed additional payment standards for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit in the group market. HHS proposed parallel payment standards for fixed indemnity excepted benefits coverage in the individual market. Under the 2023 proposed rules, fixed indemnity excepted benefits would be required to be paid regardless of the items or services received, actual or estimated amount of expenses incurred, severity of illness or injury experienced, or any other characteristics particular to a course of treatment received by a covered participant, beneficiary, or enrollee.

The preamble to the 2023 proposed rules also explained that the Departments are aware that some employers offer employees a ''package'' of coverage options that include a non-excepted benefit group health plan that provides minimal coverage (for example, coverage of preventive services only) with fixed indemnity insurance that provides benefits associated with receiving a broad category of other services for which coverage is excluded from the non-excepted benefit group health plan. The Departments explained they are concerned that some employers are attempting to circumvent the Federal consumer protections and requirements for comprehensive coverage that

otherwise apply to group health plans by offering most benefits associated with receiving health care services under fixed indemnity insurance labeled as an excepted benefit, potentially leaving employees without crucial Federal consumer protections.

To address this concern and clarify the Departments' interpretation of the requirement that hospital indemnity and other fixed indemnity insurance must offer ''noncoordinated'' benefits to be considered an excepted benefit, the Departments proposed to add a new example to the group market regulations to reflect that the prohibition on coordination of benefits is not limited to only those situations involving a formal coordination-of-benefits arrangement. The proposed example illustrated a scenario with a fixed indemnity insurance policy and a group health plan maintained by the same plan sponsor in which a formal coordination-of-benefits arrangement was not present but there was nonetheless coordination between the provision of benefits under the fixed indemnity insurance policy and an exclusion of benefits under the group health plan. HHS proposed to apply the same interpretation of the noncoordination requirement to individual market fixed indemnity excepted benefits coverage.[232]

The Departments proposed a consumer notice for group market fixed indemnity benefits coverage. HHS also proposed amendments to the existing consumer notice for individual market fixed indemnity excepted benefits coverage. These proposals would ensure that fixed indemnity excepted benefits coverage is properly identified in marketing, application, and enrollment (or reenrollment) materials as fixed indemnity excepted benefits coverage, rather than comprehensive health insurance that is subject to Federal consumer protections, which would help a prospective enrollee distinguish between fixed indemnity excepted benefits coverage and comprehensive coverage options. With these proposals, the Departments aimed to support informed consumer choice by promoting consumer awareness of the limitations of fixed indemnity excepted benefits coverage and to help prevent consumers from mistakenly purchasing such coverage as an alternative to or replacement for comprehensive coverage.

The Departments received many comments in response to all of these proposals. These final rules adopt the new notice for fixed indemnity excepted benefits coverage offered in the group market and update the existing notice for such coverage offered in the individual market. In response to comments and consumer testing, the Departments have modified the content and applicability date of the notice, as discussed in more detail later in sections III.B.1 and III.B.3 of this preamble. However, to provide more time to study the issues and concerns raised in comments, these final rules do not address any other provision of the 2023 proposed rules relating to fixed indemnity excepted benefits coverage (with the exception of certain technical amendments to the HHS individual market regulation proposed in the 2023 proposed rules, as discussed in more detail later in section III.B.2 of this preamble). The Departments remain concerned with practices that appear to circumvent Federal consumer protections and requirements and intend to address the other proposals for hospital indemnity or other fixed indemnity insurance in future rulemaking, taking into account comments received on these issues.

No inference should be drawn from the decision not to finalize the proposed payment standards or noncoordination example as part of these final rules, and plans and issuers should not assume that current market practices that are inconsistent with the 2023 proposed payment standards or noncoordination example comply with the existing Federal regulations that apply to fixed indemnity excepted benefits coverage.

To the contrary, many comments received in response to the 2023 proposed rules underscored the Departments' concerns that hospital indemnity or other fixed indemnity insurance is being used by some issuers, plan sponsors, plans, agents, and brokers to circumvent the Federal consumer protections and requirements applicable to comprehensive coverage, while offering products that blur the lines between the two types of coverage. The Departments remain concerned about the deceptive marketing and sale of hospital indemnity and other fixed indemnity insurance, including the creation of hospital indemnity or other fixed indemnity insurance with detailed fee schedules. These types of fixed indemnity insurance products are not consistent with the traditional role of hospital or other fixed indemnity insurance serving as a form of income or wage replacement that the statutory exception was intended to cover. Instead, they mimic comprehensive coverage, without providing the Federal consumer protections or meeting the requirements applicable to comprehensive coverage. This leaves individuals who mistakenly purchase such coverage in lieu of comprehensive coverage without critical consumer protections, exposing them to significant health and financial risk.

Similarly, the Departments remain concerned about the practice of offering a ''package'' of coverage options that includes a non-excepted benefit plan that provides minimal coverage (such as coverage only for preventive services)[233] plus a fixed indemnity insurance policy that provides benefits associated with a broad range of items and services for which the other coverage maintained by the employer (or, in the individual market, maintained by the same issuer) excludes benefits. The Departments remain concerned that these plan designs are structured as coordinated arrangements to circumvent the Federal consumer protections and requirements for comprehensive coverage that otherwise would apply. This is particularly concerning if the employers, employees, or individuals are under the impression or are misled to believe that their two coverages, when combined, provide comprehensive coverage, and they therefore forgo pursuing other available options that would provide comprehensive coverage. The Departments intend to address these issues in future rulemaking.

The Departments emphasize that, to be considered fixed indemnity excepted benefits coverage under the current Federal group market regulations, the benefits must be paid only on a per-period basis. Under this standard, the Departments expect that fixed indemnity excepted benefit coverage would not be designed with fee schedules that, in effect, provide benefits for specific items and services, such as wellness screening exams or prescription drugs, rather than wage or income replacement. The Departments are aware that some issuers merely affix a ''per day'' term to benefits for specific items and services, such as $50 per

[232] Consistent with the interpretation and application of the statutory requirement that fixed indemnity excepted benefits coverage in the individual market must be offered on a noncoordinated basis, HHS proposed to modify the requirement at current 45 CFR 148.220(b)(4)(ii) to specify that benefits under fixed indemnity excepted benefits coverage must be paid with respect to an event without regard to whether benefits are provided with respect to such an event under any other health coverage ''maintained by the same issuer.''. HHS is not finalizing this proposed modification to the individual market noncoordination standard at this time.

[233] The Departments note that such an arrangement would not be treated as providing minimum value if it failed to provide substantial coverage of inpatient hospital services and physician services. 26 CFR 1.36B–6; 45 CFR 156.145.

blood test per day. As stated in the preamble to the 2023 proposed rules, when analyzing whether a policy, certificate, or contract of insurance is subject to the Federal consumer protections and requirements for comprehensive coverage, the Departments will look past the label used to examine whether the policy, certificate, or contract of insurance qualifies as an excepted benefit or whether it is comprehensive coverage that is subject to the Federal consumer protections and requirements applicable to such coverage. The Departments encourage State regulators to take a similar approach and intend to work with States to ensure that issuers comply with relevant requirements.

1. Notices

To ensure that consumers purchasing fixed indemnity excepted benefits coverage are aware of the type of coverage they are purchasing, including the limitations of the coverage, and that it is not mistakenly purchased as an alternative or replacement for comprehensive coverage, the Departments proposed to require a consumer notice be prominently displayed when offering fixed indemnity excepted benefits coverage in the group market, in alignment with the existing requirement to provide such a notice when offering fixed indemnity excepted benefits coverage in the individual market. The Departments proposed that if a plan or issuer provides the required group market notice in accordance with the provisions in the 2023 proposed rules, the obligation to provide the notice would be satisfied for both the plan and issuer.

In developing the proposed notice for the group market and revising the notice for the individual market, the Departments sought to balance two goals. One goal was to combat potential sources of misinformation by directing consumers to appropriate resources to learn more about comprehensive coverage and understand how that coverage differs from fixed indemnity excepted benefits coverage. The other goal was to provide a concise, understandable notice that would be meaningful to, and actionable by, consumers.

HHS also proposed technical amendments reorganizing the regulatory text to move the provision regarding the placement and materials on which the notice must appear for fixed indemnity excepted benefits coverage in the individual market, as well as amendments to the content and formatting for the notice itself, to align with the proposal to adopt a notice for the group market.

Many commenters supported requiring prominent display of the proposed consumer notice in both markets to help consumers distinguish fixed indemnity excepted benefits coverage from comprehensive coverage, make individuals aware of opportunities to purchase comprehensive coverage, and inform them of possible eligibility for subsidies to purchase comprehensive coverage. Commenters strongly supported disclosures to explain the limited nature of fixed indemnity excepted benefits coverage. One commenter stated that there is a need for a model consumer notice that is succinct, clear, and prominent, especially because prior efforts have not stopped abusive marketing tactics. One commenter stated that clear, consistent, and consumer-friendly disclosures are the best mechanism to ensure fixed indemnity policies are marketed in a clear and appropriate manner, particularly if consumers are purchasing coverage online. Another commenter stated that the proposed notice language was consistent with current industry standards and expressed support for even stronger disclosure language.

The Departments agree with these commenters. By requiring a prominent disclosure notice to consumers who are considering enrolling or reenrolling in individual or group market fixed indemnity excepted benefits coverage, the Departments aim to ensure that consumers are informed about the type of coverage they are purchasing, and thereby reduce the potential for consumers to mistakenly enroll in such coverage as their primary source of coverage and to increase consumer understanding of the differences between fixed indemnity excepted benefits coverage and comprehensive coverage.

The Departments also agree with commenters that the notices should provide information to consumers in a clear and concise manner regarding opportunities to purchase comprehensive coverage, especially regarding their possible eligibility for subsidies. As noted in the preamble to the 2023 proposed rules and in section III.A.1 of this preamble, individuals belonging to underserved populations often experience greater health challenges, as well as greater challenges accessing and using health care services, compared to the general population, including worse health outcomes, higher rates of chronic conditions, lower access to health care, and more frequent experiences of discrimination in health care settings.[234] Members of these populations may be particularly vulnerable to misinformation or misleading or aggressive sales tactics. A notice can help combat misinformation and misleading or aggressive sales practices by helping consumers distinguish between comprehensive coverage and fixed indemnity excepted benefits coverage.

For these reasons, as well as research identifying disparities in health insurance literacy among underserved populations and people with incomes below the FPL,[235] the Departments proposed, and are finalizing in these rules, the adoption of a consumer notice that must be provided when offering fixed indemnity excepted benefits coverage in the group market. HHS is also finalizing revisions to the existing consumer notice that must be provided when offering fixed indemnity excepted benefits coverage in the individual market. In the Departments' view, these notices will help ensure that all consumers, including those in underserved communities, have the necessary information to make an informed choice after considering and comparing the full range of health coverage options available to them.

Some commenters stated that changes or additional notices were not necessary because existing notice provisions are sufficient. One commenter stated that although they agree that consumers need to understand what they are buying, the proposed notice provisions are not necessary since State-required consumer warnings already exist, and a Federal notice is not the proper mechanism to promote consumer education or awareness. Some commenters suggested that existing fixed indemnity insurance policies should be exempt from any notice requirement since the consumer has already enrolled and presumably knows what they purchased.

The Departments disagree with commenters that stated that existing notice provisions are sufficient, that the

[234] *See* CMS Office of Minority Health (2022). ''The Path Forward: Improving Data to Advance Health Equity Solutions,'' available at: *https://www.cms.gov/files/document/path-forwardhe-data-paper.pdf.*

[235] Edward, Jean, Amanda Wiggins, Malea Hoepf Young, and Mary Kay Rayens (2019). ''Significant Disparities Exist in Consumer Health Insurance Literacy: Implications for Health Care Reform,'' *Health Literacy Research and Practice,* available at: *https://pubmed.ncbi.nlm.nih.gov/31768496/. See also* Villagra, Victor and Bhumika Bhuva (2019). ''Health Insurance Literacy: Disparities by Race, Ethnicity, and Language Preference,'' *The American Journal of Managed Care,* available at: *https://www.ajmc.com/view/health-insurance-literacy-disparities-by-race-ethnicity-and-language-preference.*

proposed notice provisions are unnecessary because State-required notices exist, and that a Federal notice is not the proper mechanism to promote consumer education or awareness. The existing Federal notice provision only applies to the individual market, leaving consumers in the group market potentially uninformed about the limited nature of their fixed indemnity excepted benefit coverage and unaware of resources to learn more about other coverage options. In addition, while some State-required notices may exist, they are not mandated nationwide. In the Departments' view, a Federal notice provision is the proper mechanism to promote consumer education or awareness by conveying a consistent message at or before the time a consumer has an opportunity to enroll in the fixed indemnity excepted benefit coverage in the individual and group markets. Without such a notice consumers may be left unaware or uninformed, because notices may not be provided at all, or would be provided at the plan's or issuer's discretion. Other mechanisms, such as public service announcements, would not ensure that information has been provided to every prospective consumer. Additionally, the Departments are of the view that requiring issuers to provide the consumer notice contemporaneously with marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage (rather than separately from the application process or after a product has already been purchased) will ensure that consumers are made aware of the type of coverage they are considering, are made aware of information resources at their State Department of Insurance, and are provided with options for purchasing comprehensive coverage at the time when they most need this information to support their decision-making process.

The Departments also do not agree that existing policies should be exempt from the applicable notice. Although a consumer may have already purchased fixed indemnity excepted benefit coverage in the past, the consumer may not have been aware of the limitations of such coverage or available comprehensive coverage options and may wish to evaluate all of their options before reenrolling. Therefore, the Departments are finalizing the proposal to provide the group market notice at or before the time participants are given the opportunity to enroll or reenroll in coverage prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment (or reenrollment) materials, and decline to provide an exemption for existing group market fixed indemnity excepted benefit coverage. HHS is similarly finalizing the individual market proposal to prominently display the notice on the first page of any marketing, application, and enrollment or reenrollment materials that are provided at or before the time an individual has the opportunity to apply, enroll or reenroll in coverage, and on the first page of the policy, certificate, or contract of insurance, and also declines to provide an exemption for existing individual market fixed indemnity excepted benefit coverage. These changes will ensure that fixed indemnity excepted benefit coverage is clearly identified as fixed indemnity coverage and not comprehensive coverage when marketed and sold in both the group and individual markets.

Some commenters opposed the adoption of a notice requirement in the group market and questioned its permissibility in the individual market. These commenters argued the Departments have no legal authority to require group health plans and issuers offering fixed indemnity excepted benefits coverage in the group market to provide such a notice. One commenter, while recognizing that the existing individual market notice was not at issue in *Central United Life Ins. Co.* v. *Burwell,* argued that requiring a notice was akin to the type of additional criterion that the D.C. Circuit found impermissible in the case.[236]

The Departments disagree with commenters that question the Departments' legal authority to adopt a consumer notice for fixed indemnity excepted benefits coverage in the group and individual markets. Through the enactment of the Federal excepted benefits statutes,[237] Congress generally preserved Federal authority to interpret and implement the statutory provisions governing these insurance products. Congress also provided the Departments with explicit authority to promulgate regulations as the Secretaries determine may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act.[238] These statutes collectively provide the Departments authority to interpret and implement the requirements for hospital indemnity or other fixed indemnity insurance to qualify as excepted benefits coverage under the Federal framework, and to adopt a consumer disclosure notice in regulation to ensure that the statutes themselves function as Congress intended. As explained in the 2023 proposed rules [239] and in section I.D. and this section III.B of the preamble of these final rules, fixed indemnity excepted benefits coverage is not an adequate substitute for comprehensive coverage, in part because it is not subject to Federal consumer protections and requirements that apply to comprehensive coverage. Consumers who purchase fixed indemnity excepted benefits coverage under the mistaken impression that such coverage is subject to Federal consumer protections and requirements for comprehensive coverage are at significant risk of financial and health hardships that may not become clear to the consumer until the occurrence of a costly health event.[240]

Consumers cannot adequately access Federal consumer protections to which they are entitled when it is unclear to which products they apply, and the effects of these protections are diluted when consumers are unclear what type of product they are purchasing and how and when they are protected by Federal law. Therefore, a consumer notice that clearly identifies a product as fixed indemnity excepted benefits coverage and distinguishes such a product from comprehensive coverage, clarifies and strengthens these protections for consumers. In addition, the notice prevents plans and issuers from marketing products that have been approved as an excepted benefit as comprehensive coverage to which Federal protections apply. Therefore, the Departments are of the view that it is necessary and appropriate for plans and issuers to provide consumers with a consumer notice that clearly labels fixed indemnity excepted benefits coverage and provides consumers with information sufficient to notify the consumer that such coverage is not subject to the Federal consumer protections and requirements for comprehensive coverage.

[236] 827 F.3d 70 (D.C. Cir. 2016).

[237] *See* section 9831 of the Code, section 732 of ERISA, and sections 2722(b)–(c), 2763, and 2791(c) of the PHS Act.

[238] *See* section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

[239] *See, for example,* 88 FR 44596 at 44619, 44620, 44645–44646 (July 12, 2023).

[240] *See id.* at 44605, 44606 (citing Appleby, Julie (2017). ''Brokers Tout Mix-And-Match Coverage To Avoid High-Cost ACA Plans,'' KFF, available at: *https://kffhealthnews.org/news/brokers-tout-mix-and-match-coverage-to-avoid-high-cost-aca-plans*), 44608 (citing Avila, Jaie (2019). ''Show Me Your Bill Helps Wipe Out $70K in Charges After Heart Attack,'' News 4 San Antonio, available at: *https://news4sanantonio.com/news/trouble-shooters/show-me-your-bill-helps-wipe-out-70k-in-charges-after-heart-attack*) (July 12, 2023).

The Departments also disagree with the commenter who stated requiring a notice was akin to the type of additional criterion that the D.C. Circuit found impermissible in *Central United Life Ins. Co.* v. *Burwell.* Adoption of the Federal consumer notice is not an impermissible requirement being added to the statutory criteria for fixed indemnity excepted benefits coverage. To ensure that the Code, ERISA, and the PHS Act function as intended, the notice ensures that fixed indemnity excepted benefits coverage is marketed and labeled as such, rather than as comprehensive coverage. As discussed in this section III.B.1 of this preamble, the rules do not require the provision of a notice, but instead simply provide that insurance offered without such a notice would not qualify as fixed indemnity excepted benefits coverage and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. Plans and issuers will not be prohibited from selling hospital indemnity and other fixed indemnity insurance, and consumers may continue to choose to purchase it, but unless the coverage includes the requisite notice identifying it as coverage not subject to the Federal consumer protections and requirements subject to comprehensive coverage, it would be subject to such protections and requirements. Additionally, the notice is being adopted to further the Departments' interest in ensuring that consumers are fully aware that they are purchasing fixed indemnity excepted benefits coverage rather than comprehensive coverage, are aware of their options to purchase comprehensive coverage, and have access to information resources that support informed consumer decision-making with regard to health coverage.

Further, the changes to the individual market consumer notice and the adoption of a notice in the group market are reflective and responsive to changes observed by the Departments in market conditions and the legal landscape. As discussed in section II.A of this preamble, market conditions have changed and increased the availability of affordable options for comprehensive coverage. As discussed in section II.D of this preamble, the legal landscape has also changed. The decision in *Central United Life Ins. Co.* v. *Burwell* and the passage of the Tax Cuts and Jobs Act increase the likelihood that individuals would purchase fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage. As a result of those changes, the Departments are of the view that notices will help combat deceptive marketing practices and potential sources of misinformation by clearly identifying fixed indemnity excepted benefits coverage and distinguishing such coverage from comprehensive coverage, directing consumers to appropriate resources to learn more about comprehensive coverage, and identifying key differences between that coverage and fixed indemnity excepted benefits coverage.

Many commenters stated that the proposals regarding notices in the 2023 proposed rules usurp States' authority. Several commenters pointed to the McCarran-Ferguson Act, stating that only Congress may infringe on the States' exercise of their authority to regulate insurance. Several commenters stated that Federal regulatory changes are not necessary because States and the NAIC have been working on the NAIC Models 40, 170, 171 and 880 that address these coverage options,[241] and when those are adopted by States, they will adequately address the Departments' concerns. Several commenters stated that amendments to the Federal regulations are not necessary because States have enforcement authority to discipline agents, discipline issuers, limit marketing practices, and limit product features if there are instances of fixed indemnity excepted benefits coverage being sold as a replacement for comprehensive coverage.

The Departments agree that the States play an important role in regulating fixed indemnity excepted benefits coverage and acknowledge the federalism implications of the proposed rules and these final rules.[242] As noted by commenters, the McCarran-Ferguson Act generally affirms the preeminence of State regulation, and also explicitly allows for Federal regulation when an act of Congress specifically relates to the business of insurance. As discussed in section III.A.1 of this preamble, the McCarran-Ferguson Act balances State and Federal interests in regulating the business of insurance. Section 1012(a) of the McCarran-Ferguson Act maintained State regulatory authority by enabling State preemption of some Federal law, and section 1012(b) of the McCarran-Ferguson Act limited Federal regulatory authority by generally exempting the ''business of insurance'' from Federal law. Although Congress allowed for State preemption of Federal law in this way, Congress also preserved Federal authority to regulate insurance provided that, to overcome the State preemption, congressional action must specifically relate to the business of insurance. As previously noted, HIPAA, the ACA, and the other Acts of Congress specifically relate to the business of insurance. Given that Congress defined and set forth criteria for fixed indemnity excepted benefits coverage to be exempt from the Federal consumer protections and requirements for comprehensive coverage,[243] there is clear congressional action specifically addressing the business of insurance, thereby preserving Federal regulatory authority to interpret and implement the Federal statutory provisions governing these insurance products.

In addition, as previously noted, Congress also provided the Secretaries of the Treasury, Labor, and HHS with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act.[244] This includes the authority for the Departments to interpret and implement the requirements for hospital indemnity or other fixed indemnity insurance to qualify as excepted benefits coverage under Federal law, and also provides the authority to adopt a consumer notice. The Code, ERISA, and the PHS Act impose certain requirements on comprehensive coverage and do not impose those same requirements on fixed indemnity excepted benefits coverage. The Departments believe it is necessary and appropriate that plans and issuers provide consumers considering the purchase (or renewal) of fixed indemnity excepted benefits coverage, and those actually purchasing such insurance, a notice that clearly identifies the insurance as fixed indemnity excepted benefits coverage and is sufficient to put consumers on notice that such coverage is not subject to the Federal consumer protections and requirements for comprehensive coverage. The notices also direct consumers to resources where they can learn about the range of available coverage options, and the notices are designed to help combat the misinformation and deceptive tactics that can lead to consumers mistakenly enrolling in fixed indemnity excepted benefits coverage in lieu of comprehensive coverage. This will help ensure that consumers who purchase

[241] NAIC model laws are available at: *https://content.naic.org/model-laws.*

[242] For further discussion of the Federalism implications of these final rules, see section V.H of this preamble.

[243] *See* sections 9831 and 9832 of the Code, sections 732 and 733 of ERISA, and sections 2722, 2763, and 2791 of the PHS Act.

[244] *See* section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

fixed indemnity excepted benefits coverage are doing so based on an informed decision and not in error.

The notice provisions being finalized in these final rules do not infringe on States' authority to regulate insurance. States retain authority to regulate fixed indemnity excepted benefits coverage. States may impose standards or requirements on hospital indemnity or other fixed indemnity insurance for purposes of State law, such as a requirement to provide a State-specific notice in relation to fixed indemnity excepted benefits coverage offered by issuers in their State, including any notice developed as part of an NAIC Model Act or Regulation. However, hospital indemnity or other fixed indemnity insurance that does not include the language in the revised notice under these final rules would not be considered fixed indemnity excepted benefits coverage for purposes of Federal law and thus would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage.

The Departments are of the view that these final rules appropriately balance States' interests in regulating health insurance issuers and their health insurance markets with Congress' intent to establish a general Federal framework for health insurance coverage, including the provision of certain key protections to consumers enrolled in comprehensive coverage and the creation of an exemption for insurance products that meet the requirements to be considered excepted benefits coverage. The Departments recognize that States have been working with the NAIC to revise several model acts and regulations related to marketing and sales practices and those models might address some of the Departments' concerns. However, those models establish minimum standards and States' adoption of any NAIC model is optional. States may choose to codify some or none of the standards set forth in the NAIC models, which have yet to be finalized. The Departments will engage with States and the NAIC as they revise several NAIC Model Acts and regulations to update the minimum standards for non-comprehensive coverage products, including fixed indemnity excepted benefits coverage. The Departments look forward to reviewing the information and data collected on such products from the NAIC data call that is currently underway.

A few commenters stated that the notice provisions in the individual and group markets raised First Amendment concerns, alleging that the Departments did not articulate a compelling governmental interest because the 2023 proposed rules failed to provide any substantial evidence that consumer confusion is widespread. Those commenters further asserted that the notice provisions for the group and individual markets are not narrowly tailored, and that requiring display on the first page of marketing and enrollment materials (in addition to application materials) is not justified.

The Departments disagree that the proposed notice provisions for fixed indemnity excepted benefits coverage raise First Amendment concerns. The rules do not require the provision of a notice, but instead simply provide that hospital indemnity or other fixed indemnity insurance offered without such a notice would not qualify as fixed indemnity excepted benefits coverage and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. Moreover, as the United States Supreme Court recognized in *Zauderer* v. *Office of Disciplinary Counsel,*[245] and later reiterated in *National Institute of Family and Life Advocates* v. *Becerra,*[246] required disclosures of factual, uncontroversial information in commercial speech are subject to more deferential First Amendment scrutiny. Under the approach articulated in *Zauderer,* courts have upheld required disclosures of factual information in the realm of commercial speech where the disclosure reasonably relates to a substantial government interest and is not unjustified or unduly burdensome such that it would chill protected speech. Regardless, the Departments believe that the revised notice standard would pass muster under any form of First Amendment scrutiny.[247]

The language on the Federal notices for fixed indemnity excepted benefits coverage includes factual, uncontroversial information, reasonably relates to a government interest, and is not unjustified or unduly burdensome. In addition, the Departments have reviewed and responded to public comments that raised concerns about proposed text. For example, certain language that appeared in the proposed rules that commenters deemed controversial, such as ''Warning,'' are not being finalized. HHS conducted consumer testing to ensure the language in the required notice was not misinterpreted to deliver any untrue messages.

The Departments have a substantial, and even compelling, government interest in ensuring consumers are aware of the type of product they are considering purchasing, are informed about key differences between fixed indemnity excepted benefits coverage and comprehensive coverage, are aware of their option to purchase comprehensive coverage, and have access to resources for additional information about the range of available health coverage options so consumers can make informed choices. As discussed in section II.B of this preamble, this is of particular importance at present due to the changing legal landscape and low health literacy, as well as the increased reports of deceptive marketing practices that play on consumer confusion about the benefits and limitations of fixed indemnity excepted benefits coverage. The notices clearly label products as fixed indemnity excepted benefits coverage and communicate factual information to consumers about the differences between fixed indemnity excepted benefits coverage and comprehensive coverage and explain how consumers can find resources when they have questions about the different coverage options. As stated in the preamble to the 2023 proposed rules, the Departments are concerned about consumers who mistakenly enroll in fixed indemnity excepted benefits coverage in lieu of comprehensive coverage and are therefore at risk of significant financial liability because their health care costs may greatly exceed the fixed cash benefit to which they may be entitled—if benefits are even provided for their health-related event.[248] Accordingly, the notices adopted in these final rules serve a legitimate government interest, are justified, and are reasonably related to these government interests.

Furthermore, these notices do not unduly burden plan or issuer speech because nothing in the final rules would ''drown out'' a plan's or issuer's own message or ''effectively rule out'' any mode of communication.[249] Plans and issuers remain free to communicate with consumers using methods and media they have always used or may choose to use in the future. The burden associated with displaying the applicable notice should be low since the Departments have adopted static language, meaning that the plan or issuer does not have to tailor or modify

[245] 471 U.S. 626 (1985).

[246] 585 U.S. 755 (2018).

[247] *See also Pharmaceutical Care Management Association* v. *Rowe,* 429 F.3d 294, 316 (1st Cir. 2005).

[248] 88 FR 44596 at 44606 (July 12, 2023).

[249] *See NIFLA,* 138 S. Ct. at 2378.

the Federal notice. For the reasons discussed previously, the Departments are of the view that informing consumers prior to purchase or reenrollment of fixed indemnity excepted benefits coverage and directing them to resources to learn more about the range of available coverage options is highly related to the government's aforementioned interest in ensuring that consumers make informed decisions.

The Departments are aware of some complex fixed indemnity policies in the individual market that pay benefits based on extensive variable schedules and other policies that promote a certain network of providers. Such plan designs mimic comprehensive coverage and can skew a consumer's understanding of the nature and extent of the fixed indemnity excepted benefits coverage. The Departments provided examples of consumer confusion regarding the limitations and exclusions associated with fixed indemnity excepted benefits coverage in the preamble to the 2023 proposed rules [250] and received additional examples from commenters. Some commenters provided examples of benefit designs that are modeled after comprehensive coverage and may cause confusion, including products requiring that enrollees meet a deductible before benefits are paid, making payments directly to providers, or using provider networks that purport to give the member a reduced or discounted medical bill for using an in-network provider. The preamble to the 2023 proposed rules also described certain arrangements in the group market that the Departments are concerned can mislead enrollees into believing they have comprehensive coverage when that is not the case.

Both the draft notice that was proposed for the group and individual markets in the 2023 proposed rules and the version being finalized in these rules are reasonably related and narrowly tailored to the government's interest in informing consumers about the limitations of fixed indemnity excepted benefits coverage, and combating deceptive marketing practices and potential sources of misinformation, by directing consumers to appropriate resources to learn more about the range of available health coverage options.[251] The notices do not include irrelevant or superfluous information unrelated to these interests.

As the Departments explained in the preamble to the 2023 proposed rules, requiring plans and issuers to display a notice on the first page of marketing, application, and enrollment materials in both markets plus on the first page of the policy, certificate, or contract of insurance in the individual market is justified to ensure that the notice is provided on documents that consumers are most likely to have the opportunity to review before application, enrollment, or reenrollment. In the Departments' view, requiring the notice only on the first page of the application is insufficient, as evidenced by ongoing consumer confusion.

The Departments proposed to require that plans and issuers prominently display the notice (in either paper or electronic form, including on a website) in at least 14-point font on the first page of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the group market fixed indemnity excepted benefit coverage. In addition, if participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of group market fixed indemnity excepted benefits coverage, the Departments proposed that the notice must be displayed in all reenrollment materials that are provided to participants at or before the time participants are given the opportunity to reenroll in coverage. The Departments explained that they consider marketing materials to include any documents or website pages that advertise the benefits or offer an opportunity to enroll (or reenroll) in group market fixed indemnity excepted benefits coverage. The Departments are finalizing the proposed requirements related to the placement of the group market consumer notice as proposed.

HHS proposed slightly different placement standards for the individual market consumer notice. The requirements reflect the differences between the types of documents that consumers typically receive when considering enrolling or reenrolling in fixed indemnity excepted benefits coverage in the individual market compared to participants in the group market. With respect to individual market fixed indemnity excepted benefits coverage, HHS proposed that issuers must also prominently display the notice (in either paper or electronic form) in at least 14-point font on the first page of the policy, certificate, or contract of insurance, including renewals or extensions, because individual market consumers are likely to receive those documents upon enrollment. This is in addition to prominently displaying the notice on the first page (in either paper or electronic form) of any marketing, application, and enrollment (or reenrollment) materials for individual market fixed indemnity excepted benefit coverage, and prominently displaying the notice on websites that advertise or offer an opportunity to enroll (or reenroll) in such coverage. HHS proposed the additional locations for display, rather than just application materials as required in the 2014 final rule, due to concern of ongoing consumer confusion. These proposals related to notice placement were intended to ensure that the notice is provided on documents that consumers are most likely to have the opportunity to review before application, enrollment, or reenrollment, based on the Departments' understanding of how consumers receive information related to group market versus individual market fixed indemnity excepted benefits coverage. HHS is finalizing the proposed requirements related to placement of the individual market consumer notice as proposed.

Many commenters supported the proposed placement of the notices in marketing, application, and enrollment and reenrollment materials, including websites and materials shared electronically. Some commenters also generally stated that the notices should be provided early and often so that consumers are not confronted with notice or warning language only after selecting a plan for purchase.

Some commenters expressed opposition to including the applicable notice with all marketing, application, and enrollment materials, suggesting such requirements are excessive and may reduce the impact of the notice. These commenters recommended the notice be provided in only the enrollment materials or using the existing individual market standard, which requires placement in the application materials only.

The Departments are finalizing the proposed standards regarding the placement and applicable materials on which the group market notice must appear without modification. HHS is similarly finalizing the proposed standards regarding the placement and applicable materials on which the revised individual market notice must appear without modification. The Departments disagree with the commenters who stated that including the notice on all of these materials is

[250] 88 FR 44596 at 44621–22 (July 12, 2023).

[251] 88 FR 44625 ''[T]he Departments aim to reduce the potential for consumers to mistakenly enroll in hospital indemnity or other fixed indemnity insurance as their primary source of coverage and increase consumer understanding of the differences between fixed indemnity excepted benefits coverage and comprehensive coverage.''

excessive and may reduce the impact of the notice itself. Including the notice on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment (or reenrollment) materials (as well as, in the individual market, the policy, certificate, or contract of insurance) is intended to ensure that the notice is provided on documents that consumers are most likely to have the opportunity to review before application, enrollment or reenrollment. To achieve this, as some commenters pointed out, it is important that the notice be available both early in the enrollment (or reenrollment) process and often. Therefore, it is the Departments' view that requiring the notice in several locations—rather than just the enrollment materials or only in the application—is not excessive due to the goal of maximizing consumers' opportunity to review the notice throughout their decision-making process, which is likely to increase the impact of the notice. The repetition will also help mitigate the potential for consumers to mistakenly enroll in fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage and will help combat deceptive marketing practices and potential sources of misinformation by directing consumers to appropriate resources to learn more about the range of available health coverage options.

The Departments recognize that providing notices imposes costs on plans and issuers and identified other scenarios where the benefits to consumers would be minimal and do not justify the administrative burden on plans and issuers to provide the notice. Specifically, these final rules do not require plans and issuers to provide the notice to beneficiaries, as well as participants, in the group market. In the Departments' view, requiring plans and issuers offering fixed indemnity excepted benefits coverage in the group market to provide notice to participants (rather than to both participants and any beneficiaries) appropriately balances the need to ensure that participants who are considering whether to enroll themselves and their beneficiaries in such coverage are sufficiently informed of their health coverage options with the administrative burden on plans and issuers to provide the notice.

In addition, because the group policy, certificate, or contract of insurance in the group market is often provided to the plan sponsor or the group health plan administrator, these final rules do not require that plans and issuers include the consumer notice in those documents for group market fixed indemnity excepted benefits coverage because doing so would not support the goal of ensuring that the consumers themselves receive the information so they can make an informed decision before enrolling (or reenrolling) in coverage. Similarly, in the individual market, HHS did not propose and is not finalizing a requirement for the notice to be provided to dependents of the individual enrolling in coverage. Instead, the individual market notice must be provided only to the policyholder.

The Departments proposed and are finalizing that the group market notice must be prominently displayed in at least 14-point font on the first page of any applicable marketing, application or enrollment materials.[252] Consistent with the approach outlined in the 2023 proposed rules, under these final rules, the Departments consider a notice to be prominently displayed if it is easily noticeable to a typical consumer within the context of the page (either paper or electronic) on which it is displayed (for example, using a font color that contrasts with the background of the document; ensuring the notice is not obscured by any other written or graphic content on the page; and, when displayed on a website, ensuring the notice is visible without requiring the viewer to click on a link to view the notice). HHS proposed, and is finalizing, the same prominent display requirements for the individual market notices that must appear on the first page of any applicable materials.[253]

Some commenters supported the proposal that the notices be prominently displayed on the first page of applicable materials in at least 14-point font. Another commenter suggested that instead of the 14-point font standard, the Departments should require that the notices are ''easily noticeable to a typical consumer within the context of the page.'' One commenter recommended that when fixed indemnity excepted benefits coverage is sold as part of a bundled package, the applicable notice should be displayed on the front page of the bundled package, not just on the first page of fixed indemnity material, to help consumers see the notice instead of having it be embedded among many pages of material. One commenter stated that State regulators will often require pre-approval of any materials if the issuer adds any language to a previously approved insurance document, and that commenter requested that issuers have the flexibility to provide the required consumer notice on a separate document rather than the first page of the marketing, application, or enrollment (or reenrollment) materials.

The Departments agree with commenters who supported the prominent display of the notice on the first page of applicable materials in at least 14-point font. The Departments are of the view that this will help ensure that the notice is displayed in a location and font size that consumers are likely to see and will do so more effectively than a less subjective standard like an ''easily noticeable'' standard. The individual market regulations have required the prominent display of the notice in at least 14-point font and the Departments maintain that standard for simplicity and consistency.

The Departments appreciate the suggestion that when fixed indemnity excepted benefits coverage is sold as part of a bundled package, the notice should be displayed on the front page of the bundled package, not just on the first page of fixed indemnity material, to help consumers see the notice instead of having it be embedded among many pages of material. However, in some cases, placing the notice on the front of such a bundle may lead to increased consumer confusion if, for example, the consumer is unclear as to which insurance sold as part of the bundle is described in the notice. Therefore, the Departments decline to adopt a standard that requires the notice be displayed on the front page of a bundled package.

Likewise, the Departments decline to specify the manner in which materials must be presented to States for review and approval including approval of new language in a previously approved document. Issuers should work with States to determine which pages that include the notice must be submitted to the State for review and approval, the manner of submission, and how to verify that the submission is the first page of the material.

[252] As previously discussed in this section III.B.1 of this preamble, the Departments are finalizing the proposed requirements regarding the placement and materials on which the group market notice must appear without modification. As such, the group market notice must be prominently displayed on all marketing, application, and enrollment (or reenrollment) materials. The notice must also be prominently displayed on websites that advertise or offer an opportunity to enroll (or reenroll) in group market fixed indemnity excepted benefits coverage.

[253] As previously discussed in this section III.B.1 of this preamble, HHS is finalizing the proposed requirements regarding the placement and materials on which the individual market notice must appear without modification. As such, the revised individual market notice must be prominently displayed on the first page of the policy, certificate, or contract of insurance, as well as on all marketing, application, and enrollment (or reenrollment) materials. The notice must also be prominently displayed on websites that advertise or offer an opportunity to enroll (or reenroll) in individual market fixed indemnity excepted benefits coverage.

The Departments are finalizing the proposal that the group market notice must be prominently displayed in at least 14-point font on the first page of the applicable materials, and HHS is finalizing the parallel proposal for prominent display of the individual market notice on the first page of the applicable materials.

The existing notice requirement, which currently applies only in the individual market, requires that the following language be provided in application materials in at least 14-point type:

THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES.

To align the notice with the changes made by the Tax Cuts and Jobs Act to section 5000A of the Code (reducing the individual shared responsibility payment to $0), and to clarify the message to consumers, the 2023 proposed rule proposed revisions to the individual market notice and solicited comments on two options for the notice. As previously discussed, the Departments also proposed to adopt a new notice provision for the group market and solicited comments on the same two options for the group market notice.

The first option (Format A) was as follows:

BILLING CODE 4830–01–P

Notice to Consumers About Fixed Indemnity Insurance

IMPORTANT: This is fixed indemnity insurance. **This isn't comprehensive health insurance** and **doesn't** have to include most Federal consumer protections for health insurance.

Visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325) to review your options for comprehensive health insurance. If you're eligible for coverage through your employer or a family member's employer, contact the employer for more information. Contact your State department of insurance if you have questions or complaints about this policy.

The second option (Format B) was as follows:

WARNING

This is not comprehensive health insurance. This is fixed indemnity insurance.

This may provide a cash benefit when you are sick or hospitalized. It is not intended to cover the cost of your care.

Contact your State department of insurance if you have questions or complaints about this policy.

For info on comprehensive health insurance coverage options:

- Visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325)
- Contact your employer or family member's employer

BILLING CODE 4830–01–C

One commenter stated that the general promise of a cash benefit on Format B could be read too broadly by a consumer with low health insurance literacy. Another commenter suggested that the phrase ''Important Notice—Please Read Carefully'' should appear at the top of the notice because that phrase would better catch the attention of consumers and inform them that this is important information that they should consider prior to making a decision. Another commenter suggested the notice should include the words ''by law'' before the phrase ''does not have to include'' most Federal consumer protections on Format A to make it clear that this coverage, by law, is not subject to the ACA or other Federal health coverage mandates. Several commenters indicated that information on the notice should be provided in a bulleted format to ensure that all factors are clearly listed. Some commenters recommended adopting Format B for greater accessibility and stated that version is written more concisely and in plain language. One commenter suggested Format B provides clarity to the reader about the nature of the insurance product by using the term ''WARNING'' instead of ''IMPORTANT.''

Other commenters opposed the use of Format B, stating that this option was misleading, confusing, and inaccurate. Several commenters suggested that the use of the term ''WARNING'' inappropriately implies that the coverage is inherently dangerous, noting that in other Federal labeling requirements, the use of the term ''WARNING'' is limited to extreme situations where the product itself is inherently unsafe. These commenters stated that hospital indemnity or other fixed indemnity insurance is not inherently hazardous or harmful, and the term ''IMPORTANT'' would be more appropriate and accurate. Some commenters stated that Format B included language regarding covering the cost of care, which is not entirely accurate, and that the language suggests the policy is subject to, but avoiding, Federal coverage mandates. Those commenters stated that Format B may therefore exacerbate consumer confusion.

In response to the comments on the proposed content for the notices and the different formats outlined in the 2023 proposed rules, HHS performed consumer testing to evaluate commenters' suggestions and better understand how the different formats for the notice could be interpreted by consumers. This consumer testing found that some consumers were unclear on the meaning of the phrase ''cash benefit'' within the context of the notice in Format B. Consumers also reported they were confused by the phrase ''it is not intended to cover the cost of your care'' in Format B of the proposed notice; some consumers noted that phrase only referred to their out-of-pocket costs that may be associated with the policy, such as a deductible or copay. The consumer testing also revealed that consumers prefer ''IMPORTANT'' and viewed ''WARNING'' as too strong. They stated that ''IMPORTANT'' was sufficient to draw their attention to the notice, and that adding the words ''by law'' before the phrase regarding Federal consumer protections was superfluous and not necessary.

In response to comments stating that Format B was written more concisely and in plain language, as well as the results of the consumer testing and feedback from plain language experts, the Departments are finalizing a modified version of Format B. The modified version provides information using a bulleted format to ensure all information is clearly listed, as commenters recommended.

The Departments modified Format B to address comments that claimed that format was misleading, confusing, and inaccurate. The finalized notice does not include the phrase ''cash benefit'' or ''by law'' or the word ''Warning.'' HHS is similarly not including these same phrases in the individual market notice that is finalized in these final rules. The Departments also decline to add ''Important Notice—Please Read Carefully'' because consumer testing revealed that including the word ''IMPORTANT'' in all uppercase was sufficient to identify the applicable notice as a document that should be read. The Departments have revised the group market notice language to include ''You're still responsible for paying the cost of your care'' because consumers who were tested understood that terminology better than the proposed phrase ''It is not intended to cover the cost of your care'' included in Format B of the proposed notice. In addition to that phrase, the Departments are also adding the statement ''The payment you get isn't based on the size of your medical bill'' to highlight that the fixed indemnity excepted benefit is a fixed payment amount and not related to the billed amount. For the same reason, the Departments have also revised the group market notice language to state ''Since this policy isn't health insurance, it doesn't have to include most [F]ederal consumer protections that apply to health insurance,'' rather than the proposed statement in Format B of the proposed notice that the policy ''doesn't have to include most Federal consumer protections for health insurance.'' The revised phrasing avoids suggesting that the policy is subject to, but avoiding, the Federal consumer protections and requirements applicable to comprehensive coverage. HHS is adopting the same revisions to the language in the revised individual market consumer notice.

The Departments welcomed comments on any benefits or burdens that would be associated with including information to direct consumers to State-specific resources as part of the notice, including identifying the applicable State Exchange if the fixed indemnity excepted benefits coverage is filed in a State that does not use HealthCare.gov. The Departments also welcomed comments on any burdens that would be created by providing State-specific contact information for the State agency responsible for regulating fixed indemnity excepted benefits coverage in the State where the coverage is filed, rather than a generic reference to the consumer's State department of insurance, as proposed in both Format A and Format B. For products that are filed in multiple States, the Departments solicited comments on whether the notice should include the name and phone number for the State department of insurance of the State in which the individual to whom the fixed indemnity excepted benefits coverage is sold or marketed resides, unless the product is not filed in that State. Under this approach, if the product is not filed in the State in which the individual to whom the fixed indemnity excepted benefits coverage is sold or marketed resides, the notice would need to include the name and phone number for the department of insurance of the State in which the fixed indemnity excepted benefits coverage policy is filed.

Several commenters supported including State-specific details in the notice, including contact information for the State's Exchange and department of insurance. One commenter strongly supported including State-specific contact information in the notice, to ensure that consumers have access to the resources they need to understand their hospital indemnity and other fixed indemnity insurance policy.

Other commenters opposed customization of the notice to include State-specific resources, stating customization would increase administrative burden and cost and potentially create consumer confusion. One commenter noted that some

companies that make fixed indemnity excepted benefits products available in multiple States often use universally applicable brochures for those products, and those issuers would be required to stop longstanding, efficient marketing and enrollment processes with little benefit to consumers, who can easily obtain State-specific contact information elsewhere.

One commenter did not support the inclusion of contact information for each State department of insurance but recommended that the Departments consider directing consumers to the NAIC's online directory, available at *naic.org*. The Departments did not receive comments regarding which State agency's contact information should be included for products that are filed in multiple States.

In developing the notice language, the Departments sought to balance the goals of distinguishing fixed indemnity excepted benefits coverage from comprehensive coverage, combatting deceptive marketing practices, and reducing misinformation by directing consumers to appropriate resources to learn about the range of available coverage options, with the need to provide a concise, understandable notice that would be meaningful and useful to consumers. The Departments understand commenters' concerns regarding the burden associated with customizing notices to include State-specific information. However, the Departments also recognize the value of including State-specific information, such as appropriate contact information if the consumer has questions or wants more information about available coverage options.

After consideration of comments and the results of consumer testing, the Departments are finalizing changes to the notice to incorporate uniform language as part of the required content for the Federal notices that directs individuals to an NAIC web page where they can find the contact information for the applicable State regulatory agency. As discussed in section III.A.4 of this preamble, the inclusion of the NAIC link in the notice does not constitute an endorsement by the Departments. Since the Departments are not requiring State-specific contact information on the Federal notice, the Departments decline to specify a certain agency's contact information that should be included for products that are filed in multiple States.

The Departments are also incorporating static language as part of the content for the group market notice in these final rules that direct individuals to HealthCare.gov, where individuals can navigate to their State's Exchange, whether a Federally-facilitated Exchange, State Exchange on the Federal platform or a State Exchange. HHS is adopting similar static language for the individual market notice. This approach is intended to balance the desire to ensure individuals can access State-specific information with not increasing the burden on plans and issuers associated with the development of customized notices that provide State-specific information.

The Departments also solicited comments on whether it would be beneficial to consumers to require plans and issuers to include language on the notice that clearly informs consumers that the notice is an officially required document, such as ''This notice is required by Federal law.'' The Departments did not receive comments regarding inclusion of that phrase on the required notice for fixed indemnity excepted benefits coverage but performed consumer testing on notices that included the phrase. Consumer testing revealed that some consumers stated that including that phrase at the bottom of the notice was helpful and that it made the information on the notice seem more legitimate, while other consumers stated the phrase meant the fixed indemnity excepted benefits policy itself was endorsed by the Federal Government. Given the potential for consumer confusion, the Departments are not including a statement that the notice is required by Federal law.

In response to comments and after consideration of the results from the consumer testing, to enhance readability, the Departments made several changes to incorporate a combination of the language from both Format A and Format B in the 2023 proposed rules and are finalizing the following content for the group market notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (**naic.org**) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

HHS is finalizing the same content for the revised individual market notice for fixed indemnity excepted benefits coverage.

Some commenters recommended requiring that the formatting of the notice be accessible to people with a range of disabilities and that it be made available in the most commonly spoken languages in each State. The Departments agree that it is important that the notices are accessible and understandable to individuals with disabilities, as well as to individuals with limited English proficiency. The Departments are mindful of the challenges faced by individuals with physical, sensory, or cognitive disabilities, including but not limited to individuals who use screen readers and other assistive technology.

While the Departments did not propose and are not finalizing accessibility or language access standards specific to these notices as part of this rulemaking, the Departments remind plans and issuers that they are required to comply with other State and Federal laws establishing accessibility and language access standards to the extent applicable. For example, recipients of Federal financial assistance must comply with Federal civil rights laws that prohibit discrimination. These laws may include section 1557 of the Affordable Care Act,[254] title VI of the Civil Rights Act of 1964,[255] section 504 of the Rehabilitation Act of 1973,[256] and the Americans with Disabilities Act of 1990.[257] Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as written translation of written content, in paper or electronic form into languages other than English.

[254] 42 U.S.C. 18116.
[255] 42 U.S.C. 2000d *et seq.*
[256] 29 U.S.C. 794.
[257] 42 U.S.C. 12101 *et seq.*

Sections 1557 and 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Additionally, section 508 of the Rehabilitation Act of 1973 requires that information provided through information and communication technology also must be accessible to individuals with disabilities unless certain exceptions apply.

2. Technical Amendment

HHS proposed a technical amendment to the individual market excepted benefits rules to remove the existing requirement at 45 CFR 148.220(b)(4)(i) that fixed indemnity excepted benefits coverage must be provided only to individuals who attest, in their fixed indemnity insurance application, that they have other health coverage that is MEC, or that they are treated as having MEC due to their status as a bona fide resident of any possession of the United States pursuant to section 5000A(f)(4)(B) of the Code. This proposal would strike from the regulatory text the provision that was vacated in *Central United Life Ins. Co.* v. *Burwell*.[258] HHS did not receive any comments regarding this proposed technical amendment and is finalizing as proposed. HHS is also finalizing the proposed conforming amendments to 45 CFR 148.220 to redesignate paragraphs (b)(4)(ii) through (iv) as paragraphs (b)(4)(i) through (iii).[259]

3. Applicability Dates

The Departments proposed that the new group market notice provisions would apply to both new and existing group market fixed indemnity excepted benefits coverage for plan years beginning on or after the effective date of the final rules. HHS proposed a similar applicability date for the revised individual market fixed indemnity excepted benefits coverage notice. After consideration of comments, the Departments are finalizing delayed applicability dates for the notices, such that plans and issuers will be required to comply with the notice provisions finalized in these rules for plan years (in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025. To streamline the regulatory text, the Departments are finalizing the applicability date for the notice provision for fixed indemnity excepted benefits coverage in the group market at 26 CFR 54.9831–1(c)(4)(ii)(D), 29 CFR 2590.732(c)(4)(ii)(D), and 45 CFR 146.145(b)(4)(ii)(D) rather than at 26 CFR 54.9831–1(c)(4)(iv), 29 CFR 2590.732(c)(4)(iv), and 146.145(b)(4)(iv), as proposed. HHS is finalizing the applicability date for the notice provisions for fixed indemnity excepted benefit coverage in the individual market at 45 CFR 148.220(b)(4)(iii),[260] rather than at 148.220(b)(4)(iv).

Several commenters supported issuing updated notices to existing policyholders by applying the notice provisions finalized in these rules to coverage periods (including renewals) beginning on or after January 1, 2025. Other commenters stated the notice provisions should not apply before January 1, 2027, for all individual and group coverage, regardless of when the coverage is issued or sold. Some commenters urged the Departments to apply the notice provisions only to new coverage sold after the effective date of the final rules, alleging that the application to existing coverage would be impermissibly retroactive. Those commenters stated that applying the notice to existing policies would inappropriately interfere with a covered individual's current contract and their choice to continue the policy. Some commenters asserted that imposing the notice provision on existing policies would be confusing and impractical. Another commenter recommended the applicability date for the notice provision for new coverage should be at least 24 months after publication of the final rules, to allow issuers time to update and refile products and marketing materials to reflect the necessary changes and provide State regulators with the time necessary to review and approve products and updated marketing materials. The commenters stated that it would be extremely difficult or impossible for issuers of group market coverage to make the required changes for notices to all marketing and enrollment materials for hospital indemnity and other fixed indemnity products before the effective date of these final rules. One commenter stated that it would be impossible for issuers of individual market coverage to comply with the proposed applicability dates because of the length of time necessary to obtain State-level approval for revised individual insurance contracts.

The Departments decline to extend the applicability date to January 1, 2027, as suggested by some commenters. In the Departments' view the benefits of providing the notice to consumers at an earlier time outweighs the burden on plans and issuers to incorporate the notice by the delayed applicability date for plan years (in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025. To minimize the burden, the Departments are finalizing notices that cannot be modified or customized; therefore, plans and issuers will not have to spend time or resources to develop their own notices to comply with the Federal notice standard. Plans and issuers may need to modify their website or other marketing materials to comply with the Federal notice standard and may need to submit materials for State review, but the Departments do not agree with commenters that those modifications require 24 months or more.

The Departments also disagree with commenters who stated that applying the notice to existing policies would inappropriately interfere with a covered individual's current contract. The notice does not change the terms of the contract to which the issuer and policyholder agreed. The notice will be provided to a currently covered individual at the time of renewal; therefore, there is no interference with a current contract, and the notice does not prevent an individual from renewing or reenrolling in fixed indemnity excepted benefits coverage. The Departments therefore disagree that the application of the notice provisions to existing enrollees at the time of renewal or reenrollment is impermissibly retroactive because it applies to future coverage periods and does not take away or impair vested rights or create new obligations or duties with respect to past transactions. The Departments also disagree that applying the notice provisions to existing policies would be confusing and impractical. The Departments are of the view that consumers should have information about the range of available

[258] 827 F.3d 70 (D.C. Cir. 2016).

[259] These provisions are being redesignated without any changes to the regulatory text.

[260] Under 45 CFR 148.220(b)(4)(iii)(B) of these final rules, the notice in § 148.220(b)(4)(iv) contained in 45 CFR part 148, revised as of October 1, 2023, continues to apply to individual market fixed indemnity excepted benefits coverage for coverage periods beginning before January 1, 2025. However, HHS will not consider insurance to fail to be fixed indemnity excepted benefits coverage in the individual market under the Federal framework if an issuer adopts the revised notice in these final rules for coverage periods beginning before January 1, 2025. HHS encourages States to adopt a similar approach if their issuers elect to adopt the revised notice for coverage periods that begin before January 1, 2025.

coverage options and have an opportunity to reconsider their coverage options. The notice standard under these final rules allows consumer to make an informed decision whether to maintain their existing fixed indemnity excepted benefits coverage and whether to also pursue or maintain comprehensive coverage.

The Departments are not persuaded by comments suggesting it would be extremely difficult or impossible for plans and issuers to make changes to incorporate the applicable notice in all applicable materials for hospital indemnity and other fixed indemnity products before the proposed applicability date, which was the effective date of these final rules. Nevertheless, after consideration of the comments requesting additional time to modify marketing materials and plan documents, the Departments are finalizing an applicability date for the notices adopted under these final rules to apply in the group and individual markets of plan years (in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025.[261]

The Departments proposed that the severability provisions described in section IV of this preamble would apply to both new and existing group market fixed indemnity excepted benefits coverage beginning on the effective date of these final rules. HHS proposed that the technical amendment described in section III.B.2 of this preamble and the severability provisions described in section IV of this preamble would apply to both new and existing individual market fixed indemnity excepted benefits coverage on the effective date of these final rules. HHS is only finalizing the technical amendment to remove the language in existing 45 CFR 148.220(b)(4)(i) and make conforming amendments to redesignate paragraphs (b)(4)(ii) through (iv) as paragraphs (b)(4)(i) through (iii).

HHS did not receive comments related to the applicability date for the technical amendments it is finalizing in these final rules or severability provision in the individual market regulations and is finalizing them as proposed. The Departments are also finalizing as proposed the applicability date for the group market severability provisions.

IV. Severability

The Departments are finalizing amendments to the Federal definition of ''short-term, limited-duration insurance'' and certain regulatory provisions regarding the requirements for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the group or individual market, for the purpose of distinguishing STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage. The Departments' authority to finalize and adopt these amendments is well-established in law and practice and should be upheld in any legal challenge. However, in the event that any portion of these final rules is declared invalid, the Departments intend that the other provisions, which could still function sensibly, would be severable.

Specifically, if any provision finalized in these final rules related to STLDI is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be considered severable from its section and other sections of these rules; and it shall not affect the remainder thereof or the application of the provision to other entities not similarly situated or to dissimilar conditions. Thus, if a court were to find the portion of the STLDI definition that limits stacking, the portion of the STLDI definition that establishes a Federal consumer notice, or any other aspect of the revised Federal STLDI definition to be unlawful, the Departments intend the remaining aspects of these final rules related to STLDI to stand.

Similarly, if any finalized provision in this rulemaking related to group or individual market fixed indemnity excepted benefits coverage is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be considered severable from its section and other sections of these rules; and such invalidation shall not affect the remainder thereof or the application of the provision to other entities not similarly situated or to dissimilar conditions.

The Departments also intend for the STLDI amendments in this rulemaking to be severable from the fixed indemnity excepted benefits coverage amendments, and vice versa.

The Departments did not receive any comments on the proposed group market severability provisions and are finalizing the proposed severability provisions as proposed. HHS also did not receive any comments on the proposed individual market severability provision and is finalizing that provision as proposed.

V. Regulatory Impact Analysis

A. Summary—Departments of Health and Human Services and Labor

These final rules revise the Federal definition of STLDI for new policies, certificates, or contracts of insurance sold or issued on or after September 1, 2024, to provide that the coverage must have an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date. These final rules also revise the Federal definition of STLDI so that the maximum total coverage duration, taking into account any renewals or extensions, is no longer than 4 months. For purposes of this definition, a renewal or extension includes the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance.

For new STLDI—meaning policies, certificates, or contracts of STLDI sold or issued on or after September 1, 2024—the amendments to the definition of STLDI addressing maximum term and duration in these final rules apply for coverage periods beginning on or after September 1, 2024. Under these final rules, existing STLDI—meaning policies, certificates, or contracts of STLDI sold or issued before September 1, 2024 (including any subsequent renewals or extensions consistent with applicable law)—may continue to have an initial contract term of less than 12 months and a maximum duration of up to 36 months (taking into account any renewals or extensions), subject to any limits under applicable State law.

These final rules further revise the Federal definition of STLDI to provide that a revised notice must be prominently displayed (in either paper or electronic form) in at least 14-point font on the first page of the policy, certificate, or contract of insurance and in any marketing, application, and enrollment materials, including for renewals or extensions (including on websites that advertise or enroll

[261] HHS reminds issuers that the existing individual market notice for fixed indemnity excepted benefits coverage, codified in 45 CFR 148.220(b)(4)(iv), revised as of October 1, 2023, continues to apply for coverage periods beginning before January 1, 2025. However, HHS will not consider insurance to fail to be fixed indemnity excepted benefits coverage in the individual market under the Federal framework if an issuer adopts the revised notice in these final rules for coverage periods beginning before January 1, 2025. HHS encourages States to adopt a similar approach if their issuers elect to adopt the revised notice for coverage periods that begin before January 1, 2025.

individuals in STLDI). These notice provisions apply for both new and existing STLDI for coverage periods beginning on or after September 1, 2024.

Additionally, these final rules amend the regulations regarding fixed indemnity excepted benefits coverage in the individual market to provide that a revised notice must be prominently displayed (in either paper or electronic form) on the first page of the policy, certificate, or contract of insurance, and any marketing, application, and enrollment (or reenrollment) materials that are provided at or before the time an individual has the opportunity to apply, enroll, or reenroll in coverage. These final rules also amend the regulations regarding fixed indemnity excepted benefits coverage in the group market to provide that a notice must be prominently displayed (in either paper or electronic form) on the first page of any marketing, application, and enrollment (or reenrollment) materials that are provided to participants at or before the time participants are given the opportunity to enroll (or reenroll) in the coverage. These notice provisions for group and individual market fixed indemnity excepted benefits coverage are applicable to both new and existing coverage with respect to plan years (in the individual market, coverage periods) beginning on or after January 1, 2025.

The Departments are finalizing the proposed severability provisions and HHS is also finalizing technical and conforming amendments to the individual market regulation regarding fixed indemnity excepted benefits coverage, which are not expected to have a material impact.

The Departments have examined the effects of these final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993),[262] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011),[263] Executive Order 14094 (April 6, 2023),[264] the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999),[265] and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866, 13563, and 14094—Departments of Health and Human Services and Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) for changes in gross domestic product), or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866, as specifically authorized in a timely manner by the Administrator of OIRA in each case.[266]

A regulatory impact analysis (RIA) must be prepared for significant rules. Based on the Departments' estimates, OMB's OIRA has determined this rulemaking is significant under section 3(f)(1) as measured by the $200 million threshold in any 1 year. Therefore, OMB has reviewed these rules, and the Departments have provided the following assessment of their impact. With respect to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act, OMB's OIRA has also determined that these rules fall within the definition provided by 5 U.S.C. 804(2).

1. Need for Regulatory Action

The 2018 final rules permit enrollment in an STLDI policy with a total duration that could extend up to 36 months (including renewals or extensions). This insurance might therefore be viewed as (and, in some cases, has been deceptively marketed as) a substitute for comprehensive coverage, rather than as a way to bridge a temporary gap in comprehensive coverage.[267] Evidence shows that the number of consumers buying STLDI increased following the effective date of the 2018 final rules. Data from the NAIC indicate that the number of individuals covered by STLDI in the individual market more than doubled between 2018 and 2019, from approximately 87,000 to 188,000, and further increased to approximately 238,000 in 2020, before declining to approximately 173,000 in 2021 following the expansion of PTC subsidies provided through the ARP.[268] The number of individuals covered by STLDI sold to individuals (not enrolled as members of an association) rose once again in 2022, however, to approximately 236,000.[269] While these figures do not capture the total number of individuals covered by STLDI throughout each year (rather, only at the end of the calendar year), and do not include individuals covered by STLDI sold to or through associations, they do show the trend of increased enrollment in STLDI following the implementation of the 2018 final rules. Projections by the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) suggest that 1.5 million people could

[262] Executive Order 12866 of September 30, 1993, 58 FR 51735 (October 4, 1993).

[263] Executive Order 13563 of January 18, 2011, 76 FR 3821 (January 21, 2011).

[264] Executive Order 14094 of April 6, 2023, 88 FR 21879 (April 11, 2023).

[265] Executive Order 13132 of August 4, 1999, 64 FR 43255 (August 10, 1999).

[266] Executive Order 14094 of April 6, 2023, 88 FR 21879 at 21879 (April 11, 2023).

[267] For one example of deceptive marketing practices, *see* Federal Trade Commission (2022). ''FTC Action Against Benefytt Results in $100 Million in Refunds for Consumers Tricked into Sham Health Plans and Charged Exorbitant Junk Fees,'' available at: *https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-action-against-benefytt-results-100-million-refunds-consumers-tricked-sham-health-plans-charged.*

[268] National Association of Insurance Commissioners (2022). Accident and Health Policy Experience Reports for 2018–2021, available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/SimpleSearch.*

[269] National Association of Insurance Commissioners (2023). ''2022 Accident and Health Policy Experience Report,'' available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

currently be enrolled in STLDI,[270] and CMS previously estimated that 1.9 million individuals would enroll in STLDI by 2023.[271] However, as noted in section V.B.2.b of this preamble, these projections were developed prior to the expansion of PTC subsidies provided through the ARP and the IRA.

Given that STLDI generally is not subject to the Federal consumer protections and requirements for comprehensive coverage applicable to individual health insurance coverage, STLDI policies tend to offer limited benefit coverage and have relatively low actuarial values.[272] These plans therefore expose enrollees to the risk of high out-of-pocket health expenses and medical debt.[273]

In recent years, fixed indemnity insurance is increasingly being designed to resemble comprehensive coverage, and consumers might therefore mistakenly view it as a substitute for comprehensive coverage rather than as an insurance policy that provides independent, noncoordinated income replacement benefits that is distinct from comprehensive coverage.[274]

In addition, because STLDI and fixed indemnity insurance are sold outside of the Exchanges and are generally not subject to the Federal consumer protections and requirements for comprehensive coverage, consumers may have limited information about the limitations, value, and quality of the coverage being sold.[275] Recent evidence of consumer confusion and improper marketing regarding STLDI [276] and fixed indemnity insurance [277] support the need to improve consumer understanding of these types of insurance (and their coverage limitations) compared to comprehensive coverage. The provisions finalized in these final rules will help ensure that consumers can better understand and properly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage, and access resources to learn more about their health coverage options.

These final rules will encourage enrollment in comprehensive coverage and lower the risk that STLDI and fixed indemnity excepted benefits coverage are viewed or marketed as a substitute for comprehensive coverage.[278]

2. Summary of Impacts

The expected benefits, costs, and transfers associated with these final rules are summarized in Table 1 and discussed in detail later in this section V.B.2 of this preamble.

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[270] Congressional Budget Office (2020). ''CBO's Estimates of Enrollment in Short-Term, Limited-Duration Insurance,'' available at: *https://www.cbo.gov/publication/56622.* CBO and JCT projected that enrollment in STLDI would reach 1.6 million by 2028. *See* Congressional Budget Office (2019). ''How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans,'' available at: *https://www.cbo.gov/publication/54915.*

[271] CMS Office of the Actuary (2018). ''Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule,'' available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf.*

[272] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[273] *See, for example,* Deam, Jenny (2021). ''He Bought Health Insurance for Emergencies. Then He Fell Into a $33,601 Trap,'' ProPublica, available at: *https://www.propublica.org/article/junk-insurance.*

[274] *See, for example,* Young, Christen Linke and Kathleen Hannick (2020). ''Fixed Indemnity Health Coverage Is a Problematic Form of 'Junk Insurance,' '' USC-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance.*

[275] *See* Williams, Jackson (2022). ''Addressing Low-Value Insurance Products With Improved Consumer Information: The Case of Ancillary Health Products,'' National Association of Insurance Commissioners, *Journal of Insurance Regulation,* available at: *https://content.naic.org/sites/default/files/cipr-jir-2022-9.pdf.*

[276] *See, for example,* Deam, Jenny (2021). ''He Bought Health Insurance for Emergencies. Then He Fell Into a $33,601 Trap,'' ProPublica, available at: *https://www.propublica.org/article/junk-insurance. See also* Palanker, Dania and Kevin Lucia (2021). ''Limited Plans with Minimal Coverage Are Being Sold as Primary Coverage, Leaving Consumers at Risk,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2021/limited-plans-minimal-coverage-are-being-sold-primary-coverage-leaving-consumers-risk. See also* Schwab, Rachel and Maanasa Kona (2018). ''State Insurance Department Consumer Alerts on Short-Term Plans Come Up Short,'' Center on Health Insurance Reforms, available at: *https://chirblog.org/state-insurance-department-consumer-alerts-short-term-plans-come-short/. See also* Corlette, Sabrina, Kevin Lucia, Dania Palanker, and Olivia Hoppe (2019). ''The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses,'' Urban Institute, available at: *https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses.*

[277] *See, for example,* Young, Christen Linke and Kathleen Hannick (2020). ''Fixed Indemnity Health Coverage Is a Problematic Form of ''Junk Insurance,'' USC-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance. See also* Government Accountability Office (2020). ''Private Health Coverage: Results of Covert Testing for Selected Offerings,'' available at: *https://www.gao.gov/products/gao-20-634r.*

[278] As discussed in section I.B of this preamble, these final rules build on Executive Order 14009, ''Strengthening Medicaid and the Affordable Care Act,'' and Executive Order 14070, ''Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage,'' by encouraging enrollment in high-quality, comprehensive coverage. The Departments also note that the affordability of comprehensive coverage offered in the individual market has increased for many consumers in recent years, due in part to the expanded PTC subsidies provided through the ARP and the IRA, as discussed in section II of this preamble. Further, as discussed in section II of this preamble, the COVID–19 PHE has highlighted the importance of encouraging enrollment in comprehensive coverage.

TABLE 1: Accounting Table

Benefits:				
Non-Quantified: • Reductions in information asymmetries in health insurance markets through increased consumer understanding of STLDI and fixed indemnity excepted benefits coverage in relation to comprehensive coverage. • Increased enrollment in comprehensive coverage, with an estimated increase in enrollment in individual health insurance coverage purchased on an Exchange by approximately 60,000 people in 2026, 2027 and 2028 associated with the provisions regarding STLDI. • Improvement in market stability and market risk pools for comprehensive coverage. • Reduction in the risk of high out-of-pocket health expenses, lower incidence of medical debt, improved health outcomes, and increased health equity, for individuals who switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage. • Potential reduction in the overall number of STLDI coverage rescissions or claims denials, if enrollment in STLDI declines. • Potential reduction in deceptive or aggressive marketing practices and harm from such practices involving the sale of STLDI and fixed indemnity excepted benefits coverage.				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$111,140	2024	7 percent	2024-2028
	$103,367	2024	3 percent	2024-2028
Quantified: • One-time regulatory review costs of approximately $358,578 for issuers of STLDI, issuers of fixed indemnity excepted benefits coverage, and other interested parties. • One-time costs of approximately $129,015 for issuers of STLDI and fixed indemnity excepted benefit coverage associated with complying with the notice provisions.				
Non-Quantified: • Potential increase in premium costs for individuals who switch from STLDI or fixed indemnity excepted benefit coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and who are not eligible for the PTC. • Potential increase in the number of uninsured individuals or the number of individuals experiencing a coverage gap, if some individuals with STLDI coverage purchased after the applicability date are no longer able to renew or extend their current policy, choose not to purchase a new policy from another issuer of STLDI, and can only obtain comprehensive coverage during open enrollment, or choose not to purchase comprehensive coverage. • Potential decrease in compensation for agents and brokers if there is a reduction in sales of STLDI and fixed indemnity excepted benefits coverage. • Potential increase in health care spending, if individuals switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and increase their use of health care as a result. • Potential costs to States, if States enact or implement new legislation in response to these final rules. • Potential costs to State departments of insurance associated with reviewing amended marketing materials and plan documents filed by issuers of STLDI and fixed indemnity excepted benefits coverage in response to these final rules.				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	- $67.1 million	2024	7 percent	2024-2028
	- $69.9 million	2024	3 percent	2024-2028
Quantified: • Reduction in gross premiums for individuals enrolled in individual health insurance coverage purchased on an Exchange by approximately 0.5 percent in 2026, 2027, and 2028. • Decrease in Federal PTC spending of approximately $120 million in 2026, 2027, and 2028.				
Non-Quantified: • Potential transfer from issuers to consumers if consumers switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and experience a reduction in out-of-pocket costs.				

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Table 2 presents the estimated effects of the provisions regarding STLDI on enrollment in and gross premiums for individual health insurance coverage

purchased on an Exchange, and on Federal spending on the PTC (by calendar year), as discussed further in sections V.B.2.c and V.B.2.e of this preamble. The Departments estimate that, starting in 2026, total enrollment in individual health insurance coverage purchased on an Exchange will be higher by 60,000 individuals each year, premiums for this coverage will be lower by 0.5 percent each year, and Federal spending on the PTC will be lower by $120 million each year, relative to the current status quo. The cumulative reduction in Federal spending on the PTC will be (an undiscounted) $360 million from 2026 to 2028.

TABLE 2: Estimated Effects of the Provisions Regarding STLDI on Enrollment in and Gross Premiums for Individual Health Insurance Coverage Purchased on an Exchange and on Federal Spending on the PTC

Calendar Year	2024	2025	2026	2027	2028
Change in Enrollment in Individual Health Insurance Coverage Purchased on an Exchange	0	0	60,000	60,000	60,000
Percentage Change in Gross Premiums for Individual Health Insurance Coverage Purchased on an Exchange	0	0	-0.5	-0.5	-0.5
Change in Federal Spending on the PTC (in millions)	$0	$0	-$120	-$120	-$120

a. Background

STLDI and fixed indemnity excepted benefits coverage generally are not subject to the Federal consumer protections and requirements for comprehensive coverage, as discussed in more detail in section I.A of this preamble. When used as a long-term substitute for comprehensive coverage, STLDI and fixed indemnity insurance expose enrollees to financial and health risks, as discussed in this section and section II.B of this preamble.

STLDI and fixed indemnity insurance typically do not cover all essential health benefits (including, for example, prescription drugs, maternity services, and mental health and substance use disorder services), and typically do not cover preexisting conditions.[279] STLDI may offer fewer benefits overall.[280] Fixed indemnity insurance is designed to provide a source of income replacement or financial support following a qualifying health-related event, and benefits are often far below a covered individual's incurred costs related to a medical event.[281] STLDI and fixed indemnity insurance typically have lower loss ratios or actuarial values than coverage subject to the Federal consumer protections and requirements for comprehensive coverage. In one study of the medical claims of approximately 47 million enrollees in commercial plans in 2016, for example, the implied actuarial value of the STLDI coverage in the study was 49 percent, compared to an implied actuarial value of approximately 74 percent for off-Exchange comprehensive coverage plans and an implied actuarial value of 87 percent for on-Exchange plans.[282] Additionally, according to an NAIC report, across 28 issuers of STLDI in the individual market in 2021, the nationwide loss ratio was approximately 70 percent.[283] The same report stated that across 95 issuers of ''other medical (non-comprehensive)'' coverage in the individual market, which includes fixed indemnity insurance, the nationwide loss ratio was approximately 40 percent in 2021.[284] By contrast, according to data from medical loss ratio (MLR) annual reports for the 2021 MLR reporting year, the average MLR in the individual market for comprehensive coverage was approximately 87 percent in 2021.[285]

A few commenters also noted that STLDI and fixed indemnity insurance

[279] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market. See also* Pollitz, Karen, Michelle Long, Ashley Semanskee, and Rabah Kamal (2018). ''Understanding Short-Term Limited Duration Health Insurance,'' KFF, available at: *https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/. See also* Sanger-Katz, Margot (2018). ''What to Know Before You Buy Short-Term Health Insurance,'' *The New York Times,* available at: *https://www.nytimes.com/2018/08/01/upshot/buying-short-term-health-insurance-what-to-know.html. See also* Partnership to Protect Coverage (2021). ''Under-Covered: How 'Insurance-Like' Products are Leaving Patients Exposed,'' available at: *https://www.nami.org/NAMI/media/NAMI-Media/Public%20Policy/Undercovered_Report_03252021.pdf. See also* Young, Christen Linke and Kathleen Hannick (2020). ''Fixed Indemnity Health Coverage Is a Problematic Form of ''Junk Insurance'' USC-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance.*

[280] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[281] *See* Williams, Jackson (2022). ''Addressing Low-Value Insurance Products With Improved Consumer Information: The Case of Ancillary Health Products,'' National Association of Insurance Commissioners, *Journal of Insurance Regulation,* available at: *https://content.naic.org/sites/default/files/cipr-jir-2022-9.pdf.*

[282] Pelech, Daria and Karen Stockley (2022). ''How Price and Quantity Factors Drive Spending in Nongroup and Employer Health Plans,'' Health Services Research, available at: *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13962.*

[283] The loss ratio is calculated as ((Incurred Claims Amount + Change in Contract Reserves)/Premiums Earned). Data regarding issuers of STLDI and ''other non-comprehensive coverage'' are only available for the individual market. *See* National Association of Insurance Commissioners (2022). ''2021 Accident and Health Policy Experience Report,'' available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/AdvancedSearch.*

[284] National Association of Insurance Commissioners (2022). ''2021 Accident and Health Policy Experience Report,'' available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/AdvancedSearch.* Data regarding issuers of non-comprehensive coverage are only available for the individual market.

[285] Based on internal calculations. Source: CMS, Medical Loss Ratio Data and System Resources, available at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

have low average loss ratios as compared to comprehensive coverage. These comments and the previously-mentioned statistics suggest that relative to issuers of comprehensive coverage, issuers of STLDI tend to spend a lower percentage of premium dollars on health care items and services, and issuers of fixed indemnity insurance tend to spend a lower percentage of premium dollars on payment of benefits. STLDI and fixed indemnity insurance can therefore be highly profitable for issuers,[286] depending on the extent to which issuers incur costs related to marketing (including agent/broker compensation [287]), policy underwriting, and overhead.

Low average loss ratios for STLDI and fixed indemnity insurance, along with relatively high commission rates for agents and brokers of those policies, reduce the value of STLDI and fixed indemnity insurance for consumers. Agents and brokers act as intermediaries between consumers and issuers. Their income is primarily derived from commissions, which tend to be a percentage of premiums paid by the consumer to the issuer. The commissions are incorporated into the cost of an insurance plan, and therefore indirectly affect the total price paid by the consumer for the coverage purchased. There is limited data available on commission rates paid by issuers to agents and brokers. Agent and broker commission rates tend to vary significantly between health insurance coverage options, though issuers of STLDI and fixed indemnity insurance tend to pay higher commissions.[288] The Departments received several comments indicating that agents and brokers receive a higher percentage of the plan's premium as a commission for selling STLDI or fixed indemnity insurance as compared to individual health insurance coverage. This was also confirmed in the Departments' review of some broker compensation disclosures.[289] The Departments acknowledge that lower cost alternatives to comprehensive coverage may not result in higher total compensation for agents and brokers, since the premiums for comprehensive coverage might be higher than the premiums for STLDI and fixed indemnity insurance. However, higher commission rates for agents and brokers from sales of STLDI and fixed indemnity insurance can incentivize aggressive and/or deceptive marketing tactics that may mislead customers into enrolling in STLDI or fixed indemnity insurance instead of comprehensive coverage.[290] [291] [292] One study suggests that commissions for STLDI are up to 10 times higher than those obtained for enrollment in individual health insurance coverage (averaging approximately 23 percent of premiums for STLDI, compared to 2 percent of premiums for individual health insurance coverage).[293] Another source corroborates this finding by noting that issuers of STLDI pay commissions close to 20 percent of premiums.[294]

In the 2023 proposed rules, the Departments stated that the limited coverage provided through most STLDI and fixed indemnity excepted benefits coverage exposes individuals enrolled in these policies to health and financial risks, including the risk of high medical bills and high out-of-pocket expenses. The Departments further noted that these high out-of-pocket expenses, in turn, could contribute to an increased risk of medical debt and bankruptcy, which is particularly problematic given the extent of medical debt already present in the United States.[295] As discussed in section II.B of this preamble, commenters provided the Departments with examples of how enrollment in fixed indemnity insurance, when used as a substitute for comprehensive coverage, could expose individuals to financial risk. However, many commenters also noted that fixed indemnity insurance can reduce financial risk for individuals, given that it provides payments for unexpected expenses associated with a health-related event. The Departments acknowledge that fixed indemnity insurance can reduce financial risk when used as a supplement to comprehensive coverage but remain concerned about the financial risk for individuals when it is used as a substitute for comprehensive coverage.

Misleading marketing of STLDI and fixed indemnity insurance is reported to have taken place during annual individual market open enrollment and special enrollment periods (including during the 2021 COVID–19 special enrollment period, when Exchanges using the Federal platform made available a 6-month special enrollment period on *HealthCare.gov* to allow qualified individuals to enroll in individual health insurance coverage during the COVID–19 PHE).[296] For

[286] *See* Appleby, Julie (2018). ''Short-Term Health Plans Boost Profits For Brokers And Insurers,'' NPR, available at: *https://www.npr.org/sections/health-shots/2018/12/21/678605152/short-term-health-plans-boost-profits-for-brokers-and-insurers. See* also Pear, Robert (2018). '' 'Short Term' Health Insurance? Up to 3 Years Under New Trump Policy,'' *The New York Times,* available at: *https://www.nytimes.com/2018/08/01/us/politics/trump-short-term-health-insurance.html.*

[287] Compensation includes commissions, fees, or other incentives (for example, rewards or bonuses) as established in the relevant contract between an issuer and the agent or broker.

[288] *See* Lucia, Kevin, Sabrina Corlette, Dania Palanker, and Olivia Hoppe (2018). ''Views From the Market: Insurance Brokers' Perspectives on Changes to Individual Health Insurance,'' Urban Institute, available at: *https://www.urban.org/research/publication/views-market-insurance-brokers-perspectives-changes-individual-health-insurance.*

[289] The Departments reviewed information detailing broker compensation from an agent/broker, two large issuers, and a health insurance agency.

[290] *See, for example.,* Appleby, Julie (2018). ''Short-Term Health Plans Boost Profits For Brokers And Insurers,'' NPR, available at: *https://www.npr.org/sections/health-shots/2018/12/21/678605152/short-term-health-plans-boost-profits-for-brokers-and-insurers.*

[291] Government Accountability Office (2020). ''Private Health Coverage: Results of Covert Testing for Selected Offerings,'' available at: *https://www.gao.gov/products/gao-20-634r.*

[292] However, even as some issuers offer higher compensation for STLDI, many brokers continue to refuse to sell products they view as overly risky for consumers, like STLDI. *See, for example,* Corlette, Sabrina, Erik Wengle, Ian Hill, and Olivia Hoppe (2020). ''Perspective from Brokers: The Individual Market Stabilizes While Short-Term and Other Alternative Products Pose Risks,'' Urban Institute, available at: *https://www.urban.org/research/publication/perspective-brokers-individual-market-stabilizes-while-short-term-and-other-alternative-products-pose-risks.*

[293] U.S. House of Representatives Committee on Energy and Commerce (2020). ''Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk,'' available at: *https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-investigation-finds-millions-of-americans-enrolled-in-junk-health.*

[294] Sanger-Katz, Margot (2018). ''What to Know Before You Buy Short-Term Health Insurance,'' *The New York Times,* available at: *https://www.nytimes.com/2018/08/01/upshot/buying-short-term-health-insurance-what-to-know.html.*

[295] *See, for example,* Consumer Financial Protection Bureau (2022). ''Medical Debt Burden in the United States,'' available at: *https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf.*

[296] *See* Palanker, Dania and JoAnn Volk. (2021). ''Misleading Marketing of Non-ACA Health Plans Continued During COVID–19 Special Enrollment Period,'' Center on Health Insurance Reforms, available at: *https://georgetown.app.box.com/s/mn7kgnhibn4kapb46tqmv6i7putry9gt. See* also Corlette, Sabrina, Kevin Lucia, Dania Palanker, and Olivia Hoppe (2019). ''The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses,'' Urban Institute, available at: *https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses.* Regarding the establishment of the COVID–19 special enrollment period, *see* E.O. 14009; *see* also CMS (2021). ''2021 Special Enrollment Period in Response to the COVID–19 Emergency,'' available at: *https://www.cms.gov/newsroom/fact-sheets/2021-special-enrollment-period-response-covid-19-emergency.* Regarding the extension of the COVID–19 special enrollment period (to the 6-month period between February 15, 2021, and August 15, 2021), *see* CMS (2021). ''Extended Access Opportunity to Enroll in More Affordable Coverage Through *HealthCare.gov,*'' available at: *https://www.cms.gov/newsroom/fact-*

example, one study showed that enrollment in STLDI policies through brokers increased by approximately 60 percent in December 2018 and by more than 120 percent in January 2019, suggesting that overall enrollment in STLDI spiked during the annual individual market open enrollment period.[297] One survey suggests that lead-generating websites direct consumers to insurance brokers selling both STLDI and other types of non-comprehensive coverage, including fixed indemnity insurance, and that these types of coverage are often marketed to resemble comprehensive coverage.[298]

A number of States and the District of Columbia enacted legislation or issued regulations regarding STLDI after the 2018 final rules were published. State regulatory actions regarding STLDI have been wide-ranging. For example, according to one report, as of September 2023, four States prohibited STLDI, seven States and the District of Columbia limited the total duration of enrollment in STLDI (including renewals or extensions) to less than 3 months, and eight States have limited the initial contract terms for enrollment in STLDI to less than 6 months.[299] Other State regulatory actions on STLDI have included banning coverage rescissions (except in cases of fraud on the part of the enrollee), adding preexisting condition protections, and requiring a certain MLR, among other restrictions.[300] Lastly, some States have largely aligned their regulations regarding STLDI with the 2018 final rules.[301] In some States that allow sales of STLDI, but have additional consumer protections in place (for example, prohibitions on renewals of STLDI coverage), issuers do not offer STLDI.[302]

Recent analysis has found that States that allow the initial contract term of STLDI to last up to 364 days have seen a 27 percent reduction in enrollment, on average, in non-Exchange plans that are subject to the Federal consumer protections and requirements for comprehensive coverage from 2018 to 2020, compared with a 4 percent reduction in enrollment, on average, in those plans in States that banned STLDI or limited its duration to 6 months or less.[303] This analysis also found that market-wide risk scores (a measure of relative expected health care costs for a population) declined more in States that banned or limited STLDI (-11.8 percent) than in States with less restrictions on STLDI (-8.3 percent), suggesting that the less restrictive States saw more healthier individuals enroll in STLDI policies in lieu of comprehensive coverage, which put upward pressure on the average expected health care costs among those with comprehensive coverage.

b. Number of Affected Entities

The provisions in these final rules will affect consumers enrolled in STLDI or fixed indemnity excepted benefits coverage, issuers of STLDI, issuers offering fixed indemnity excepted benefits coverage, and agents and brokers selling STLDI or fixed indemnity excepted benefits coverage. The provisions in these rules will also affect States if they enact or implement new legislation in response to these final rules. State departments of insurance will also be impacted to the extent they need to review amended marketing materials and plan documents filed by issuers.

With respect to consumers, individuals who are currently enrolled in STLDI or who may consider purchasing or choose to purchase STLDI in the future will be impacted by these final rules. Data from the NAIC indicate that 235,775 individuals were covered by STLDI sold to individuals at the end of 2022.[304] As noted in section V.B.1 of this preamble, this figure does not capture the total number of individuals covered by STLDI throughout the year and does not include individuals covered by STLDI sold to or through associations, through which most policies appear to be sold.[305] As noted in section V.B.1 of this preamble, projections by CBO and JCT suggest that 1.5 million people could currently be enrolled in STLDI,[306] and CMS previously estimated that 1.9 million individuals would enroll in STLDI by 2023.[307] However, the CBO and JCT and CMS estimates were developed prior to the expansion of PTC subsidies provided through the ARP and the IRA, which likely supported increased enrollment in individual health insurance coverage purchased on an Exchange in lieu of STLDI and other forms of health insurance not subject to the Federal consumer protections and requirements for comprehensive coverage, if only temporarily.[308] [309] The number of enrollees in STLDI also might have been affected by changes in State law or regulation that have occurred since the 2018 final rules were issued. The Departments received a comment

sheets/extended-access-opportunity-enroll-more-affordable-coverage-through-healthcaregov.

[297] U.S. House of Representatives Committee on Energy and Commerce (2020). ''Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans Is Putting Americans at Risk,'' available at: *https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-investigation-finds-millions-of-americans-enrolled-in-junk-health.*

[298] Corlette, Sabrina, Kevin Lucia, Dania Palanker, and Olivia Hoppe (2019). ''The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses,'' Urban Institute, available at: *https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses.*

[299] *See Healthinsurance.org* (2023). ''Duration and Renewals of 2023 Short-Term Medical Plans by State,'' available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf.*

[300] Palanker, Dania, Maanasa Kona, and Emily Curran (2019). ''States Step Up to Protect Insurance Markets and Consumers from Short-Term Health Plans,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/publications/issue-briefs/2019/may/states-step-up-protect-markets-consumers-short-term-plans.*

[301] *See Healthinsurance.org* (2023). ''Duration and Renewals of 2023 Short-Term Medical Plans by State,'' available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf.*

[302] *See* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[303] *See* Hall, Mark and Michael McCue (2022). ''Short-Term Health Insurance and the ACA Market,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2022/short-term-health-insurance-and-aca-market.*

[304] National Association of Insurance Commissioners (2023). ''2022 Accident and Health Policy Experience Report,'' available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

[305] Pollitz, Karen, Michelle Long, Ashley Semanskee, and Rabah Kamal (2018). ''Understanding Short-Term Limited Duration Health Insurance,'' KFF, available at: *https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.*

[306] Congressional Budget Office (2020). ''CBO's Estimates of Enrollment in Short-Term, Limited-Duration Insurance,'' available at: *https://www.cbo.gov/publication/56622.* CBO and JCT projected that enrollment in STLDI would reach 1.6 million by 2028. *See* Congressional Budget Office (2019). ''How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans,'' available at: *https://www.cbo.gov/publication/54915.*

[307] CMS Office of the Actuary (2018). ''Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule,'' available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf.*

[308] *See, for example,* Ortaliza, Jared, Krutika Amin, and Cynthia Cox (2022). ''As ACA Marketplace Enrollment Reaches Record High, Fewer Are Buying Individual Market Coverage Elsewhere,'' KFF, available at: *https://www.kff.org/policy-watch/as-aca-marketplace-enrollment-reaches-record-high-fewer-are-buying-individual-market-coverage-elsewhere/.*

[309] Based on data from the NAIC, the number of individuals covered by STLDI rose from around 173,000 in 2021 to 236,000 in 2022, reversing the downward trend from 2020 to 2021. *See* National Association of Insurance Commissioners (2023). ''2022 Accident and Health Policy Experience Report,'' available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

that also noted that the NAIC figure was likely an underestimate given that not all issuers report complete data to the NAIC. Another commenter—a State department of insurance—provided information about the number of individuals who had enrolled in STLDI in their State as of mid-2023. The Departments acknowledge that the NAIC figure likely underestimates the number of enrollees in STLDI, yet commenters did not offer additional data or information on the total number of consumers enrolled in STLDI across the country, and the Departments are not aware of another available source for these data.

Additionally, individuals who are currently enrolled in fixed indemnity excepted benefits coverage or who may choose to purchase or consider purchasing such coverage in the future will be affected by these final rules. Although the Departments are unaware of a definitive source for the number of fixed indemnity policies sold nationwide, the NAIC reports the total number of ''other non-comprehensive coverage'' policies [310] sold in the individual market. These nearly 2.6 million policies or certificates, covering approximately 4 million individuals, include fixed indemnity products along with other insurance products, and provide a potential estimate of the number of potential fixed indemnity policies or certificates and number of covered lives in the individual market. The Departments sought comments on the number of consumers who would be affected by the fixed indemnity excepted benefits coverage provisions in the proposed rules. Some commenters referenced a survey of 39 issuers of fixed indemnity or specified disease products. The survey indicated that approximately 3.4 million individuals are currently covered by fixed indemnity products in the individual market and approximately 4.7 million individuals are currently covered by fixed indemnity products in the group market.[311] Several issuers that commented on the proposed rules also provided information on the number of consumers currently enrolled in their fixed indemnity or other supplemental insurance products, with one issuer indicating that 47,900 of its customers were enrolled in fixed indemnity insurance without being enrolled in comprehensive coverage. One association commenting on the rules estimated that the number of supplemental policies in force for school employees ''is in the multi-millions.''

Based on the NAIC and industry estimates, the number of individuals with individual market fixed indemnity excepted benefits coverage who could be affected by these final rules could be up to 4 million, and the number of individuals with group market fixed indemnity excepted benefits coverage who could be affected by these final rules could be up to 4.7 million. However, because it is not clear what percentages of the NAIC and industry estimates are specific to fixed indemnity excepted benefits coverage rather than fixed indemnity insurance in general, the number of individuals affected by the provisions for fixed indemnity excepted benefits coverage in these final rules is likely to be lower than these estimates.

These final rules may also indirectly impact consumers enrolled in comprehensive coverage because of the potential impact of increased enrollment in comprehensive coverage on individual and group market risk pools, premiums, plan offerings, or issuer participation. While the Departments are unable to estimate whether or how these final rules will impact plan offerings or issuer participation in the individual and group markets for comprehensive coverage, in sections V.B.2.c and V.B.2.e of this preamble, the Departments discuss the estimated effects of the provisions regarding STLDI included in these final rules on enrollment in and premiums for individual health insurance coverage purchased on an Exchange.

Issuers of STLDI and fixed indemnity excepted benefits coverage will be directly impacted by these final rules. The NAIC reported that there were at least 28 issuers of STLDI in the individual market across the U.S. in 2022 and at least 93 issuers of ''other non-comprehensive coverage'' (including fixed indemnity insurance) in the individual market across the U.S. in 2022.[312] Data regarding issuers of STLDI and ''other medical (non-comprehensive)'' coverage are only available for the individual market. The Departments anticipate that many of these issuers also offer coverage in the group market. The Departments sought comments on the number of entities that would be affected by the proposed rules, including the number of issuers and associations offering STLDI and fixed indemnity excepted benefits coverage, but did not receive any data from commenters on the number of issuers in the STLDI or fixed indemnity excepted benefits coverage market that would be affected. Based on the NAIC data, and assuming some overlap between issuers in the individual and group market, the Departments anticipate that at least 28 issuers of STLDI and at least 93 issuers of fixed indemnity excepted benefits coverage could be affected by the provisions being finalized in these final rules. However, the Departments note that this might overestimate the number of issuers of fixed indemnity excepted benefits coverage, given that the NAIC figure captures issuers of other forms of non-comprehensive medical coverage in addition to fixed indemnity insurance, and that even for those issuers of fixed indemnity insurance that are included in this figure, it is not clear what percentage of those issuers offer fixed indemnity excepted benefits coverage in particular.

Agents and brokers selling STLDI or fixed indemnity excepted benefits coverage will be impacted by these final rules. The Bureau of Labor Statistics estimates that there are 445,540 insurance agents nationwide, which includes agents and brokers that sell health insurance products in addition to other types of insurance (for example, life and property).[313] One professional association, which is estimated to represent one-third of active health insurance agents and brokers,[314] has approximately 100,000 members.[315] However, the Departments lack data

[310] *See* National Association of Insurance Commissioners (2023). ''2022 Accident and Health Policy Experience Report,'' available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf* (''Other medical (non-comprehensive) coverage'' includes ''policies such as hospital only, hospital confinement, surgical, outpatient indemnity, intensive care, mental health/substance abuse, and organ and tissue transplant (including scheduled type policies), etc.'' It is further noted that ''expense reimbursement and indemnity plans should be included'' in this definition, but that ''this category does not include TRICARE/CHAMPUS Supplement, Medicare Supplement, or FEHB Program coverage.'' Data from the NAIC regarding issuers of ''other non-comprehensive coverage'' are only available for the individual market.

[311] *See* AHIP–ACLI–BCBSA 2023 Survey: Fixed Indemnity and Specified Disease Plans, September 7, 2023, available at: *https://www.ahip.org/resources/ahip-acli-bcbsa-2023-survey.*

[312] National Association of Insurance Commissioners (2023). ''2022 Accident and Health Policy Experience Report,'' available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

[313] Bureau of Labor Statistics (2022). ''National Occupational Employment and Wage Estimates,'' available at: *https://www.bls.gov/oes/current/oes413021.htm.*

[314] Karaca-Mandic, Pinar, Feldman, Roger, and Peter Graven (2016). ''The Role of Agents and Brokers in the Market for Health Insurance,'' *Journal of Risk and Insurance,* available at: *https://onlinelibrary.wiley.com/doi/full/10.1111/jori.12139.*

[315] National Association of Benefits and Insurance Professionals (2023). ''Who We Are,'' available at: *https://nabip.org/who-we-are.*

about the number of agents and brokers that currently enroll individuals in STLDI or fixed indemnity excepted benefits coverage and did not receive any additional data from commenters.

c. Benefits

Increase in consumer awareness. These final rules are expected to reduce the harm caused to consumers who are misled into enrolling in STLDI or fixed indemnity excepted benefits coverage as an alternative to or replacement for comprehensive coverage. The notice provisions being finalized in these final rules will improve consumer understanding of STLDI and fixed indemnity excepted benefits coverage in relation to comprehensive coverage. The Departments received some comments noting that STLDI policies are often marketed as a more affordable alternative to comprehensive coverage, and received many comments stating that STLDI policies exclude critically important health care services, as discussed in section III.A.1 of this preamble. Many commenters stated that the 2023 proposed rules would help consumers differentiate STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage when shopping for health insurance. Some commenters also stated that the notice provisions for STLDI and fixed indemnity excepted benefits coverage would help combat deceptive marketing practices and would improve consumer understanding of the different options available when shopping for insurance. One commenter stated that enrollees in STLDI policies are functionally uninsured due to the narrow benefits and design limitations that are often poorly understood by consumers. Although several commenters expressed concern about the improper marketing of fixed indemnity insurance, some commenters suggested that such improper marketing practices are limited to a few ''bad actors'' in the market. One commenter stated that concerns over widespread consumer confusion are unsupported, and that consumer confusion could be addressed by policy alternatives like increased enforcement of deceptive marketing laws or enhanced consumer awareness campaigns, rather than the provisions proposed in the 2023 proposed rules. The Departments agree that the notice provisions will help ensure individuals are made aware that STLDI and fixed indemnity excepted benefits policies are not comprehensive coverage. The Departments are of the view that the provisions finalized in these final rules will reduce the level of deceptive marketing of STLDI and fixed indemnity excepted benefits policies, reduce the harm from such deceptive marketing practices, and increase the overall awareness of coverage options that include the full range of Federal consumer protections. These provisions will also help consumers more easily distinguish between STLDI or fixed indemnity excepted benefits coverage and individual health insurance coverage, thereby mitigating the risk that they mistakenly enroll in STLDI or fixed indemnity excepted benefits coverage in lieu of comprehensive coverage. The Departments appreciate the suggestions related to increased enforcement of deceptive marketing laws, and enhanced consumer awareness campaigns, but are of the view that these actions alone would not sufficiently address consumer confusion related to the current structure of STLDI and fixed indemnity excepted benefit coverage.

Better health outcomes. Consumers who switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage are expected to have better access to health care, better consumer protections, and more robust benefits, and are therefore expected to experience better health outcomes. Several commenters stated that STLDI policies can limit access to health care and lead to negative health outcomes given the insufficient coverage of STLDI policies. Commenters stated that the inadequate coverage, particularly for individuals with chronic conditions, could lead to the use of high-cost services, such as emergency department visits or hospitalizations that could have been prevented if adequate care were accessible through their STLDI coverage. On the other hand, some commenters stated that enrollees in STLDI and fixed indemnity excepted benefits policies can benefit from receiving services provided by any provider and are not limited by provider networks established by issuers offering comprehensive coverage.[316] Some commenters suggested that the STLDI provisions could restrict patients' access to certain providers or reduce access to care in general. Other commenters suggested that the STLDI provisions could influence the composition of health care utilization and spending—because of the limited benefits or high cost-sharing requirements of most STLDI policies, enrollees in STLDI policies may underutilize preventive care and overutilize higher-cost care.

The Departments acknowledge that there may be individuals whose provider may not be in-network with an issuer offering comprehensive coverage, and that individuals may experience changes in access to certain providers if they switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage. However, given the limited benefits, limited consumer protections, and financial exposure associated with most STLDI and fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage), the Departments are of the view that individuals' overall financial risk would decrease and their overall access to health care would increase if they enrolled in comprehensive coverage. Furthermore, the Departments are of the view that overall health outcomes will improve for individuals who enroll in comprehensive coverage in lieu of STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage). For example, studies [317] that examined the potential impacts of State policies regulating STLDI found that individuals in States that prohibited or restricted the sale of STLDI policies had more favorable cancer diagnoses when compared to individuals in States that did not prohibit or restrict STLDI policies. In summary, if individuals enroll in comprehensive coverage instead of STLDI or fixed indemnity excepted benefits coverage, the Departments expect that they will have increased access to care, decreased exposure to major medical expenses, and improved health outcomes.

Potential increase in enrollment in comprehensive coverage. The Departments anticipate that these final rules will lead to an increase in enrollment in comprehensive coverage. The Departments expect that individuals will be less likely to wait until they have incurred major medical

[316] Issuers of STLDI and fixed indemnity excepted benefits coverage may also have provider networks, and one commenter (an issuer of STLDI) noted that their provider network has 1.5 million physicians and other health care professionals and approximately 7,000 hospitals and other facilities.

[317] *See* Barnes, Justin, Anne Kirchhoff, Robin Yabroff, and Fumiko Chino (2023). ''State Policies Regulating Short-Term Limited Duration Insurance Plans and Cancer Stage at Diagnosis,'' *JNCI Cancer Spectrum,* Volume 7, Issue 5, available at: *https://doi.org/10.1093/jncics/pkad060. See also* Yang, Nuo Nova Nova, Jingxuan Zhao, Justin Michael Barnes, Anne C. Kirchhoff, Fumiko Chino, Robin Yabroff, and Xuesong Han (2023). ''Association of Federal and State Policies Regulating Short-term Limited Duration Insurance (STLD) Plans and Later Cancer Stage at Diagnosis.'' *JCO Oncology Practice,* Volume 19, Issue 11, available at: *https://ascopubs.org/doi/abs/10.1200/OP.2023.19.11_suppl.197.*

expenses or developed a medical condition to look for opportunities to switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage. Increased enrollment in comprehensive coverage in lieu of enrollment in STLDI is also expected to reduce the number of coverage rescissions, claims denials, and coverage exclusions associated with STLDI. However, as noted earlier in this section V.B.b of this preamble, the expanded PTC subsidies provided through the ARP and the IRA have likely already resulted in increased enrollment in individual health insurance coverage purchased on an Exchange in lieu of STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage), so the immediate overall effects of these final rules on enrollment in, market stability of, and risk pools for comprehensive coverage are expected to be limited in 2024 and 2025.[318] The CMS Office of the Actuary (OACT) estimates that, relative to current law, the provisions regarding STLDI being finalized in these final rules will not affect enrollment in individual health insurance coverage purchased on an Exchange in 2024 and 2025, but will increase enrollment by approximately 60,000 people in 2026, 2027, and 2028.[319] Many commenters indicated that the STLDI provisions are likely to reduce premiums for individual health insurance coverage. Many commenters also pointed to the potential shift in enrollment from STLDI to individual health insurance coverage as having a potential impact on the risk pools for individual health insurance coverage.[320] The Departments agree with these comments and are of the view that the provisions for STLDI and fixed indemnity excepted benefits coverage being finalized in these final rules will lead to more stable markets and improved market risk pools for comprehensive coverage.

Reduction in financial risk for consumers. To the extent that these final rules lead to an increase in enrollment in individual health insurance coverage subject to the Federal consumer protections and requirements for comprehensive coverage in lieu of STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage), the Departments are of the view that these final rules will result in a reduction in out-of-pocket expenses, medical debt, and risk of medical bankruptcy for consumers switching to comprehensive coverage. These final rules could also lead to a reduction in potentially devastating surprise bills from out-of-network providers in emergency and certain other circumstances to the extent the rules lead to an increase in enrollment in individual health insurance coverage, which is subject to the surprise billing protections for consumers under the No Surprises Act. Many commenters agreed that the proposals being finalized in these final rules will support consumer protections. Many commenters also indicated that these final rules are critical to ensuring consumers' financial well-being and reducing their financial risk. Several commenters agreed that the proposed STLDI notice would ensure that consumers understand the type of coverage that they would be enrolling in and its limitations. Many commenters stated that STLDI policies expose enrollees to the risk of high out-of-pocket costs when an illness or injury occurs, and some commenters stated that this could lead to increased medical debt. One commenter indicated that families without comprehensive care are at risk of delaying care or going into debt. One commenter indicated that consumers may not realize how limited their STLDI coverage is until they are faced with high out-of-pocket costs for services commonly covered under comprehensive coverage. Commenters pointed to rehabilitation services, prescription drug costs, and cancer treatments as resulting in significantly higher out-of-pocket costs for consumers enrolled in STLDI when compared to comprehensive coverage. For example, the Departments reviewed a scenario study[321] that assessed the cost implications of a hypothetical consumer who enrolls in a typical STLDI policy and is later diagnosed with breast cancer. The study found that this hypothetical consumer would incur between $40,000 to $63,000 in out-of-pocket expenses, compared to less than $8,000 in a comprehensive coverage plan. While many commenters argued that fixed indemnity excepted benefits coverage reduces financial risk, other commenters argued that fixed indemnity excepted benefits coverage exposes individuals to financial risk when it is used as a substitute for comprehensive coverage. Lastly, some commenters specifically noted that the provisions regarding stacking of STLDI policies would benefit consumers by limiting circumvention of the provisions related to maximum duration, as discussed in section III.A.2 of this preamble. The Departments agree with these comments and are of the view that to the extent that consumers obtain comprehensive coverage in lieu of STLDI or fixed indemnity excepted benefits coverage, they are likely to experience lower out-of-pocket costs for their care. As noted in section V.B.2.a of this preamble, the Departments acknowledge that fixed indemnity excepted benefits coverage can reduce financial risk when used as a supplement to comprehensive coverage but remain concerned about the financial risk for individuals when it is used as a substitute for comprehensive coverage.

d. Costs

Increase in premiums. The Departments recognize that some

[318] *See, for example,* Ortaliza, Jared, Krutika Amin, and Cynthia Cox (2022). ''As ACA Marketplace Enrollment Reaches Record High, Fewer Are Buying Individual Market Coverage Elsewhere,'' KFF, available at: *https://www.kff.org/policy-watch/as-aca-marketplace-enrollment-reaches-record-high-fewer-are-buying-individual-market-coverage-elsewhere/. See also* Ortaliza, Jared, Krutika Amin, and Cynthia Cox (2024). ''Another Year of Record ACA Marketplace Signups, Driven in Part by Medicaid Unwinding and Enhanced Subsidies,'' KFF, available at: *https://www.kff.org/policy-watch/another-year-of-record-aca-marketplace-signups-driven-in-part-by-medicaid-unwinding-and-enhanced-subsidies/.*

[319] In developing these estimates, OACT assumed that STLDI would be significantly less expensive than individual health insurance coverage purchased on an Exchange (where available) and would be an attractive option for individuals and families with relatively low health care costs and little to no subsidies. Using their health reform model, OACT estimated that, under current law, about 60,000 people would move from individual health insurance coverage purchased on an Exchange to STLDI in 2026, when the additional PTC subsidies available through 2025 through the IRA expire. In addition, since those switching to STLDI are assumed to be healthier than average, the average premium for individual health insurance coverage purchased on an Exchange would increase by roughly 0.5 percent. Changing the maximum duration of an STLDI policy, certificate, or contract of insurance to no more than 4 months is expected to negate these effects.

[320] The Departments received an analysis from a commenter that estimated the potential impact of the STLDI provisions on enrollment and premiums in the individual market for comprehensive coverage. The analysis found that the STLDI provisions are likely to increase enrollment and lower premiums in the individual market for comprehensive coverage. The analysis utilized upper bound estimates of existing STLDI enrollment and analyzed varying scenarios of transition from STLDI coverage to individual health insurance coverage to estimate that such transitions could result in a 0.5 to 2 percent reduction in premiums. The commenter acknowledged that these impacts would vary by State given the different levels of STLDI regulations in States. Overall, the analysis notes that the net result is positive for consumers should there be a significant transition from STLDI coverage to individual health insurance coverage.

[321] American Cancer Society Cancer Action Network (2019). ''Inadequate Coverage: An ACS CAN Examination of Short-Term Health Plans,'' available at: *https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Short%20Term%20Paper%20FINAL.pdf.*

individuals with STLDI or fixed indemnity excepted benefits coverage who switch to individual health insurance coverage might incur higher premium costs depending on their choice of available Exchange and off-Exchange plans, their PTC eligibility (if applicable), and the amount of APTC they receive (if any).[322] Several commenters noted that the STLDI provisions could lead to higher premium costs for individuals if they switch to comprehensive coverage, and several commenters noted the low monthly premiums for STLDI relative to comprehensive coverage. One commenter acknowledged that STLDI has lower premiums because the Federal consumer protections and requirements for comprehensive coverage do not apply to this form of coverage. Some commenters stated that STLDI policies cover the select benefits certain consumers want. The Departments acknowledge that premiums for comprehensive coverage are generally higher than premiums for STLDI, but note that this is largely because comprehensive coverage offers more benefits with lower out-of-pocket costs. Further, as noted in section II.A of this preamble, comprehensive coverage for individuals has generally become more accessible and affordable in recent years, due in part to the expansion of PTC subsidies under the ARP and the IRA, and the provisions for STLDI finalized in these final rules are expected to put further downward pressure on gross premiums for individuals enrolled in individual health insurance coverage purchased on an Exchange. The Departments are of the view that any increase in costs is outweighed by the meaningful increase in benefits and consumer protections afforded to individuals enrolled in comprehensive coverage.

Loss of coverage. These final rules might also lead to an increase in the number of individuals without some form of health insurance coverage, if some individuals with STLDI purchased after the applicability date are no longer able to renew or extend their current policy, choose not to purchase a new policy from another issuer of STLDI, and can only obtain comprehensive coverage during an annual individual market open enrollment period, or choose not to purchase comprehensive coverage. Many commenters agreed with the Departments' analysis and noted that the provisions regarding STLDI coverage may reduce consumers' coverage options or lead to a loss of coverage or a coverage gap. Many commenters argued that restricting access to STLDI would not be appropriate for certain populations given their coverage needs (for seasonal employees working in another State, for example). These commenters noted that specific groups who benefit from STLDI policies are most likely to go without insurance as a result of the STLDI provisions, such as gig-economy workers, contract workers, college students, commercial truck drivers, and travel nurses. Some commenters suggested that the STLDI provisions could lead consumers to seek alternative forms of non-comprehensive coverage, including coverage offered in unregulated markets (for example, through health care sharing ministries). The Departments acknowledge that some individuals who purchase STLDI policies after the applicability date may lose coverage and must wait until the next annual individual market open enrollment period to purchase comprehensive coverage (for example, if an individual with STLDI purchased after the applicability date exhausts their renewal or extension options or is unable to enroll in STLDI offered by a different issuer outside of an open enrollment period) or may choose to become uninsured. Some individuals might also seek coverage in unregulated markets. Those individuals who become uninsured or obtain coverage in unregulated markets could face an increased risk of higher out-of-pocket expenses and medical debt, reduced access to health care, and potentially worse health outcomes. The Departments are of the view, however, that the overall risk that some individuals may become uninsured or lose coverage because of the above circumstances is outweighed by the fact that a substantial number of individuals will likely benefit as a result of the final rules' STLDI provisions. Overall, the Departments are of the view that STLDI serves better as a bridge between different sources of comprehensive coverage than as an alternative to comprehensive coverage.

Increase in health care spending. To the extent that these final rules lead to an increase in enrollment in comprehensive coverage, they might result in an increase in overall health care utilization and spending, given that comprehensive coverage tends to have higher loss ratios and actuarial values and generally offers lower cost-sharing requirements and more generous benefits.[323]

Impact on States. The Departments solicited comments on the magnitude of the costs that States might incur associated with enacting new legislation, implementing new laws, and updating existing regulations regarding STLDI and fixed indemnity excepted benefits coverage. However, the Departments received little information about the potential costs to States associated with the provisions being finalized in these final rules. One commenter generally stated that the STLDI provisions would cause economic harm to States, but the commenter did not quantify or otherwise specify the type or extent of the economic impact on States. While no State is required to enact new legislation or change its regulations under the provisions being finalized in these final rules, the Departments anticipate that some States could incur a one-time cost if they do enact new legislation or update their regulations.

Many commenters also stated that the 2023 proposed rules would generate costs for States associated with evaluating and approving redesigned products and policy forms. The Departments acknowledge that some State departments of insurance may incur costs to the extent they need to review amended marketing materials and plan documents filed by issuers.

Costs to agents and brokers. The Departments sought information on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by the provisions proposed in

[322] This might occur if premiums for STLDI are lower than premiums for individual health insurance coverage. One study, for example, showed that by screening out individuals with pre-existing conditions and providing fewer comprehensive benefits, issuers may be able to offer STLDI at rates 54 percent below those for (unsubsidized) comprehensive coverage. *See* Levitt, Larry, Rachel Fehr, Gary Claxton, Cynthia Cox, and Karen Pollitz (2018). ''Why do Short-Term Health Insurance Plans Have Lower Premiums than Plans that Comply with the ACA?'' KFF, available at: *https://files.kff.org/attachment/Issue-Brief-Why-Do-Short-Term-Health-Insurance-Plans-Have-Lower-Premiums-Than-Plans-That-Comply-with-the-ACA.*

[323] As noted earlier in this RIA, many STLDI and fixed indemnity excepted benefits policies offer limited benefits coverage and have relatively low actuarial values. Many STLDI and fixed indemnity excepted benefit coverage issuers spend a relatively high percentage of premium dollars on administration and overhead *See* National Association of Insurance Commissioners (2022). ''Accident and Health Policy Experience Report for 2021,'' available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/AdvancedSearch.* Regarding the differences in cost-sharing requirements and out-of-pocket expenses between STLDI and individual health insurance coverage, *see, for example,* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

the 2023 proposed rules. Many commenters anticipated that the financial impacts of the proposals on agents and brokers would be significant, particularly given the relatively low commission rates that agents and brokers receive from the sale of Exchange plans as compared to STLDI and fixed indemnity insurance. Another commenter stated that the Departments' analysis lacked sufficient data to account for the potential impacts on agents and brokers. However, commenters did not provide information on the number of agents and brokers that sell STLDI or fixed indemnity excepted benefits coverage or data that would assist in quantifying the impact of the provisions proposed in the 2023 proposed rules on agents and brokers. Nevertheless, the Departments acknowledge that the provisions being finalized in these final rules may affect agents and brokers if there is an impact on enrollment in STLDI or fixed indemnity excepted benefits products. There is the potential for agent and broker compensation associated with the sale of STLDI or fixed indemnity excepted benefits coverage to be negatively affected if there is a reduction in the sale of these types of coverage. There is also the potential for agent and broker compensation associated with the sale of individual health insurance coverage to be positively affected if there is an increase in sales of that coverage.

Costs to issuers. In the 2023 proposed rules, the Departments explained they expected that issuers would incur minimal costs associated with the notice provisions. The Departments also expected that since issuers change their policy documents routinely, the costs to issuers to make changes in response to these final rules would be part of issuers' usual business costs. However, many commenters stated that issuers would incur operational costs associated with the provisions for fixed indemnity excepted benefits coverage proposed in the 2023 proposed rules (to make necessary updates to systems and processes, and other administrative tasks, for example). Many commenters noted the costs to refile documents with State departments of insurance, obtain State approvals, and ensure compliance, and the costs associated with new policy issuance, marketing, enrollment, and administration. While one commenter provided an estimate of the overall costs of implementing all of the provisions for fixed indemnity excepted benefits coverage proposed in the 2023 proposed rules, no commenter provided estimates of the costs associated with the provisions for STLDI or estimates specific to the notice provisions for STLDI and fixed indemnity excepted benefits coverage proposed in the 2023 proposed rules.

The Departments acknowledge these comments and anticipate that issuers will incur one-time costs to modify their products and plan documents to comply with the provisions for STLDI and fixed indemnity excepted benefits coverage that are being finalized in these final rules, with issuers also incurring costs related to filing amended marketing materials and plan documents with State departments of insurance. These costs are expected to vary by issuer depending on the number of States in which they offer products, State law requirements for STLDI or fixed indemnity excepted benefits coverage, the number of products they offer, and the overall scale of their operations.[324] These costs will include the costs associated with the notice provisions. Using wage information from the Bureau of Labor Statistics to account for median labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs),[325] the Departments estimate that, on average for each issuer, a business operations specialist will need 4 hours (at an hourly labor cost of $73.06), an administrative assistant will need 4 hours (at an hourly labor cost of $42.38), and a web developer will need 8 hours (at an hourly labor cost of $75.56) to revise or place the notice that must be displayed in their marketing, application, and enrollment materials (including on websites) and in the individual market also to place the notice in the policy, certificate, or contract of insurance, to come into compliance with these final rules. The average cost per issuer to comply with the notice provisions is estimated to be approximately $1,066.[326] As noted earlier in this RIA, the NAIC estimates that there are currently 28 issuers of STLDI in the individual market and 93 issuers of ''other medical (non-comprehensive)'' coverage in the individual market, which include fixed indemnity insurance. Therefore, using the NAIC estimates, the total one-time cost to issuers of STLDI and fixed indemnity coverage to comply with the notice provisions will be at least approximately $129,015.[327]

e. Transfers

Transfers associated with transitions to comprehensive coverage. Individuals currently enrolled in STLDI may be healthier—on average—than individuals enrolled in comprehensive coverage, because comprehensive coverage is subject to Federal consumer protections and requirements for comprehensive coverage that prohibit those plans from excluding individuals or charging higher premiums on the basis of health status, gender, and other factors, whereas STLDI policies do not have to comply with these requirements and are typically subject to medical underwriting. These final rules are expected to cause some individuals with relatively low health care costs to enroll in individual health insurance coverage in lieu of STLDI, which is expected to improve the risk pools for individual health insurance coverage and lead to lower overall average premiums for individual health insurance coverage.

CMS previously estimated that gross premiums for individual health insurance coverage purchased on an Exchange in 2022 would be 6 percent higher under the 2018 proposed rules than they would have been in the absence of those rules.[328] CBO and JCT previously estimated that the 2018 final rules for STLDI, in conjunction with changes made through the 2018 Department of Labor rule entitled ''Definition of 'Employer' Under Section 3(5) of ERISA—Association Health Plans,'' [329] would increase premiums in the individual and small group health insurance coverage markets by around 3 percent.[330] An analysis of individual health insurance coverage rate filing materials for 2020 also found that the few issuers that explicitly included a premium adjustment because of the 2018 final rules increased premiums by

[324] The Departments do not have enough data or information to quantify these costs.

[325] *See* Bureau of Labor Statistics (2022). ''National Occupational Employment and Wage Estimates,'' available at: *https://www.bls.gov/oes/current/oes_nat.htm.*

[326] (4 business operation specialist hours * $73.06) + (4 administrative assistant hours * $42.38) + (8 web developer hours * $75.56) = $1,066.24.

[327] (28 STLDI issuers + 93 issuers of other medical (non-comprehensive) coverage) * [(4 business operation specialist hours * $73.06) + (4 administrative assistant hours * $42.38) + (8 web developer hours * $75.56)] = $129,015.04.

[328] CMS Office of the Actuary (2018). ''Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule,'' available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf.*

[329] 83 FR 28912 (June 21, 2018). This rule was vacated by the District Court of D.C. in *State of New York, et al.* v. *United States Department of Labor, et al.,* 363 F.Supp.3d 109 (D.D.C. 2019).

[330] Congressional Budget Office (2019). ''How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans,'' available at: *https://www.cbo.gov/publication/54915.*

between 0.5 percent and 2 percent in 2020.[331] These analyses suggest that these final rules should have an effect in the opposite direction, reducing gross premiums for individual health insurance coverage. OACT estimates that the provisions regarding STLDI will not affect gross premiums for individuals with individual health insurance coverage purchased on an Exchange in 2024 and 2025, given the expanded PTC subsidies provided through the IRA, but will reduce gross premiums by approximately 0.5 percent in 2026, 2027, and 2028, after the expanded PTC subsidies have ended.[332]

Many commenters agreed with the Departments that enrollment in STLDI adversely affects the risk pools for individual health insurance coverage, leading to higher premiums for individual health insurance coverage. Specifically, one commenter stated that this adverse selection and its effects would particularly disadvantage individuals with preexisting conditions. Furthermore, one study suggests that the 2018 final rules had a negative effect on the risk pools for individual health insurance coverage.[333] As such, the Departments continue to be of the view that access to STLDI has negative effects on the risk pools for individual health insurance coverage.

Some commenters also noted that enrollment in STLDI in lieu of comprehensive coverage could lead to fewer issuers in the Exchanges or otherwise distort or destabilize the markets for comprehensive coverage, while one commenter stated that the impact of enrollment in STLDI on the markets for comprehensive coverage would be rather limited (as indicated by OACT's impact estimates). A few commenters suggested that the STLDI provisions could potentially harm the market for individual health insurance coverage due to a reduction in competition, for example, with one commenter suggesting that the 2018 final rules promoted issuer competition in the overall market.[334] The Departments disagree with these commenters and note that STLDI and individual health insurance coverage are two very different products that are generally subject to different laws and regulations, and issuers of individual health insurance coverage are unlikely to have changed their product offerings to compete with STLDI.

Some commenters stated that enrollment in fixed indemnity excepted benefits coverage can adversely affect the risk pools for comprehensive coverage. A few commenters stated that the impact of fixed indemnity excepted benefits coverage on the risk pools for individual health insurance coverage purchased on an Exchange is limited or nonexistent. While the Departments expect that the notice provisions being finalized in these final rules will encourage some individuals to enroll in comprehensive coverage instead of fixed indemnity excepted benefits coverage, the Departments do not expect such increased enrollment to have a significant impact on market risk pools and therefore expect a limited impact on premiums for comprehensive coverage, if any.

Transfers from the Federal Government to individuals. The provisions regarding STLDI are expected to reduce Federal PTC spending after the end of the expanded PTC subsidies provided through the IRA. Specifically, these provisions are expected to reduce gross premiums for individual health insurance coverage purchased on an Exchange and therefore lower per capita PTC spending. This effect is expected to be partly offset by an increase in the number of individuals enrolling in Exchange coverage that would be eligible to receive the PTC (by approximately 20,000 in 2026, 2027, and 2028). On net, OACT estimates that these provisions will have no impact on Federal spending on PTC in 2024 and 2025 given the expanded PTC subsidies provided through the IRA, but will reduce Federal spending on the PTC by approximately $120 million in 2026, 2027, and 2028.[335] This reduction in Federal spending on the PTC is viewed as a reduction in the amount of the transfer from the Federal Government to individuals.

Transfers among issuers, consumers, and providers. These final rules could lead to a transfer in the form of reduced out-of-pocket expenses from issuers to consumers who switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage, since more health care services would be covered under comprehensive coverage and the out-of-pocket expenses (such as cost-sharing requirements) for comprehensive coverage might be lower than out-of-pocket expenses for STLDI or fixed indemnity excepted benefits coverage.[336]

Some commenters suggested that the STLDI provisions could lead to an increase in uncompensated care provided by providers and facilities, to the extent they lead to an increase in the number of individuals without any form of health insurance coverage who are unable to pay providers and facilities on an out-of-pocket basis, which would be a transfer from providers and facilities to uninsured individuals. However, a few commenters suggested that the STLDI provisions could lead to a decrease in uncompensated care provided by providers and facilities, to the extent that individuals with STLDI enroll in comprehensive coverage (which would generally offer more benefits and lower cost-sharing requirements, and increased access to health care) in lieu of STLDI; this would be a transfer from issuers of comprehensive coverage to providers and facilities. One commenter also suggested that the fixed indemnity excepted benefits coverage proposals in the 2023 proposed rules could generate costs for providers regarding receipt of payments from patients, which would be a transfer from providers to these individuals. The Departments lack data that would allow for a quantification of

[331] Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[332] *See* section V.B.2.c of this preamble for a discussion of the enrollment effects that drive these premium changes.

[333] *See* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[334] The commenter cited a study that compared the trends in Exchange enrollment, premiums, and issuer participation in States that had additional restrictions on or prohibited STLDI and in States that fully permitted STLDI (in accordance with the 2018 final rules). The study concluded that States that fully permitted STLDI ''. . . have lost fewer enrollees in the individual market, have had far more insurers offer coverage in the market, and have had larger premium reductions since the [2018 final rules] took effect,'' further noting that ''the only States where individual market premiums have increased since 2018 are the five [S]tates that effectively prohibit short-term plans.'' *See* Blase, Brian (2021). ''Individual Health Insurance Markets Improving in States that Fully Permit Short-Term Plans,'' Galen Institute, available at: *https://galen.org/assets/Individual-Health-Insurance-Markets-Improving-in-States-that-Fully-Permit-Short-Term-Plans.pdf.*

[335] In fiscal year terms, this would be a reduction in Federal spending of $90 million in 2026, $120 million in 2027, and $120 million in 2028.

[336] As noted in the Costs subsection of this RIA, regarding the differences in cost-sharing requirements and out-of-pocket expenses between STLDI and individual health insurance coverage, *see, for example,* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

these effects but acknowledge that there may be a potential increase in uncompensated care provided by providers and facilities given the previously-mentioned impact of these final rules on out-of-pocket expenditures discussed in section V.B.2.d of this preamble.

f. Uncertainty

As noted throughout this preamble, due to a lack of data and information, there are several areas of uncertainty regarding the potential impacts of these final rules. The Departments are unable to forecast how all of the provisions of these final rules will affect enrollment in STLDI and fixed indemnity excepted benefits coverage, as the Departments are uncertain how many individuals are currently enrolled in STLDI or fixed indemnity excepted benefits coverage, how many of those individuals will switch to comprehensive coverage, how many individuals will try to find another issuer of STLDI once their current policy ends, how many individuals will choose to remain enrolled in fixed indemnity excepted benefits coverage, or how many individuals will choose not to purchase any form of coverage.[337] As a result, there is also some uncertainty about the impacts on market risk pools, premiums, Federal expenditures on PTC, and on compensation for agents and brokers selling STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage. One commenter noted that the uncertainty in the estimates pertaining to the number of affected entities undermines the Departments' analysis of impacts.

The Departments sought comments on all of these areas of uncertainty regarding the impacts of the 2023 proposed rules and where possible incorporated data and information received during the comment period in estimating the impacts of these final rules. Despite the uncertainty discussed in this section and throughout this preamble, the Departments have enough data to be confident that the benefits of these final rules outweigh the costs, and that these final rules will help ensure that consumers can clearly distinguish STLDI and fixed indemnity excepted benefits from comprehensive coverage, protect market risk pools and stabilize premiums for comprehensive coverage, and promote access to affordable comprehensive coverage.

g. Health Equity Impact

The Departments stated in section II.B of the preamble to the 2023 proposed rules that due to the typical underwriting practices and plan eligibility requirements in the market for STLDI, individuals might face higher premiums or might not be able to purchase STLDI because of preexisting health conditions, gender, or other factors.[338] STLDI and fixed indemnity excepted benefits coverage policies typically do not cover certain essential health benefits including prescription drugs, mental health and substance use disorder services, or maternity services,[339] which could contribute to disparities in access to health care and health outcomes (regarding mental health, maternal health, or infant health, for instance).[340] Many commenters stated that issuers of STLDI policies are able to discriminate against individuals on the basis of health status or preexisting conditions, age, or gender.

Consumers with low health literacy, which disproportionately includes consumers with low incomes,[341] might also be misled into purchasing STLDI or fixed indemnity excepted benefits coverage under the mistaken impression that it would lower their out-of-pocket costs while providing comprehensive coverage with lower premiums. Consumers with low income or who are members of underserved racial and ethnic groups are more likely to be uninsured and face barriers in accessing care.[342] Individuals in these populations arguably face the greatest health and financial consequences if STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) proves inadequate. These individuals are also potentially most vulnerable to practices like post-claims underwriting and rescission that are common in the STLDI market, which could leave them without any coverage in a health crisis. Some commenters shared the Departments' concern over the disproportionate impact that non-comprehensive products may have on consumers with low incomes and consumers of underserved racial and ethnic groups. Some commenters indicated that individuals with low health literacy are disproportionately impacted by misleading and deceptive marketing practices, as discussed in section III.A of this preamble.

These final rules are expected to help address these health inequities by ensuring that consumers can more easily distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage and thereby encouraging enrollment in comprehensive coverage.

h. Regulatory Review Cost Estimation

If regulations impose administrative costs on entities (for example, the time needed to read and interpret rules), regulatory agencies should estimate the

[337] Previous studies have estimated the impact of the STLDI definition adopted in the 2018 final rules on enrollment in individual health insurance coverage, but in conjunction with the impact of elimination of the individual shared responsibility payment. *See* Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[338] *See, for example,* Barnes, Justin and Fumiko Chino (2022). ''Short-term Health Insurance Plans Come Up Short for Patients with Cancer,'' *JAMA Oncology,* Volume 8, Issue 8, available at: *https://jamanetwork.com/journals/jamaoncology/article-abstract/2793127.*

[339] Dieguez, Gabriela and Dane Hansen (2020). ''The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market,'' Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[340] *See, for example,* Hill, Latoya, Samantha Artiga, and Usha Ranji (2022). ''Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them,'' KFF, available at: *https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/.*

[341] *See, for example,* Hill, Latoya, Samantha Artiga, and Usha Ranji (2022). ''Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them,'' KFF, available at: *https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/.*

[341] *See, for example,* Rikard, RV, Maxine Thompson, Julie McKinney, and Alison Beauchamp (2016). ''Examining Health Literacy Disparities in the United States: A Third Look at the National Assessment of Adult Literacy,'' *BMC Public Health,* Volume 16, Issue 1, available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5022195/. See also* Davis, Stacy, Jonathan Wischhusen, Steven Sutton, Shannon Christy, Emmanuel Chavarria, Megan Sutter, Siddhartha Roy, Cathy Meade, and Clement Gwede (2020). ''Demographic and Psychosocial Factors Associated with Limited Health Literacy in a Community-based Sample of Older Black Americans,'' *Patient Education and Counseling,* Volume 103, Issue 2, available at: *https://doi.org/10.1016/j.pec.2019.08.026.*

[342] *See* Tolbert, Jennifer, Kendal Orgera, and Anthony Damico (2020). ''Key Facts about the Uninsured Population,'' KFF, available at: *https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/. See also* Artiga, Samantha, Latoya Hill, Kendal Orgera, and Anthony Damico (2021). ''Health Coverage by Race and Ethnicity, 2010–2019,'' KFF, available at: *https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/. See also* KFF (2021). ''Adults Who Report Not Having a Personal Doctor/Health Care Provider by Race/Ethnicity,'' available at: *https://www.kff.org/other/state-indicator/percent-of-adults-reporting-not-having-a-personal-doctor-by-raceethnicity/. See also* KFF (2021). ''Adults Who Report Not Seeing a Doctor in the Past 12 Months Because of Cost by Race/Ethnicity,'' available at: *https://www.kff.org/other/state-indicator/percent-of-adults-reporting-not-seeing-a-doctor-in-the-past-12-months-because-of-cost-by-raceethnicity/.*

total cost associated with regulatory review.[343] In the 2023 proposed rules, the Departments assumed that approximately 250 entities would review the 2023 proposed rules. The Departments acknowledged that the number of entities reviewing the 2023 proposed rules could be higher or lower than anticipated. The Departments ultimately received 571 unique comments on the 2023 proposed rules that pertained to the proposals for STLDI and fixed indemnity excepted benefits coverage, of which 247 commenters were identified as entities (for example, issuers, State insurance departments, industry associations, and advocacy organizations). Based on the comments received, the Departments now estimate that the 571 unique commenters that commented on the 2023 proposed rules, along with at least one additional individual from each of the 247 entities commenting on the 2023 proposed rules, will review these final rules. That is, the Departments estimate that at least 818 individuals will read and interpret these final rules.

Using wage information from the Bureau of Labor Statistics, for Business Operations Specialists (All Other), to account for median labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs), the Departments estimate that the cost of reviewing these final rules will be $73.06 per hour.[344] The Departments estimate that it will take each reviewing individual approximately 6 hours on average to review these final rules, with an associated cost of $438.36 (6 hours × $73.06). Therefore, the Departments estimate that the (one-time) total cost of reviewing these final rules will be approximately $358,578 (818 × $438.36). The Departments sought comments on this approach to estimating the total burden and cost for interested parties to read and interpret the rules, and received one comment arguing that reading and understanding the rules would take far longer than the 4 hours estimated in the 2023 proposed rules. The Departments agree that it might take some reviewers longer than the previously estimated 4 hours, or the currently estimated 6 hours, to read and interpret the rules, but that an average estimate is reasonable.

[343] *See* Office of the Assistant Secretary for Planning and Evaluation (2017). ''Guidelines for Regulatory Impact Analysis,'' available at: *https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.*

[344] *See* Bureau of Labor Statistics (2022). ''National Occupational Employment and Wage Estimates,'' available at: *https://www.bls.gov/oes/current/oes_nat.htm.*

C. Regulatory Alternatives—Departments of Health and Human Services and Labor

In developing the proposed rules, the Departments considered various alternative approaches. The Departments considered leaving in place the duration standards for STLDI established in the 2018 final rules but concluded that the 2018 final rules' duration standards were too lengthy for the reasons described in section III.A.2 of this preamble. The Departments also considered proposing to limit the maximum duration of STLDI policies to a less-than-6-month period to minimize disruption for consumers in some (but not all) States that have implemented a less than-6-month period, to a less than-3-month period as implemented in the 2016 final rules, or otherwise shortening the maximum duration to a time period shorter than allowed under current regulations. However, as further discussed in in section III.A.2 of this preamble, the Departments ultimately decided to propose and finalize a maximum duration of no more than 4 months to align with the rules regarding the 90-day waiting period limitation and the 1-month reasonable and bona fide employment-based orientation period that is permitted under the ACA.

The Departments considered proposing to limit stacking of STLDI policies, whether sold by the same or different issuer. However, after considering the potential challenges issuers and State regulators would face in attempting to determine whether an individual had previously enrolled in an STLDI policy with a different issuer, the Departments decided to propose to limit stacking only where STLDI is sold to an individual by the same issuer and sought comments on whether to extend the limit on stacking to STLDI sold to an individual by issuers that are members of the same controlled group. Some commenters suggested limiting stacking of multiple or consecutive STLDI policies sold by issuers that are members of the same controlled group or sold to members of the same household. Other commenters supported the Departments preventing stacking of STLDI policies sold by unaffiliated issuers. The Departments decided that limiting the sale of STLDI policies offered by issuers that are members of the same controlled group would prevent issuers from using their corporate structure to circumvent the rules related to maximum duration, but it is not apparent to the Departments that limiting stacking across unaffiliated issuers or different members of the same household accomplishes any similar goal.

For new STLDI sold or issued on or after the effective date of the final rules, the Departments proposed an applicability date for the amendments to the Federal definition of STLDI that would apply for coverage periods beginning on or after the effective date of the final rules. Some commenters expressed concern that issuers of STLDI would need more time to complete a number of administrative tasks—such as evaluating plan designs, updating system processes, and re-filing policy forms with State regulators—and suggested the Departments finalize an applicability date between 90 days and 12 months after the effective date of the final rules. Other commenters were concerned about the potential for consumer confusion when STLDI is marketed and sold during the annual individual market open enrollment period. To provide more time for issuers to come into compliance with these final rules for new STLDI policies and ensure that STLDI with a longer maximum duration is not marketed during the next annual individual market open enrollment period, the Departments decided that for new STLDI sold or issued on or after September 1, 2024, the revised Federal definition of STLDI under these final rules will apply for coverage periods beginning on or after September 1, 2024. This will allow consumers who enroll in a new STLDI policy on or after September 1, 2024, to avoid a gap between the STLDI policy and when comprehensive coverage purchased during the next individual market open enrollment period will begin.

The Departments considered proposing a limit on the marketing or sale of STLDI during the annual individual market open enrollment period. The Departments are concerned that aggressive and deceptive marketing practices by some issuers have lured consumers, looking for comprehensive coverage, into enrolling in STLDI, exposing them to financial risk. The Departments appreciated the comments received regarding how the Departments can support State efforts to limit the marketing and/or sale of STLDI during the open enrollment period and will take these comments into consideration as the Departments consider potential actions they can take to address the marketing and sale of STLDI during the individual market open enrollment period.

With respect to the proposed amendments to the notices provided to consumers considering enrolling in or purchasing STLDI, the Departments

considered including a complete list of Federal protections that apply to consumers enrolled in comprehensive coverage versus STLDI. This approach would more fully distinguish STLDI from comprehensive coverage and highlight in greater detail the risks to consumers of enrolling in STLDI instead of comprehensive coverage. However, after a review of the comments, consulting with plain language experts and conducting consumer testing, the Departments are of the view that providing a complete comparison of protections that a consumer would forgo by enrolling in STLDI rather than comprehensive coverage would result in a lengthy, complex notice that could be difficult for the typical consumer to understand. Increasing the length and complexity of the notice would also increase burden for issuers to provide the notice on policy documents and marketing and application materials as required by these final rules. The Departments solicited comments on all aspects of the revised notice, including whether a different format or presentation would result in a more useful, consumer-friendly notice. For a more detailed discussion of the notices considered, please reference section III.A.4 of this preamble.

The Departments considered several options when finalizing the notice requirements for fixed indemnity excepted benefits coverage in the group market. HHS considered the same options when revising the content and standards for the consumer notice in the individual market. As discussed in section III.B.1 of this preamble, consideration was given to changes to the wording, appearance and timing related to the notice provisions. The Departments considered different applicability dates for these notices, including applying the notice to plan years (or in the individual market, coverage periods) (including renewals) beginning on or after the effective date of these final rules (as proposed), September 1, 2024 (which would align with the applicability date finalized in these rules for the STLDI notice provision), January 1, 2025, and later dates such as January 1, 2027. The Departments concluded that applying the notice to plan years (or in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025, strikes an appropriate balance between providing plans and issuers offering fixed indemnity excepted benefits coverage with additional time to add or update the notice and ensuring that the notices are present for new enrollments and renewals offered on a calendar year basis. The Departments are of view that a large proportion of group market fixed indemnity excepted benefits coverage, for which the notice will be new, are likely to be offered on a calendar year basis, as part of an employer's open enrollment period for their employees. In addition, one commenter suggested that the Departments should require an attestation from whomever sells fixed indemnity excepted benefits coverage, confirming that the risks and limitations were explained during the sale. The Departments are of the view that it would be more effective and efficient to provide all prospective enrollees with consistent messaging on all marketing, application, and enrollment materials (and, in the individual market, also on the first page of the policy, certificate, or contract of insurance). The Departments also declined to impose an attestation requirement based on the associated cost and administrative burden to plans, issuers, plan sponsors, agents, and brokers.

One commenter suggested that the Departments should explore additional consumer protection measures, such as requiring plans and issuers to provide prospective consumers with a complete and easily searchable schedule of benefits prior to purchase, as well as a longer free-look period in which an enrollee can cancel the plan for any reason at no cost. The Departments agree that these features would be beneficial and encourage plans and issuers to offer them to the extent feasible.

D. Paperwork Reduction Act

These final rules revise the Federal definition of STLDI to provide that a revised notice must be prominently displayed (in either paper or electronic form) in at least 14-point font on the first page of the policy, certificate, or contract of insurance and in any marketing, application, and enrollment materials, including for renewals or extensions (including on websites that advertise or enroll in STLDI). These notice provisions apply for both new and existing STLDI for coverage periods beginning on or after September 1, 2024.

These final rules also amend the regulations regarding fixed indemnity excepted benefits coverage in the individual market to provide that a revised notice must be prominently displayed (in either paper or electronic form) on the first page of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment (or reenrollment) materials. These final rules also amend the regulations regarding fixed indemnity excepted benefits coverage in the group market to provide that a notice must be prominently displayed (in either paper or electronic form) on the first page of any marketing, application, and enrollment (or reenrollment) materials. These notice provisions for group and individual market fixed indemnity excepted benefits coverage are applicable to both new and existing coverage with respect to plan years (in the individual market, coverage periods) beginning on or after January 1, 2025.

The Departments are providing the exact text for the STLDI and fixed indemnity excepted benefits coverage notices in these final rules, and the language will not need to be customized. The burden associated with these notices is therefore not subject to the Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2) because these notices do not contain a ''collection of information'' as defined in 44 U.S.C. 3502(3). Consequently, this document need not be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Departments solicited comments on the potential burden on issuers if the final rules were to include required notices with language that would need to be customized with State-specific information, as discussed in this preamble at section III.A.4 for STLDI and section III.B.1.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*) requires agencies to analyze options for regulatory relief of small entities and to prepare a regulatory flexibility analysis to describe the impact of a rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' The data and conclusions presented in this section amount to the Departments' final regulatory flexibility analysis under the RFA.

1. Need for Regulatory Action, Objectives, and Legal Basis

This rulemaking is authorized by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act, which authorize the Secretaries of the

Treasury, Labor, and HHS to issue such regulations as may be necessary or appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act.

These final rules address specific issues that are critical to ensuring that consumers can clearly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage and make better informed decisions about the coverage they chose to purchase. As discussed earlier in this RIA, STLDI and fixed indemnity insurance tend to offer limited benefits and have relatively low actuarial values when compared to comprehensive coverage. Because STLDI and fixed indemnity insurance are sold outside of the Exchanges and are generally not subject to the Federal consumer protections and requirements for comprehensive coverage, consumers may have limited information about the limitations, value, and quality of the coverage being sold, and it might be mistakenly viewed as a substitute for comprehensive coverage.

Generally, these final rules revise the Federal definition of STLDI for new policies, certificates, or contracts of insurance to limit their term to 3 months and maximum duration, within a 12-month period, to 4 months. Additionally, these final rules further revise the Federal definition of STLDI and amend the regulations regarding fixed indemnity excepted benefits coverage to provide that a notice for both new and existing STLDI and fixed indemnity excepted benefits coverage must be prominently displayed (in either paper or electronic form) on the first page of any marketing, application, and enrollment (or reenrollment) materials, as described in this preamble at sections III.A.5 and III.B.1.

These final rules will support the goals of the ACA by increasing access to affordable and comprehensive health coverage, strengthening health insurance markets, and promote better consumer understanding of coverage options.

2. Number of Affected Small Entities as Defined by the Regulatory Flexibility Act

The provisions in these final rules will affect issuers of STLDI, issuers of fixed indemnity excepted benefits coverage, and agents and brokers selling STLDI and fixed indemnity excepted benefits coverage. For purposes of analysis under the RFA, the Departments consider issuers of STLDI and issuers of fixed indemnity excepted benefits coverage that have average annual receipts of $47 million or less as small entities. Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[345] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from MLR annual report submissions for the 2021 MLR reporting year, approximately 87 out of 483 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[346] However, it should be noted that over 77 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $47 million. The Departments expect this to be the case for issuers of STLDI and fixed indemnity excepted benefits coverage. As noted earlier in this RIA, the Departments are unable to precisely determine how many small issuers of STLDI and fixed indemnity excepted benefits coverage will be affected by these final rules. Nevertheless, the Departments note that the NAIC reported that there were at least 28 issuers of STLDI in the individual market across the U.S. in 2022 and at least 93 issuers of ''other non-comprehensive coverage'' (including fixed indemnity insurance) in the individual market across the U.S. in 2022.[347] Data regarding issuers of STLDI and ''other medical (non-comprehensive)'' coverage are only available for the individual market. The Departments have identified 2 issuers of STLDI and 3 issuers of fixed indemnity insurance that fall below the $47 million threshold and could potentially be impacted by these final rules.[348] These issuers will incur costs associated with the notice provisions and could also incur one-time costs to modify their products to comply with the provisions for STLDI and fixed indemnity excepted benefits coverage that are being finalized in these final rules and to file amended marketing materials and plan documents with State departments of insurance, as discussed further in section V.E.3 of this preamble. The Departments solicited comments on the number of small issuers of STLDI and the number of small issuers of fixed indemnity excepted benefits coverage but did not receive any additional information to inform the analysis.

For purposes of analysis under the RFA, the Departments consider agents and brokers that have average annual receipts of $15 million or less as small entities. Agents and brokers are classified under NAICS code 524210 (Insurance Agencies and Brokerages), with a size standard of $15 million or less. These rules may affect agents and brokers if there is an impact on enrollment in STLDI or fixed indemnity excepted benefits products. There is the potential for the agent and broker compensation[349] associated with the sale of STLDI and fixed indemnity excepted benefits coverage to be negatively affected if there is a reduction in sales of that coverage. There is also the potential for agent and broker compensation associated with the sale of individual health insurance coverage to be positively affected if there is an increase in sales of that coverage. However, due to a lack of data, the Departments were unable to precisely estimate how many agents and brokers might be affected by the 2023 proposed rules and the magnitudes of the potential changes in compensation.[350] The Departments solicited comments on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by the 2023 proposed rules. Many commenters stated that the financial impacts of the proposed Federal definitions for STLDI and fixed indemnity excepted benefits coverage on agents and brokers would be significant, particularly given the relatively low commission rates that agents and brokers receive from the sale of Exchange plans as compared to STLDI and fixed indemnity insurance. Another commenter stated that the regulatory flexibility analysis lacked sufficient data to account for the

[345] Small Business Administration (2023). ''Table of Size Standards (last updated March 2023),'' available at: *https://www.sba.gov/document/support-table-size-standards.*

[346] Based on internal calculations. Source: CMS, Medical Loss Ratio Data and System Resources, available at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[347] *Id.*

[348] This was informed by a review of issuers' financial records ranging from 2018–2022.

[349] Compensation includes commissions, fees, or other incentives (for example, rewards or bonuses) as established in the relevant contract between an issuer and the agent or broker.

[350] Previously, in 86 FR 51730, 51756, the Departments noted that a total of 55,541 agents and brokers work with issuers. Many of these agents and brokers are likely to be employed by small entities.

potential impacts on agents and brokers. Commenters did not provide additional information on the number of agents and brokers that sell STLDI and fixed indemnity insurance or data that would assist in quantifying the impact of these final rules on agents and brokers. As noted throughout this preamble, and discussed in section V.B.2.f of this preamble, due to a lack of data and information, there are several areas of uncertainty regarding the potential market impacts of these final rules. As a result, there is also some uncertainty about the potential impact on the compensation of agents and brokers.

To summarize, there is some uncertainty about the impacts of these rules on the revenue of issuers of STLDI and fixed indemnity excepted benefits coverage and the compensation of agents and brokers selling STLDI and fixed indemnity insurance. Nevertheless, the Departments acknowledge that to comply with these final rules, issuers of STLDI fixed indemnity excepted benefits coverage will incur a cost and that agents and brokers may be impacted by these final rules due to the potential impacts on enrollment in STLDI or fixed indemnity excepted benefits products. A brief discussion of the regulatory alternatives is found in section V.E.4 of this preamble and a more detailed discussion of the regulatory alternatives considered is found in section V.C of this preamble.

3. Compliance Requirements and Costs

As discussed in section V.B.2.h of this preamble, the Departments estimate the one-time cost to review these final rules will be approximately $438 per entity (6 hours x $73.06). As noted in section V.B.2.d of this preamble, the Departments acknowledge that issuers will also incur one-time costs to modify their products to comply with the provisions for STLDI and fixed indemnity excepted benefits coverage that are being finalized in these rules and filing amended marketing materials and plan documents with State departments of insurance. These costs are expected to vary by issuer depending on the number of States in which they offer products, the number of products they offer, and the overall scale of their operations.[351] Issuers of STLDI and fixed indemnity excepted benefits coverage will incur costs associated with the notice provisions in these final rules, which the Departments estimate to be approximately $1,066 per issuer,[352] as described in section V.B.2.d of this preamble.

4. Duplication, Overlap, and Conflict With Other Rules and Regulations

The Departments do not anticipate any duplication, overlap, or conflict with other rules and regulations associated with these rules. These rules revise current regulations to ensure that consumers can clearly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage.

5. Significant Alternatives

The regulatory alternatives considered in developing these rules are discussed in section V.C of this preamble. The Departments are of the view that none of these alternatives would both achieve the policy objectives and goals of these final rules as previously stated and be less burdensome to small entities. The Departments did receive comments on alternative timelines for issuers to comply with the requirements (including small entities). The Departments decided to delay the applicability dates for certain provisions to provide more time for issuers (including small entities) to modify their products and implement the required changes while still achieving the objectives of these final rules. For a more detailed discussion of the regulatory alternatives considered, please refer to section V.C of this preamble.

6. Impact on Small Rural Hospitals

In addition, section 1102(b) of the Social Security Act requires agencies to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. The Departments welcomed comments on this and did not receive any comments specifically regarding the impact of the provisions proposed in the 2023 proposed rules on small rural hospitals. Many commenters did note that the provisions proposed in the 2023 proposed rules could increase the potential number of uninsured individuals and a few commenters indicated that hospitals may find themselves treating more uninsured patients that are unable to pay for the services rendered. While these final rules are not subject to section 1102 of the Social Security Act, the Departments are of the view that these final rules will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Special Analyses—Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a rule that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. That threshold is approximately $183 million in 2024. As detailed in section V.B.2.d of this preamble, the combined impact on State, local, or Tribal governments and the private sector is not expected to be above the $183 million threshold.

H. Federalism

Executive Order 13132 establishes certain requirements that Federal agencies must meet when they issue rules that impose substantial direct costs on State and local governments, preempt State law, or otherwise have federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy-making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC.

In the Departments' view, these final rules have Federalism implications because they may have direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among various levels of government. Health insurance issuers offering STLDI and plans and issuers

[351] The Departments do not have enough data or information to quantify these costs.

[352] (4 business operation specialist hours * $73.06) + (4 administrative assistant hours * $42.38) + (8 web developer hours * $75.96) = $1,066.24.

offering fixed indemnity excepted benefits coverage must meet the minimum Federal standards for such coverage not to be subject to the Federal consumer protections and requirements for comprehensive coverage. States with State requirements for STLDI or fixed indemnity excepted benefits coverage that do not follow the minimum Federal standards for such coverage, as amended by these final rules, may therefore choose to update their laws and regulations regarding STLDI or fixed indemnity excepted benefits coverage to align with the minimum Federal standards so that such coverage issued in the State is treated as exempt from the Federal consumer protections and requirements for comprehensive coverage.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating an employee benefit plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and sections 2724 and 2762 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a) and 148.210(b)) apply so that the Federal consumer protections and requirements for comprehensive coverage are not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a Federal requirement.[353] The conference report accompanying HIPAA, when this Federal preemption standard was first established for the requirements in title XXVII of the PHS Act, indicates that this is intended to be the ''narrowest'' preemption of State laws.[354]

These final rules define STLDI for purposes of the Code, ERISA, and the PHS Act. Insurance coverage that meets the definition of STLDI in these final rules will qualify for the exception to the Federal definition of individual health insurance coverage and be exempt from the Federal consumer protections and requirements applicable to comprehensive coverage. Nothing in these final rules prevents regulation of STLDI for purposes of State law. For example, States may determine whether to permit the sale of STLDI in their insurance markets. If a State law permits or requires an action that is inconsistent with the Federal definition of STLDI, any coverage offered pursuant to that State law that does not meet the standards set forth in these final rules would not qualify as STLDI under Federal law and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. For example, if a State were to prohibit policies issued in that State from including the Federal consumer notice, then coverage in that State that did not include the Federal consumer notice language would not qualify for the exclusion from the PHS Act definition of individual health insurance coverage and thus would be subject to the Federal consumer protections and requirements applicable to individual health insurance coverage.

Similarly, if a State law were to require the removal of language from the Federal consumer notice for fixed indemnity excepted benefits coverage finalized in these final rules, any policy issued in the State that did not include the Federal notice would not be considered fixed indemnity excepted benefits coverage for purposes of Federal law and thus would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage.

Many commenters on the 2023 proposed rules discussed the federalism implications of the proposed provisions for STLDI and fixed indemnity excepted benefits coverage, as discussed in sections III.A.1 and III.B.1, respectively of this preamble.

The Departments continue to be of the view that there is a need for action regarding STLDI and fixed indemnity excepted benefits coverage at the Federal level given, among other factors, the need to promote consumer understanding of coverage options and ensure consumers do not mistakenly enroll in STLDI and fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage, the prevalence of aggressive and deceptive sales and marketing practices, reports of increased enrollment in STLDI through out-of-State associations, and the potential inability of States to regulate and collect information about these associations.[355]

While developing these final rules, the Departments have attempted to balance States' interests in regulating health insurance issuers and their health insurance markets with Congress' intent to establish a general Federal framework for health insurance coverage, including the provision of certain key, uniform minimum protections to consumers enrolled in comprehensive coverage in every State. It is the Departments' view that by doing so they have complied with the requirements of Executive Order 13132.

I. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, this rule has been transmitted to the Congress and the Comptroller General for review.

Heather C. Maloy,

Acting Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Aviva Aron-Dine,

Acting Assistant Secretary (Tax Policy), Department of the Treasury.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Child support, Employee benefit plans, Health care, Health insurance, Infants and children, Maternal and child health, Penalties, Pensions, Privacy, Reporting and recordkeeping requirements.

[353] A similar preemption provision was established for the Exchange and other Federal health insurance requirements that are codified outside of title XXVII of the PHS Act. See sections 1311(k) and 1321(d) of the ACA.

[354] *See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018 and available at: *https://www.congress.gov/congressional-report/104th-congress/house-report/736/1.*

[355] Keith, Katie (2020). ''New Congressional Investigation of Short-Term Plans,'' *Health Affairs,* available at: *https://www.healthaffairs.org/do/10.1377/forefront.20200626.227261/full/. See also* Curran, Emily, Dania Palanker, and Sabrina Corlette (2019). ''Short-Term Health Plans Sold Through Out-of-State Associations Threaten Consumer Protections,'' Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/short-term-health-plans-sold-through-out-state-associations-threaten-consumer-protections.*

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Insurance companies, Penalties, Reporting and recordkeeping requirements.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

For the reasons stated in the preamble, the Department of the Treasury and the IRS amend 26 CFR part 54 as set forth below:

PART 54—PENSION AND EXCISE TAX

■ 1. The general authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ 2. Section 54.9801–2 is amended by revising the definition of ''Short-term, limited-duration insurance'' to read as follows:

§ 54.9801–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

(2) For purposes of paragraph (1)(i) of this definition, the term ''controlled group'' means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such

holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

* * * * *

■ 3. Section 54.9831–1 is amended by adding paragraphs (c)(4)(ii)(D) and (c)(4)(iv) to read as follows:

§ 54.9831–1 Special rules relating to group health plans.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (c)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(*3*) If a plan or issuer provides a notice satisfying the requirements in paragraphs (c)(4)(ii)(D)(*1*) and (*2*) of this section to a participant, the obligation to

provide the notice is considered to be satisfied for both the plan and issuer.

* * * * *

(iv) *Severability.* If any provision of this paragraph (c)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (c)(4) and shall not affect the remainder thereof.

* * * * *

■ 4. Section 54.9833–1 is revised to read as follows:

§ 54.9833–1 Applicability dates.

Sections 54.9801–1 through 54.9801–6, and 54.9831–1 and this section are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 54.9801–2 applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 26 CFR 54.9801–2, revised as of April 1, 2023, continues to apply, except that paragraph (2) of the definition of *short-term, limited-duration insurance* in § 54.9801–2 applies for coverage periods beginning on or after September 1, 2024.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 5. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 6. Section 2590.701–2 is amended by revising the definition of ''Short-term, limited-duration insurance'' to read as follows:

§ 2590.701–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

(2) For purposes of paragraph (1)(i) of this definition, the term ''controlled group'' means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to

entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

* * * * *

■ 7. Section 2590.732 is amended by adding paragraphs (c)(4)(ii)(D) and (c)(4)(iv) to read as follows:

§ 2590.732 Special rules relating to group health plans.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (c)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(*3*) If a plan or issuer provides a notice satisfying the requirements in paragraphs (c)(4)(ii)(D)(*1*) and (*2*) of this section to a participant, the obligation to provide the notice is considered to be satisfied for both the plan and issuer.

* * * * *

(iv) *Severability.* If any provision of this paragraph (c)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (c)(4) and shall not affect the remainder thereof.

* * * * *

■ 8. Section 2590.736 is revised to read as follows:

§ 2590.736 Applicability dates.

Sections 2590.701–1 through 2590.701–8 and 2590.731 through 2590.736 are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 2590.701–2 applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 29 CFR 2590.701–2, revised as of July 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 2590.701–2 applies for coverage periods beginning on or after September 1, 2024.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 146, and 148 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 9. The authority citation for part 144 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended.

■ 10. Section 144.103 is amended by revising the definition of ''Short-term, limited-duration insurance'' to read as follows:

§ 144.103 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

(2) For purposes of paragraph (1)(i) of this definition, the term ''controlled group'' means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to

entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 11. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

■ 12. Section 146.125 is revised to read as follows:

§ 146.125 Applicability dates.

Section 144.103 of this subchapter and §§ 146.111 through 146.119, 146.143, and 146.145 are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 144.103 of this subchapter applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 45 CFR 144.103, revised as of October 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 144.103 applies for coverage periods beginning on or after September 1, 2024.

■ 13. Section 146.145 is amended by adding paragraphs (b)(4)(ii)(D) and (b)(4)(iv) to read as follows:

§ 146.145 Special rules relating to group health plans.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (b)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(*3*) If a plan or issuer provides a notice satisfying the requirements in paragraphs (b)(4)(ii)(D)(*1*) and (*2*) of this section to a participant, the obligation to provide the notice is considered to be satisfied for both the plan and issuer.

* * * * *

(iv) *Severability.* If any provision of this paragraph (b)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (b)(4) and shall not affect the remainder thereof.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 14. The authority citation for part 148 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–11 300gg–91, and 300gg–92, as amended.

■ 15. Section 148.102 is amended by revising paragraph (b) to read as follows:

§ 148.102 Scope and applicability dates.

* * * * *

(b) *Applicability dates.* Except as provided in §§ 148.124, 148.170, and 148.180, the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 144.103 of this subchapter applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 45 CFR 144.103, revised as of October 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 144.103 applies for coverage periods beginning on or after September 1, 2024.

■ 16. Section 148.220 is amended by revising paragraph (b)(4) to read as follows:

§ 148.220 Excepted benefits.

* * * * *

(b) * * *

(4) Hospital indemnity or other fixed indemnity insurance only if—

(i) There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage;

(ii) The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, $100/day or $50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage; and

(iii)(A) For coverage periods beginning on or after January 1, 2025, the issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment or reenrollment materials that are provided at or before the time an individual has the opportunity to apply, enroll or reenroll in coverage, and on the first page of the policy, certificate, or contract of insurance, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

(B) For coverage periods beginning on or after January 1, 2015, and prior to January 1, 2025, the issuer continues to follow the notice provision in 45 CFR 148.220(b)(4)(iv), revised as of October 1, 2023.

(iv) If any provision of this paragraph (b)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (b)(4) and shall not affect the remainder thereof.

* * * * *

[FR Doc. 2024–06551 Filed 3–28–24; 8:45 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–C

FEDERAL REGISTER

Vol. 89 Wednesday,

No. 65 April 3, 2024

Part VII

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 488

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2025; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 488

[CMS–1802–P]

RIN 0938–AV30

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2025

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This rule proposes changes and updates to the policies and payment rates used under the Skilled Nursing Facility (SNF) Prospective Payment System (PPS) for FY 2025. First, we are proposing to rebase and revise the SNF market basket to reflect a 2022 base year. Next, we are proposing to update the wage index used under the SNF PPS to reflect data collected during the most recent decennial census. Additionally, we are proposing several technical revisions to the code mappings used to classify patients under the Patient Driven Payment Model (PDPM) to improve payment and coding accuracy. Finally, this proposed rule includes a Request for Information (RFI) on potential updates to the Non-Therapy Ancillary (NTA) component of PDPM. This rulemaking also proposes to update the requirements for the SNF Quality Reporting Program and the SNF Value-Based Purchasing Program. We are also proposing to expand CMS' enforcement authority for imposing civil money penalties (CMPs). Finally, this proposed rule includes proposals to strengthen nursing home enforcement requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 28, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1802–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1802–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1802–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *PDPM@cms.hhs.gov* for issues related to the SNF PPS.

Heidi Magladry, (410) 786–6034, for information related to the skilled nursing facility quality reporting program.

Christopher Palmer, (410) 786–8025, for information related to the skilled nursing facility value-based purchasing program.

Celeste Saunders, (410) 786–5603, for information related to Nursing Home.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this proposed rule can be accessed on the SNF PPS Wage Index home page, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Burwell at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

I. Executive Summary

A. Purpose

This proposed rule would update the SNF prospective payment rates for fiscal year (FY) 2025, as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of this proposed rule) in the **Federal Register** before the August 1 that precedes the start of each FY. Additionally, in this proposed rule, we are proposing to rebase and revise the SNF market basket to reflect a 2022 base year. Next, we are proposing to update the wage index used under the SNF PPS to reflect data collected during the most recent decennial census. We are also proposing several technical revisions to the code mappings used to classify patients under the PDPM to improve payment and coding accuracy. This proposed rule includes an RFI on potential updates to the non-therapy ancillary (NTA) component of PDPM. This proposed rule proposes the collection of four new items as standardized patient assessment data elements and the modification of one item collected and submitted using the Minimum Data Set (MDS) beginning with the FY 2027 SNF QRP. This proposed rule also proposes that SNFs, which participate in the SNF QRP, participate in a validation process beginning with the FY 2027 SNF QRP, and also includes a request for information on quality measure concepts under consideration for future SNF QRP program years. Finally, this proposed rule proposes new requirements for the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program, including a proposed measure selection, retention, and removal policy, a proposed technical measure updates policy, a proposed measure minimum for FY 2028 and subsequent years, proposed updates to the review and correction policy to include new measure data sources, proposed updates to the Extraordinary Circumstances Exception policy, and proposed SNF VBP regulation text updates. We are also proposing revisions to existing long-term care (LTC) enforcement regulations that would enable CMS and the States to impose civil money penalties to better reflect amounts that are more consistent with the type of noncompliance that occurred.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the Federal rates in this proposed rule would update the annual rates that we published in the SNF PPS final rule for FY 2024 (88 FR 53200, August 7, 2023). In addition, this proposed rule includes a forecast error adjustment for FY 2025. Additionally, in this proposed rule we are proposing to rebase and revise the SNF market basket to reflect a 2022 base year. Next, we are proposing to update the wage index used under the SNF PPS to reflect data collected during the most recent decennial census. We are also proposing several technical revisions to the code mappings used to classify patients under the PDPM to improve payment and coding accuracy. Finally, this proposed rule includes an RFI on potential updates to the NTA component of PDPM.

We propose revisions to CMS' existing enforcement authority to expand the number of CMPs that can be imposed on LTC facilities. The proposed revisions will allow for more per-instance (PI) CMPs to be imposed in conjunction with per-day (PD) CMPs. This proposal will also expand our authority to impose multiple PI CMPs when the same type of noncompliance is identified on more than one day. CMS' current enforcement regulation does not allow for PI and PD CMPs to be imposed for the same survey and also makes it difficult for CMS to impose multiple PI CMPs for the same type of noncompliance. Lastly, the proposed revisions will enable CMS or the States to impose a CMP for the number of days of past noncompliance since the last three standard surveys to ensure that identified noncompliance that is subject to a penalty may receive one, if that is the remedy that is imposed.

We are proposing several updates for the SNF VBP Program. We are proposing to adopt a measure selection, retention, and removal policy that aligns with policies we have adopted in other CMS quality programs. We are proposing a technical measure updates policy to allow us to update the numerical values of the performance standards for a program year if necessary to account for the implementation of non-substantive technical updates to the measure specifications between the baseline period and the performance period. We are proposing to adopt the same measure minimum we previously finalized for the FY 2027 program year for the FY 2028 program year and subsequent program years. We are proposing modifications to Phase One of our review and correction policy to account for measures that are calculated using Payroll-Based Journal (PBJ) and MDS measure data beginning with the FY 2026 and FY 2027 program years, respectively. We are proposing to update the instructions for requesting an extraordinary circumstance exception (ECE) and to allow SNFs to request an ECE if the SNF can demonstrate that, as a result of the extraordinary circumstance, it cannot report SNF VBP data on one or more measures by the specified deadline. Lastly, we are proposing several updates to the SNF VBP regulation text to align with previously finalized definitions and policies.

Beginning with the FY 2027 SNF QRP, we are proposing to require SNFs to collect and submit through the MDS four new items as standardized patient assessment data elements under the social determinants of health (SDOH) category: one item for Living Situation, two items for Food, and one item for Utilities. We are also proposing to modify the current Transportation item. We are also proposing to adopt a similar validation process for the SNF QRP that we adopted for the SNF VBP beginning with the FY 2027 SNF QRP. We are also proposing to amend regulation text at § 413.360 to implement the validation process we propose. Finally, this proposed rule also includes a Request for Information (RFI) on quality measure concepts under consideration for future SNF QRP years.

C. Summary of Cost and Benefits

TABLE 1—ESTIMATED COST AND BENEFITS

Proposals	Estimated total transfers/costs
FY 2025 SNF PPS payment rate update	The overall economic impact of this proposed rule is an estimated increase of $1.3 billion in aggregate payments to SNFs during FY 2025.
FY 2027 SNF QRP changes	The overall economic impact of this proposed rule to SNFs is an estimated cost of $2,322,541.48 annually to SNFs beginning with the FY 2027 SNF QRP.
FY 2026 Changes Due to Removal of MDS Items No Longer Needed for Case-Mix Determination.	The overall economic impact of this proposed rule to SNFs is an estimated savings of $14,128,696.47 annually to SNFs beginning with FY 2026.
FY 2027 Changes Due to Proposal for Participation in a Validation Process.	The overall economic impact of this proposed rule to SNFs is an estimated cost of $813,067.95 annually to SNFs beginning with the FY 2027 SNF QRP.
FY 2025 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $187.69 million in aggregate payments to SNFs during FY 2025.
FY 2025 Nursing Home Enforcement changes	The overall economic impact the proposed changes to CMS' enforcement authority results in an estimated additional penalty amount totaling $25 million annually to long term care facilities, and $163,800 in annual administrative costs to CMS and states.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers virtually all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1888(g) to the Act, requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. In 2014, section 2(c)(4) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185, enacted October 6, 2014) amended section 1888(e)(6) of the Act, which requires the Secretary to implement a QRP for SNFs under which SNFs report data on measures and resident assessment data. Finally, section 111 of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, enacted December 27, 2020) amended section 1888(h) of the Act, authorizing the Secretary to apply up to nine additional measures to the VBP program for SNFs.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the Federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full Federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted Federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2024 (88 FR 53200, August 7, 2023), as amended by the subsequent correction notice (88 FR 68486, October 4, 2023).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** the following:

- The unadjusted Federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this proposed rule would set out the required annual updates to the per diem payment rates for SNFs for FY 2025.

III. Proposed SNF PPS Rate Setting Methodology and FY 2025 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem Federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the Federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using the SNF market basket, and then standardized for geographic variations

in wages and for the costs of facility differences in case-mix. In compiling the database used to compute the Federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the Federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas and adjusted the portion of the Federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2022 (86 FR 42444 through 42463), we rebased and revised the SNF market basket, which included updating the base year from 2014 to 2018. In this proposed rule, we propose to update the base year from 2018 to 2022.

The SNF market basket is used to compute the market basket percentage increase that is used to update the SNF Federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage increase is adjusted by a forecast error adjustment, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.4. of this proposed rule.

As outlined in this proposed rule, we propose a FY 2025 SNF market basket percentage increase of 2.8 percent based on IHS Global Inc.'s (IGI's) fourth quarter 2023 forecast of the proposed 2022-based SNF market basket (before application of the forecast error adjustment and productivity adjustment). We also propose that if more recent data subsequently become available (for example, a more recent estimate of the market basket and/or the productivity adjustment), we would use such data, if appropriate, to determine the FY 2025 SNF market basket percentage increase, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the SNF PPS final rule.

2. Proposed Market Basket Update for FY 2025

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage increase as the percentage change in the SNF market basket from the midpoint of the previous FY to the midpoint of the current FY. For the Federal rates outlined in this proposed rule, we use the percentage change in the SNF market basket to compute the update factor for FY 2025. This factor is based on the FY 2025 percentage increase in the proposed 2022-based SNF market basket reflecting routine, ancillary, and capital-related expenses. Sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(B)(i) of the Act require that the update factor used to establish the FY 2025 unadjusted Federal rates be at a level equal to the SNF market basket percentage increase. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2023 through September 30, 2024 to the average market basket level for the period of October 1, 2024 through September 30, 2025. This process yields a percentage increase in the proposed 2022-based SNF market basket of 2.8 percent.

As further explained in section III.B.3. of this proposed rule, as applicable, we adjust the percentage increase by the forecast error adjustment from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage increase in the market basket exceeds a 0.5 percentage point threshold in absolute terms. Additionally, section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage increase by the productivity adjustment (the 10-year moving average of changes in annual economy-wide private nonfarm business total factor productivity (TFP) for the period ending September 30, 2025) which is estimated to be 0.4 percentage point, as described in section III.B.4. of this proposed rule.

We also note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act (the market basket increase). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket percentage change being less than zero for a fiscal year and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004 and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2023 (the most recently available FY for which there is final data), the forecasted or estimated increase in the SNF market basket was 3.9 percent, and the actual increase for FY 2023 was 5.6 percent, resulting in the actual increase being 1.7 percentage points higher than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket

exceeds the 0.5 percentage point threshold, under the policy previously described (comparing the forecasted and actual market basket percentage increase), the FY 2025 market basket percentage increase of 2.8 percent would be adjusted upward to account for the forecast error adjustment of 1.7 percentage points, resulting in a SNF market basket percentage increase of 4.5 percent, which is then reduced by the productivity adjustment of 0.4 percentage point, discussed in section III.B.4. of this proposed rule. This results in a proposed SNF market basket update for FY 2025 of 4.1 percent.

Table 2 shows the forecasted and actual market basket increases for FY 2023.

TABLE 2—DIFFERENCE BETWEEN THE ACTUAL AND FORECASTED MARKET BASKET INCREASES FOR FY 2023

Index	Forecasted FY 2023 increase *	Actual FY 2023 increase **	FY 2023 difference
SNF	3.9	5.6	1.7

* Published in **Federal Register**; based on second quarter 2022 IGI forecast (2018-based SNF market basket).
** Based on the fourth quarter 2023 IGI forecast (2018-based SNF market basket), with historical data through third quarter 2023.

4. Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period).

The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of productivity for the U.S. We note that previously the productivity measure referenced at section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term MFP with TFP. BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. We refer readers to the BLS website at *www.bls.gov* for the BLS historical published TFP data. A complete description of the TFP projection methodology is available on our website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.* In addition, in the FY 2022 SNF final rule (86 FR 42429) we noted that, effective with FY 2022 and forward, we changed the name of this adjustment to refer to it as the ''productivity adjustment,'' rather than the ''MFP adjustment.''

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the productivity adjustment may result in the market basket percentage being less than zero for a FY and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the productivity adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in a productivity-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted Federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

Based on the data available for this FY 2025 SNF PPS proposed rule, the proposed productivity adjustment (the 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending September 30, 2025) is projected to be 0.4 percentage point.

Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), and as discussed previously in section III.B.1. of this proposed rule, the proposed market basket percentage increase for FY 2025 for the SNF PPS is based on IGI's fourth quarter 2023 forecast of the SNF market basket percentage increase, which is estimated to be 2.8 percent. This market basket percentage increase is then increased by 1.7 percentage points, due to application of the forecast error adjustment discussed earlier in section III.B.3. of this proposed rule. Finally, as discussed earlier in section III.B.4. of this proposed rule, we are applying a 0.4 percentage point productivity adjustment to the FY 2025 SNF market basket percentage increase. Therefore, the resulting proposed productivity-adjusted FY 2025 SNF market basket update is equal to 4.1 percent, which reflects a market basket percentage increase of 2.8 percent, plus the 1.7 percentage points forecast error adjustment, and reduced by the 0.4 percentage point productivity adjustment. Thus, we propose to apply a net SNF market basket update factor of 4.1 percent in our determination of the FY 2025 SNF PPS unadjusted Federal per diem rates.

5. Unadjusted Federal Per Diem Rates for FY 2024

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), in FY 2020 we implemented a new case-mix classification system to classify SNF patients under the SNF PPS, the PDPM. As discussed in section V.B.1. of that final rule (83 FR 39189), under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix

component, as existed under the previous RUG–IV model. We propose to use the SNF market basket, adjusted as described previously in sections III.B.1. through III.B.4. of this proposed rule, to adjust each per diem component of the Federal rates forward to reflect the change in the average prices for FY 2024 from the average prices for FY 2023. We also propose to further adjust the rates by a wage index budget neutrality factor, described in section III.D. of this proposed rule.

Further, in the past, we used the revised Office of Management and Budget (OMB) delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS proposed and final rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021. However, as further described in section V.A of this proposed rule, the current CBSAs are based on OMB standards contained in Bulletin 20–01, which is based on data collected during the 2010 Decennial Census. In this proposed rule, we are proposing to update the SNF PPS wage index using the CBSAs defined within Bulletin 23–01.

Tables 3 and 4 reflect the proposed unadjusted Federal rates for FY 2025, prior to adjustment for case-mix.

TABLE 3—PROPOSED FY 2025 UNADJUSTED FEDERAL RATE PER DIEM—URBAN

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$73.16	$68.10	$27.31	$127.52	$96.21	$114.20

TABLE 4—PROPOSED FY 2025 UNADJUSTED FEDERAL RATE PER DIEM—R

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$83.39	$76.59	$34.41	$121.83	$91.92	$116.31

C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the Federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, which took effect beginning October 1, 2019. The previous RUG–IV model classified most patients into a therapy payment group and primarily used the volume of therapy services provided to the patient as the basis for payment classification, thus creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

The PDPM uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS, consistent with the provisions of section 1888(e)(4)(G)(i) of the Act. As discussed in section IV.A. of this proposed rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The proposed FY 2025 payment rates set forth in this proposed rule reflect the use of the PDPM case-mix classification system from October 1, 2023, through September 30, 2024. The proposed case-mix adjusted PDPM payment rates for FY 2025 are listed separately for urban and rural SNFs, in Tables A5 and A6 with corresponding case-mix values.

Given the differences between the previous RUG–IV model and PDPM in terms of patient classification and billing, it was important that the format of Tables A5 and A6 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim to bill for covered SNF services. Under RUG–IV, the HIPPS code included the three-character RUG–IV group into which the patient classified, as well as a two-character assessment indicator code that represented the assessment used to generate this code. Under PDPM, while providers still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies.

Finally, the fifth character represents the assessment used to generate the HIPPS code.

Tables 5 and 6 reflect the PDPM's structure. Accordingly, Column 1 of Tables 5 and 6 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group.

Tables 5 and 6 do not reflect adjustments which may be made to the SNF PPS rates as a result of the SNF VBP Program, discussed in section VI. of this proposed rule, or other adjustments, such as the variable per diem adjustment.

TABLE 5—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.45	$106.08	1.41	$96.02	0.64	$17.48	ES3	3.84	$489.68	3.06	$294.40
B	1.61	117.79	1.54	104.87	1.72	46.97	ES2	2.90	369.81	2.39	229.94
C	1.78	130.22	1.60	108.96	2.52	68.82	ES1	2.77	353.23	1.74	167.41
D	1.81	132.42	1.45	98.75	1.38	37.69	HDE2	2.27	289.47	1.26	121.22
E	1.34	98.03	1.33	90.57	2.21	60.36	HDE1	1.88	239.74	0.91	87.55
F	1.52	111.20	1.51	102.83	2.82	77.01	HBC2	2.12	270.34	0.68	65.42
G	1.58	115.59	1.55	105.56	1.93	52.71	HBC1	1.76	224.44	.....	.....
H	1.10	80.48	1.09	74.23	2.7	73.74	LDE2	1.97	251.21	.....	.....
I	1.07	78.28	1.12	76.27	3.34	91.22	LDE1	1.64	209.13	.....	.....
J	1.34	98.03	1.37	93.30	2.83	77.29	LBC2	1.63	207.86	.....	.....
K	1.44	105.35	1.46	99.43	3.50	95.59	LBC1	1.35	172.15	.....	.....
L	1.03	75.35	1.05	71.51	3.98	108.69	CDE2	1.77	225.71	.....	.....
M	1.20	87.79	1.23	83.76	.....	.....	CDE1	1.53	195.11	.....	.....
N	1.40	102.42	1.42	96.70	.....	.....	CBC2	1.47	187.45	.....	.....
O	1.47	107.55	1.47	100.11	.....	.....	CA2	1.03	131.35	.....	.....
P	1.02	74.62	1.03	70.14	.....	.....	CBC1	1.27	161.95	.....	.....
Q	.....	.....	.....	.....	.....	.....	CA1	0.89	113.49	.....	.....
R	.....	.....	.....	.....	.....	.....	BAB2	0.98	124.97	.....	.....
S	.....	.....	.....	.....	.....	.....	BAB1	0.94	119.87	.....	.....
T	.....	.....	.....	.....	.....	.....	PDE2	1.48	188.73	.....	.....
U	.....	.....	.....	.....	.....	.....	PDE1	1.39	177.25	.....	.....
V	.....	.....	.....	.....	.....	.....	PBC2	1.15	146.65	.....	.....
W	.....	.....	.....	.....	.....	.....	PA2	0.67	85.44	.....	.....
X	.....	.....	.....	.....	.....	.....	PBC1	1.07	136.45	.....	.....
Y	.....	.....	.....	.....	.....	.....	PA1	0.62	79.06	.....	.....

TABLE 6—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.45	$120.92	1.41	$107.99	0.64	$22.02	ES3	3.84	$467.83	3.06	281.28
B	1.61	134.26	1.54	117.95	1.72	59.19	ES2	2.90	353.31	2.39	219.69
C	1.78	148.43	1.60	122.54	2.52	86.71	ES1	2.77	337.47	1.74	159.94
D	1.81	150.94	1.45	111.06	1.38	47.49	HDE2	2.27	276.55	1.26	115.82
E	1.34	111.74	1.33	101.86	2.21	76.05	HDE1	1.88	229.04	0.91	83.65
F	1.52	126.75	1.51	115.65	2.82	97.04	HBC2	2.12	258.28	0.68	62.51
G	1.58	131.76	1.55	118.71	1.93	66.41	HBC1	1.76	214.42	.....	.....
H	1.10	91.73	1.09	83.48	2.7	92.91	LDE2	1.97	240.01	.....	.....
I	1.07	89.23	1.12	85.78	3.34	114.93	LDE1	1.64	199.80	.....	.....
J	1.34	111.74	1.37	104.93	2.83	97.38	LBC2	1.63	198.58	.....	.....
K	1.44	120.08	1.46	111.82	3.50	120.44	LBC1	1.35	164.47	.....	.....
L	1.03	85.89	1.05	80.42	3.98	136.95	CDE2	1.77	215.64	.....	.....
M	1.20	100.07	1.23	94.21	.....	.....	CDE1	1.53	186.40	.....	.....
N	1.40	116.75	1.42	108.76	.....	.....	CBC2	1.47	179.09	.....	.....
O	1.47	122.58	1.47	112.59	.....	.....	CA2	1.03	125.48	.....	.....
P	1.02	85.06	1.03	78.89	.....	.....	CBC1	1.27	154.72	.....	.....
Q	.....	.....	.....	.....	.....	.....	CA1	0.89	108.43	.....	.....
R	.....	.....	.....	.....	.....	.....	BAB2	0.98	119.39	.....	.....
S	.....	.....	.....	.....	.....	.....	BAB1	0.94	114.52	.....	.....
T	.....	.....	.....	.....	.....	.....	PDE2	1.48	180.31	.....	.....
U	.....	.....	.....	.....	.....	.....	PDE1	1.39	169.34	.....	.....
V	.....	.....	.....	.....	.....	.....	PBC2	1.15	140.10	.....	.....
W	.....	.....	.....	.....	.....	.....	PA2	0.67	81.63	.....	.....
X	.....	.....	.....	.....	.....	.....	PBC1	1.07	130.36	.....	.....
Y	.....	.....	.....	.....	.....	.....	PA1	0.62	75.53	.....	.....

D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We will continue this practice for FY 2025, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data under the inpatient prospective payment system (IPPS) also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, without applying the occupational mix, rural floor, or outmigration adjustment, as the basis for the SNF PPS wage index. For FY 2025, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2020 and before October 1, 2021 (FY 2021 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) gave the Secretary the discretion to establish a geographic reclassification procedure specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. To date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of the data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. Adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors (MACs), potentially far in excess of those required under the IPPS, given that there are nearly five times as many SNFs as there are inpatient hospitals. While we do not believe this undertaking is feasible at this time, we will continue to explore implantation of a spot audit process to improve SNF cost reports, which is determined to be adequately accurate for cost development purposes, in such a manner as to permit us to establish a SNF-specific wage index in the future.

In addition, we will continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2025 SNF PPS wage index. For rural geographic areas that do not have hospitals and, therefore, lack hospital wage data on which to base an area wage adjustment, we will continue using the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2025, the only rural area without wage index data available is North Dakota. We have determined that the borders of 18 rural counties are local and contiguous with 8 urban counties. Therefore, under this methodology, the wage indexes for the counties of Burleigh/Morton/Oliver (CBSA 13900: 0.9020), Cass (CBSA 22020: 0.8763), Grand Forks (CBSA 24220: 0.7865), and McHenry/Renville/Ward (CBSA 33500: 0.7686) are averaged, resulting in an imputed rural wage index of 0.8334 for rural North Dakota for FY 2025. In past years for rural Puerto Rico, we did not apply this methodology due to the distinct economic circumstances there; due to the close proximity of almost all of Puerto Rico's various urban and non-urban areas, this methodology will produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas. However, because rural Puerto Rico now has hospital wage index data on which to base an area wage adjustment, we will not apply this policy for FY 2025. For urban areas without specific hospital wage index data, we will continue using the average wage indexes of all urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2025, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), after the expiration of this 1-year transition on September 30, 2006, we used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013 and were adopted under the SNF PPS in the FY 2017 SNF PPS final rule (81 FR 51983, August 5, 2016). In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300) which was adopted in the SNF PPS final rule for FY 2019 (83 FR 39173, August 8, 2018).

As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5

percent cap on any decrease in a hospital's wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the SNF PPS.

In the FY 2023 SNF PPS final rule (87 FR 47521 through 47525), we finalized a policy to apply a permanent 5 percent cap on any decreases to a provider's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. We amended the SNF PPS regulations at 42 CFR 413.337(b)(4)(ii) to reflect this permanent cap on wage index decreases. Additionally, we finalized a policy that a new SNF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new SNF would not have a wage index in the prior FY. A full discussion of the adoption of this policy is found in the FY 2023 SNF PPS final rule.

As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. OMB issued further revised CBSA delineations in OMB Bulletin No. 20–01, on March 6, 2020 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). However, we determined that the changes in OMB Bulletin No. 20–01 do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, we did not propose to adopt the revised OMB delineations identified in OMB Bulletin No. 20–01 for FY 2022 through FY 2024.

On July 21, 2023, OMB issued OMB Bulletin No. 23–01 which updates and supersedes OMB Bulletin No. 20–01 based on the decennial census. OMB Bulletin No. 23–01 revised delineations for CBSAs which are made up of counties and equivalent entities (*e.g.,* boroughs, a city and borough, and a municipality in Alaska, planning regions in Connecticut, parishes in Louisiana, municipios in Puerto Rico, and independent cities in Maryland, Missouri, Nevada, and Virginia). For FY 2025, we propose to adopt the revised OMB delineations identified in OMB Bulletin No. 23–01 (available at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*). The wage index applicable to FY 2025 is set forth in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Once calculated, we will apply the wage index adjustment to the labor-related portion of the Federal rate. Each year, we calculate a labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2022 (86 FR 42437), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2018-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. The methodology for calculating the labor-related portion beginning in FY 2022 is discussed in detail in the FY 2022 SNF PPS final rule (86 FR 42461 through 42463). As described later in section V.A. of this proposed rule, we are proposing to rebase and revise the labor-related share to reflect the relative importance of the proposed 2022-based SNF market basket cost weights for the following categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses.

We calculate the proposed labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2025. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2025 than the base year weights from the SNF market basket. We calculate the labor-related relative importance for FY 2025 in four steps. First, we compute the FY 2025 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2025 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2025 relative importance for each cost category by multiplying this ratio by the base year (2022) weight. Finally, we add the FY 2025 relative importance for each of the labor-related cost categories (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of Capital-Related expenses) to produce the proposed FY 2025 labor-related relative importance.

Table 7 summarizes the labor-related share for FY 2025, based on IGI's fourth quarter 2023 forecast of the proposed 2022-based SNF market basket, compared to the labor-related share that was used for the FY 2024 SNF PPS final rule.

TABLE 7—LABOR-RELATED SHARE, FY 2024 AND FY 2025

	Final FY 2024 labor-related share based on 2023q2 forecast of the 2018-based SNF market basket [1]	Proposed FY 2025 labor-related share based on 2023q4 forecast of the proposed 2022-based SNF market basket [2]
Wages and salaries	52.5	53.2
Employee benefits	9.3	9.1
Professional fees: Labor-related	3.4	3.5
Administrative & facilities support services	0.6	0.4
Installation, maintenance & repair services	0.4	0.5

TABLE 7—LABOR-RELATED SHARE, FY 2024 AND FY 2025—Continued

	Final FY 2024 labor-related share based on 2023q2 forecast of the 2018-based SNF market basket [1]	Proposed FY 2025 labor-related share based on 2023q4 forecast of the proposed 2022-based SNF market basket [2]
All other: Labor-related services	2.0	2.0
Capital-related (.391)	2.9	3.2
Total	71.1	71.9

[1] Published in the **Federal Register**; Based on the second quarter 2023 IHS Global Inc. forecast of the 2018-based SNF market basket.
[2] Based on the fourth quarter 2023 IHS Global Inc. forecast of the proposed 2022-based SNF market basket.

To calculate the labor portion of the case-mix adjusted per diem rate, we will multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the proposed FY 2025 labor-related share percentage provided in Table 7. The remaining portion of the rate would be the non-labor portion. Under the previous RUG–IV model, we included tables which provided the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, as we discussed in the FY 2020 final rule (84 FR 38738), under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that existed in the prior rulemaking.

Therefore, to aid interested parties in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2025 (Federal rates effective October 1, 2023), we apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted Federal rates by a budget neutrality factor, equal to the ratio of the weighted average wage adjustment factor for FY 2025 to the weighted average wage adjustment factor for FY 2025. For this calculation, we will use the same FY 2023 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor portion of the rate component multiplied by the wage index plus the non-labor portion of the rate component. The proposed budget neutrality factor for FY 2025 is 1.0002.

We note that if more recent data become available (for example, revised wage data), we would use such data, if appropriate, to determine the wage index budget neutrality factor in the SNF PPS final rule.

E. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VII. of this proposed rule for further discussion of the updates we are proposing for the SNF VBP Program.

F. Adjusted Rate Computation Example

Tables 8 through 10 provide examples generally illustrating payment calculations during FY 2025 under PDPM for a hypothetical 30-day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 23224), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 8 shows the adjustments made to the Federal per diem rates (prior to application of any adjustments under the SNF VBP Program as discussed) to compute the provider's proposed case-mix adjusted per diem rate for FY 2025, based on the patient's PDPM classification, as well as how the variable per diem (VPD) adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 9 shows the adjustments made to the case-mix adjusted per diem rate from Table 8 to account for the provider's wage index. The wage index used in this example is based on the FY 2025 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* Finally, Table 10 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 10 also includes the VPD adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 10, SNF XYZ's total PPS payment for this particular patient's stay would equal $23,073.54.

TABLE 8—PDPM CASE-MIX ADJUSTED RATE COMPUTATION EXAMPLE

Per diem rate calculation				
Component	Component group	Component rate	VPD adjustment factor	VPD adj. rate
PT	N	$102.42	1.00	102.42
OT	N	$96.70	1.00	96.70
SLP	H	$73.74	1.00	73.74
Nursing	N	$187.45	1.00	187.45
NTA	C	$167.41	3.00	502.23
Non-Case-Mix		$114.20		114.20
Total PDPM Case-Mix Adj. Per Diem				1,076.74

TABLE 9—WAGE INDEX ADJUSTED RATE COMPUTATION EXAMPLE

PDPM wage index adjustment calculation						
HIPPS code	PDPM case-mix adjusted per diem	Labor portion	Wage index	Wage index adjusted rate	Non-labor portion	Total case mix and wage index adj. rate
NHNC1	$1,076.74	$774.18	0.9918	$767.83	$302.56	$1,070.39

TABLE 10—ADJUSTED RATE COMPUTATION EXAMPLE

Day of stay	NTA VPD adjustment factor	PT/OT VPD adjustment factor	Case mix and wage index adjusted per diem rate
1	3.0	1.0	$1,070.39
2	3.0	1.0	1,070.39
3	3.0	1.0	1,070.39
4	1.0	1.0	737.55
5	1.0	1.0	737.55
6	1.0	1.0	737.55
7	1.0	1.0	737.55
8	1.0	1.0	737.55
9	1.0	1.0	737.55
10	1.0	1.0	737.55
11	1.0	1.0	737.55
12	1.0	1.0	737.55
13	1.0	1.0	737.55
14	1.0	1.0	737.55
15	1.0	1.0	737.55
16	1.0	1.0	737.55
17	1.0	1.0	737.55
18	1.0	1.0	737.55
19	1.0	1.0	737.55
20	1.0	1.0	737.55
21	1.0	0.98	733.59
22	1.0	0.98	733.59
23	1.0	0.98	733.59
24	1.0	0.98	733.59
25	1.0	0.98	733.59
26	1.0	0.98	733.59
27	1.0	0.98	733.59
28	1.0	0.96	729.63
29	1.0	0.96	729.63
30	1.0	0.96	729.63
Total Payment			23,073.54

V. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.C. of this proposed rule. This

approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with § 413.345, we include in each update of the Federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. We also designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in 42 CFR 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial Medicare assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are correctly assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html* (where such designations appear in the paragraph entitled ''Case Mix Adjustment'') and would publish such designations in rulemaking only to the extent that we actually intend to propose changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the Assessment Reference Date (ARD) of the initial Medicare assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297). Effective with services furnished on or after January 1, 2024, section 4121(a)(4) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, enacted December 29, 2022) added marriage and family therapists and mental health counselors to the list of practitioners at section 1888(e)(2)(A)(ii) of the Act whose services are excluded from the consolidated billing provision.

Section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA 1999) (Pub. L. 106–113, enacted November 29, 1999) amended section 1888(e)(2)(A)(iii) of the Act by further excluding a number of individual high-cost, low probability services, identified by HCPCS codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA 1999 amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf.*

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA 1999 not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of these four specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA 1999 Conference report (H.R. Conf. Rep. No. 106–479 at 854 (1999)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA 1999 is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA 1999 do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

Effective with items and services furnished on or after October 1, 2021,

section 134 in Division CC of the CAA, 2021 established an additional fifth category of excluded codes in section 1888(e)(2)(A)(iii)(VI) of the Act, for certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders along with items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. Like the provisions enacted in the BBRA 1999, section 1888(e)(2)(A)(iii)(VI) of the Act gives the Secretary the authority to designate additional items and services for exclusion within the category of items and services related to blood clotting factors, as described in that section.

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA 1999: they must fall within one of the five service categories specified in the BBRA 1999 and CAA, 2021; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA 1999 Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791).

In this proposed rule, we specifically solicit public comments identifying HCPCS codes in any of these five service categories (chemotherapy items, chemotherapy administration services, radioisotope services, customized prosthetic devices, and blood clotting factors) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We may consider excluding a particular service if it meets our criteria for exclusion as specified previously. We request that commenters identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment and the CAA, 2021 identified a set of excluded items and services by means of specifying individual HCPCS codes within the designated categories that were in effect as of a particular date (in the case of the BBRA 1999, July 1, 1999, and in the case of the CAA, 2021, July 1, 2020), as subsequently modified by the Secretary. In addition, as noted in this section of the preamble, the statute (sections 1888(e)(2)(A)(iii)(II) through (VI) of the Act) gives the Secretary authority to identify additional items and services for exclusion within the five specified categories of items and services described in the statute, which are also designated by HCPCS code. Designating the excluded services in this manner makes it possible for us to utilize program issuances as the vehicle for accomplishing routine updates to the excluded codes to reflect any minor revisions that might subsequently occur in the coding system itself, such as the assignment of a different code number to a service already designated as excluded, or the creation of a new code for a type of service that falls within one of the established exclusion categories and meets our criteria for exclusion.

Accordingly, if we identify through the current rulemaking cycle any new services that meet the criteria for exclusion from SNF consolidated billing, we will identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, October 1, 2024). By making any new exclusions in this manner, we can similarly accomplish routine future updates of these additional codes through the issuance of program instructions. The latest list of excluded codes can be found on the SNF Consolidated Billing website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling.*

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this proposed rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.*

V. Other SNF PPS Issues

A. Rebasing and Revising the SNF Market Basket

Section 1888(e)(5)(A) of the Act requires the Secretary to establish a market basket that reflects the changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses.

The SNF market basket is used to compute the market basket percentage increase that is used to update the SNF Federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage increase is adjusted by a forecast error adjustment, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.4. of this proposed rule. The SNF market basket is also used to determine the labor-related share on an annual basis.

The SNF market basket is a fixed-weight, Laspeyres-type price index. A

Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (the proposed base period is 2022) and total base period costs are estimated for a set of mutually exclusive and exhaustive spending categories and the proportion of total costs that each category represents is calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

Since the inception of the SNF PPS, the market basket used to update SNF PPS payments has been periodically rebased and revised. We last rebased and revised the market basket applicable to the SNF PPS in the FY 2022 SNF PPS final rule (86 FR 42444 through 42463) where we adopted a 2018-based SNF market basket. References to the historical market baskets used to update SNF PPS payments are listed in the FY 2022 SNF PPS final rule (86 FR 42445).

Effective for FY 2025 and subsequent fiscal years, we are proposing to rebase and revise the market basket to reflect 2022 Medicare-allowable total cost data (routine, ancillary, and capital-related) from freestanding SNFs and to revise applicable cost categories and price proxies used to determine the market basket. Medicare-allowable costs are those costs that are eligible to be paid under the SNF PPS. For example, the SNF market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS, and therefore, these costs are not SNF PPS Medicare-allowable costs. We propose to maintain our policy of using data from freestanding SNFs, of which about 91 percent of SNFs that submitted a Medicare cost report for 2022 are represented in our sample shown in Table 11. We believe using freestanding Medicare cost report data, as opposed to the hospital-based SNF Medicare cost report data, for the cost weight calculation is most appropriate because of the complexity of hospital-based data and the representativeness of the freestanding data. Because hospital-based SNF expenses are embedded in the hospital cost report, any attempt to incorporate data from hospital-based facilities requires more complex calculations and assumptions regarding the ancillary costs related to the hospital-based SNF unit. We believe the use of freestanding SNF cost report data is technically appropriate for reflecting the cost structures of SNFs serving Medicare beneficiaries.

We are proposing to use 2022 as the base year as we believe that the 2022 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for SNFs at the time of rulemaking. We believe it is important to regularly rebase and revise the SNF market basket to reflect more recent data. Historically, the cost weights change minimally from year to year as they represent percent of total costs rather than cost levels; however, given the COVID–19 Public Health Emergency (PHE), we have been monitoring the Medicare cost report data to see if a more frequent rebasing schedule is necessary than our recent historical precedent of about every 4 years. Accordingly, while it has been only three years since the last SNF rebasing, we are proposing to incorporate data that is more reflective of recent SNF expenses that have been impacted over the COVID–19 PHE period. The 2022 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2021 and before October 1, 2022. While these dates appear to reflect fiscal year data, we note that a Medicare cost report that begins in this timeframe is generally classified as a ''2022 cost report''. For example, we found that of the available 2022 Medicare cost reports for SNFs, approximately 7 percent had an October 1, 2021 begin date, approximately 75 percent of the reports had a January 1, 2022 begin date, and approximately 12 percent had a July 1, 2022 begin date. For this reason, we are defining the base year of the market basket as ''2022-based'' instead of ''FY 2022-based''.

Specifically, we are proposing to develop cost category weights for the proposed 2022-based SNF market basket in two stages. The major types of costs underlying the proposed 2022-based SNF market basket are derived from the 2022 Medicare cost report data (CMS Form 2540–10, OMB NO. 0938–0463) for freestanding SNFs. Specifically, we use the Medicare cost reports for seven specific costs: Wages and Salaries; Employee Benefits; Contract Labor; Pharmaceuticals; Professional Liability Insurance; Home Office/Related Organization Contract Labor; and Capital-related. A residual ''All Other'' category is then estimated and reflects all remaining costs that are not captured in the seven types of costs identified above. The 2018-based SNF market basket similarly used 2018 Medicare cost report data. Second, we are proposing to divide the residual ''All Other'' cost category into more detailed subcategories, using U.S. Department of Commerce Bureau of Economic Analysis' (BEA) 2017 Benchmark Input–Output (I–O) ''The Use Table (Supply-Use Framework)'' for the Nursing and Community Care Facilities industry (NAICS 623A00) aged to 2022 using applicable price proxy growth for each category of costs. Furthermore, we are proposing to continue to use the same overall methodology as was used for the 2018-based SNF market basket to develop the capital related cost weights of the proposed 2022-based SNF market basket.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data To Develop Major Cost Weights

In order to create a market basket that is representative of freestanding SNF providers serving Medicare patients and to help ensure accurate major cost weights (which is the percent of total Medicare-allowable costs, as defined below), we propose to apply edits to remove reporting errors and outliers. Specifically, the SNF Medicare cost reports used to calculate the market basket cost weights exclude any providers that reported costs less than or equal to zero for the following categories: total facility costs (Worksheet B, part 1, column 18, line 100); total operating costs (Worksheet B, part 1, column 18, line 100 less Worksheet B, part 2, column 18, line 100); Medicare general inpatient routine service costs (Worksheet D, part 1, column 1, line 1); and Medicare PPS payments (Worksheet E, part 3, column 1, line 1). We also limited our sample to providers that had a Medicare cost report reporting period that was between 10 and 14 months. The final sample used included roughly 13,100

Medicare cost reports (about 90 percent of the universe of SNF Medicare cost reports for 2022). The sample of providers is representative of the national universe of providers by region (each region is represented within plus or minus 1 percentage point of universe distribution), by ownership-type (proprietary, nonprofit, and government) (within 0.8 percentage point of universe), and by urban/rural status (within 0.1 percentage point of universe). Of the providers that were excluded from our final sample, 86 percent were due to having a cost reporting period less than 10 months or greater than 14 months, 10 percent were due to total facility costs or total operating costs not being greater than zero, and 4 percent were due to Medicare general inpatient routine service costs or Medicare PPS payments not being greater than zero.

Additionally, for all of the major cost weights, except Home Office/Related Organization Contract Labor costs, the data are trimmed to remove outliers (a standard statistical process) by: (1) requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable costs are greater than zero; and (2) excluding the top and bottom 5 percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable costs). We note that missing values are assumed to be zero, consistent with the methodology for how missing values are treated in the 2018-based market basket methodology.

For the Home Office/Related Organization Contract Labor cost weight, we propose to first exclude providers whose Home Office/Related Organization Contract Labor costs are greater than Medicare-allowable total costs and then apply a trim that excludes those reporters with a Home Office/Related Organization Contract Labor cost weight above the 99th percentile. This allows providers with no Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation. If we were to trim the top and bottom Home Office/Related Organization Contract Labor cost weight, we would exclude providers with a cost weight of zero (84 percent of the sample) and the Medicare cost report data (Worksheet S–2 line 45) indicate that not all SNF providers have a home office. Providers without a home office would report administrative costs that might typically be associated with a home office in the Wages and Salaries and Employee Benefits cost weights, or in the residual ''All-Other'' cost weight if they purchased these types of services from external contractors. We believe the trimming methodology that excludes those who report Home Office/Related Organization Contract Labor costs above the 99th percentile is appropriate as it removes extreme outliers while also allowing providers with zero Home Office/Related Organization Contract Labor costs, which is the majority of providers, to be included in the Home Office/Related Organization Contract Labor cost weight calculation.

The trimming process is done individually for each cost category so that providers excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these trimming methods are the same types of edits performed for the 2018-based SNF market basket, as well as other PPS market baskets (including but not limited to the IPPS market basket and home health market basket). We believe this trimming process improves the accuracy of the data used to compute the major cost weights by removing possible data misreporting.

The final weights of the proposed 2022-based SNF market basket are based on weighted means. For example, the aggregate Wages and Salaries cost weight, after trimming, is equal to the sum of total Medicare-allowable wages and salaries (as defined in the ''Wages and Salaries'' section that follows) of all providers divided by the sum of total Medicare-allowable costs (as defined in the next paragraph) for all providers in the sample (as defined above in this section). This methodology is consistent with the methodology used to calculate the 2018-based SNF market basket cost weights and other PPS market basket cost weights. We note that for each of the cost weights, we evaluated the distribution of providers and costs by region, by ownership-type, and by urban/rural status. For all of the cost weights, with the exception of the PLI (which is discussed in more detail later), the trimmed sample was nationally representative.

For all of the cost weights, we use Medicare-allowable total costs as the denominator (for example, Wages and Salaries cost weight = Wages and Salaries costs divided by Medicare-allowable total costs). Medicare-allowable total costs were equal to total costs (after overhead allocation) from Worksheet B part I, column 18, for lines 30, 40 through 49, 51, 52, and 71 plus estimated Medicaid drug costs, as defined below. We included estimated Medicaid drug costs in the pharmacy cost weight, as well as the denominator for total Medicare-allowable costs. This is the same methodology used for the 2018-based SNF market basket. The inclusion of Medicaid drug costs was finalized in the FY 2008 SNF PPS final rule (72 FR 43425 through 43430), and for the same reasons set forth in that final rule, we are proposing to continue to use this methodology in the proposed 2022-based SNF market basket.

We describe the detailed methodology for obtaining costs for each of the eight cost categories determined from the Medicare Cost Report below. The methodology used in the 2018-based SNF market basket can be found in the FY 2022 SNF PPS final rule (86 FR 42446 through 42452).

(1) Wages and Salaries

To derive Wages and Salaries costs for the Medicare-allowable cost centers, we are proposing first to calculate total facility wages and salaries costs as reported on Worksheet S–3, part II, column 3, line 1. We then propose to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas), as well as a portion of overhead wages and salaries attributable to these excluded areas. Excluded area wages and salaries are equal to wages and salaries as reported on Worksheet S–3, part II, column 3, lines 3, 4, and 7 through 11 plus nursing facility and non-reimbursable salaries from Worksheet A, column 1, lines 31, 32, 50, and 60 through 63.

Overhead wages and salaries are attributable to the entire SNF facility; therefore, we are proposing to include only the proportion attributable to the Medicare-allowable cost centers. We are proposing to estimate the proportion of overhead wages and salaries attributable to the non-Medicare-allowable costs centers in two steps. First, we propose to estimate the ratio of excluded area wages and salaries (as defined above) to non-overhead total facility wages and salaries (total facility wages and salaries (Worksheet S–3, part II, column 3, line 1) less total overhead wages and salaries (Worksheet S–3, Part III, column 3, line 14)). Next, we propose to multiply total overhead wages and salaries by the ratio computed in step 1. We excluded providers whose excluded areas wages and salaries were greater than total facility wages and salaries and/or their excluded area overhead wages and salaries were greater than total facility wages and salaries (about 50 providers). This is the same methodology used to derive Wages and Salaries costs in the 2018-based SNF market basket.

(2) Employee Benefits

Medicare-allowable employee benefits are equal to total facility benefits as reported on Worksheet S–3, part II, column 3, lines 17 through 19 minus non-Medicare-allowable (that is, excluded area) employee benefits and minus a portion of overhead benefits attributable to these excluded areas. Excluded area employee benefits are derived by multiplying total excluded area wages and salaries (as defined above in the 'Wages and Salaries' section) times the ratio of total facility benefits to total facility wages and salaries. This ratio of benefits to wages and salaries is defined as total facility benefit costs to total facility wages and salary costs (as reported on Worksheet S–3, part II, column 3, line 1). Likewise, the portion of overhead benefits attributable to the excluded areas is derived by multiplying overhead wages and salaries attributable to the excluded areas (as defined in the 'Wages and Salaries' section) times the ratio of total facility benefit costs to total facility wages and salary costs (as defined above). Similar to the Wages and Salaries costs, we excluded providers whose excluded areas benefits were greater than total facility benefits and/or their excluded area overhead benefits were greater than total facility benefits (zero providers were excluded because of this edit). This is the same methodology used to derive Employee Benefits costs in the 2018-based SNF market basket.

(3) Contract Labor

We are proposing to derive Medicare-allowable contract labor costs from Worksheet S–3, part II, column 3, line 14, which reflects costs for contracted direct patient care services (that is, nursing, therapeutic, rehabilitative, or diagnostic services furnished under contract rather than by employees and management contract services). This is the same methodology used to derive the Contract Labor costs in the 2018-based SNF market basket.

(4) Pharmaceuticals

We are proposing to calculate pharmaceuticals costs using the non-salary costs from the Pharmacy cost center (Worksheet B, part I, column 0, line 11 less Worksheet A, column 1, line 11) and the Drugs Charged to Patients' cost center (Worksheet B, part I, column 0, line 49 less Worksheet A, column 1, line 49). Since these drug costs were attributable to the entire SNF and not limited to Medicare-allowable services, we propose to adjust the drug costs by the ratio of Medicare-allowable pharmacy total costs (Worksheet B, part I, column 11, for lines 30, 40 through 49, 51, 52, and 71) to total pharmacy costs from Worksheet B, part I, column 11, line 11. Worksheet B, part I allocates the general service cost centers, which are often referred to as ''overhead costs'' (in which pharmacy costs are included) to the Medicare-allowable and non-Medicare-allowable cost centers. This adjustment was made for those providers who reported Pharmacy cost center expenses. Otherwise, we assumed the non-salary Drugs Charged to Patients costs were Medicare-allowable. Since drug costs for Medicare patients are included in the SNF PPS per diem rate, a provider with Medicare days should have also reported costs in the Drugs Charged to Patient cost center. We found a small number of providers (roughly 90) did not report Drugs Charged to Patients' costs despite reporting Medicare days (an average of about 2,000 Medicare days per provider), and therefore, these providers were excluded from the Pharmaceuticals cost weight calculations. This is the same methodology used for the 2018-based SNF market basket.

Second, as was done for the 2018-based SNF market basket, we propose to continue to adjust the drug expenses reported on the Medicare cost report to include an estimate of total Medicaid drug costs, which are not represented in the Medicare-allowable drug cost weight. As stated previously in this section, the proposed 2022-based SNF market basket reflects total Medicare-allowable costs (that is, total costs for all payers for those services reimbursable under the SNF PPS). For the FY 2006-based SNF market basket (72 FR 43426), commenters noted that the total pharmaceutical costs reported on the Medicare cost report did not include pharmaceutical costs for dual-eligible Medicaid patients as these were directly reimbursed by Medicaid. Since all of the other cost category weights reflect expenses associated with treating Medicaid patients (including the compensation costs for dispensing these drugs), we made an adjustment to include these Medicaid drug expenses so the market basket cost weights would be calculated consistently.

Similar to the 2018-based SNF market basket, we propose to estimate Medicaid drug costs based on data representing dual-eligible Medicaid beneficiaries. Medicaid drug costs are estimated by multiplying Medicaid dual-eligible drug costs per day times the number of Medicaid days as reported in the Medicare-allowable skilled nursing cost center (Worksheet S–3, part I, column 5, line 1) in the SNF Medicare cost report. Medicaid dual-eligible drug costs per day (where the day represents an unduplicated drug supply day) were estimated using 2022 Part D claims for those dual-eligible beneficiaries who had a Medicare SNF stay during the year. The total drug costs per unduplicated day for 2022 of $27.43 represented all drug costs (including the drug ingredient cost, the dispensing fee, vaccine administration fee and sales tax) incurred during the 2022 calendar year (CY) for those dual-eligible beneficiaries who had a SNF Medicare stay during CY 2022. Therefore, they include drug costs incurred during a Medicaid SNF stay occurring in CY 2022. By comparison, the 2018-based SNF market basket also relied on data from the Part D claims, which yielded a dual-eligible Medicaid drug cost per day of $24.48 for 2018.

We continue to believe that Medicaid dual-eligible beneficiaries are a reasonable proxy for the estimated drug costs per day incurred by Medicaid patients staying in a skilled nursing unit under a Medicaid stay. The skilled nursing unit is the Medicare-allowable unit in a SNF, which encompasses more skilled nursing and rehabilitative care compared to a nursing facility or long-term care unit. We believe that Medicaid patients receiving this skilled nursing care would on average have similar drug costs per day to dual-eligible Medicare beneficiaries who have received Medicare skilled nursing care in the skilled nursing care unit during the year. We note that our previous analysis of the Part D claims data showed that Medicare beneficiaries with a SNF stay during the year have higher drug costs than Medicare patients without a SNF stay during the year. Also, in 2022, dual-eligible beneficiaries with a SNF stay during the year had drug costs per day of $27.43, which were approximately two times higher than the drug costs per day of $15.83 for nondual-eligible beneficiaries with a SNF Part A stay during the year.

The Pharmaceuticals cost weight using only 2022 Medicare cost report data (without the inclusion of the Medicaid dual-eligible drug costs) is 2.0 percent, compared to the proposed Pharmaceuticals cost weight (including the adjustment for Medicaid dual-eligible drug costs) of 6.4 percent. The 2018-based SNF market basket had a Pharmaceuticals cost weight using only 2018 Medicare cost report data without the inclusion of the Medicaid dual-eligible drug costs of 2.6 percent and a total Pharmaceuticals cost weight of 7.5 percent. Therefore, the 1.1 percentage point decrease in the Pharmaceuticals

cost weight between 2018 and 2022 is a result of a 0.5-percentage point decrease in the Medicaid dual-eligible drug cost weight (reflecting the 12 percent increase in the Medicaid dual-eligible drug costs per day, and a 14 percent decrease in Medicaid inpatient days between 2018 and 2022) and a 0.6-percentage point decrease in the Medicare cost report drug cost weight. The decrease in the Medicare cost report drug cost weight was consistent, in aggregate, across urban and rural status SNFs, as well as across for-profit, government, and nonprofit ownership type SNFs.

(5) Professional Liability Insurance

We are proposing to calculate the professional liability insurance (PLI) costs from Worksheet S–2 of the Medicare cost reports as the sum of premiums; paid losses; and self-insurance (Worksheet S–2, Part I, columns 1 through 3, line 41). This was the same methodology used to derive the Professional Liability costs for the 2018-based SNF market basket.

About 60 percent of SNFs (about 7,700) reported professional liability costs. After trimming, about 6,900 (reflecting about 730,000 Skilled Nursing unit beds) were included in the calculation of the PLI cost weight for the proposed 2022-based SNF market basket. These providers treated roughly 750,000 Medicare beneficiaries and had a Medicare length of stay (LOS) of 58 days, a skilled nursing unit occupancy rate of 72 percent, and an average skilled nursing unit bed size of 106 beds, which are all consistent with the national averages. We also verified that this sample of providers are representative of the national distribution of providers by ownership-type, urban/rural status, and region.

We believe the Medicare cost report data continues to be the most appropriate data source to calculate the PLI cost weight for the proposed 2022-based SNF market basket as it is representative of SNFs serving Medicare beneficiaries and reflects PLI costs (premiums, paid losses, and self-insurance) incurred during the provider's cost reporting year. A fuller discussion of the Medicare cost report data on PLI costs compared to other sources is available in the FY 2022 SNF PPS final rule (86 FR 42448).

(6) Capital-Related

We are proposing to derive the Medicare-allowable capital-related costs from Worksheet B, part II, column 18 for lines 30, 40 through 49, 51, 52, and 71. This is the same methodology to derive capital-related costs used in the 2018-based SNF market basket.

(7) Home Office/Related Organization Contract Labor Costs

We are proposing to calculate Medicare-allowable Home Office/Related Organization Contract Labor costs to be equal to data reported on Worksheet S–3, part II, column 3, line 16. About 7,100 providers (about 54 percent) in 2022 reported having a home office (as reported on Worksheet S–2, part I, line 45) about the same share of providers as those in the 2018-based SNF market basket. As discussed in section V.A.1. of this proposed rule, providers without a home office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Employee Benefits cost weights. Alternatively, providers without a home office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All-Other'' cost weight. For this reason, unlike the other major cost weights described previously, we did not exclude providers that did not report Home Office/Related Organization Contract Labor costs. This is the same methodology that was used in the 2018-based SNF market basket.

(8) All Other (Residual)

The ''All Other'' cost weight is a residual, calculated by subtracting the major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, Capital-Related, and Home Office/Related Organization Contract Labor) from 100.

Table 11 shows the major cost categories and their respective cost weights as derived from the 2022 Medicare cost reports.

TABLE 11—MAJOR COST CATEGORIES DERIVED FROM THE SNF MEDICARE COST REPORTS *

Major cost categories	Proposed 2022-based	2018-Based
Wages and Salaries	43.3	44.1
Employee Benefits	7.8	8.6
Contract Labor	10.1	7.5
Pharmaceuticals	6.4	7.5
Professional Liability Insurance	1.3	1.1
Capital-Related	8.3	8.2
Home Office/Related Organization Contract Labor	0.6	0.7
All other (residual)	22.2	22.3

* Total may not sum to 100 due to rounding.

As we did for the 2018-based SNF market basket (86 FR 42449), we are proposing to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2022 Medicare cost report data, this percentage is 85 percent (1 percentage point higher than the percentage in the 2018-based SNF market basket); therefore, we are proposing to allocate approximately 85 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 15 percent to the Employee Benefits cost weight.

Table 12 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the proposed 2022-based SNF market basket and the 2018-based SNF market basket.

TABLE 12—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Proposed 2022-based market basket	2018-Based market basket
Compensation	61.2	60.2
Wages and Salaries	51.8	50.4
Employee Benefits	9.3	9.9

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal; therefore, the detailed compensation cost weights may not add to the total compensation cost weight due to rounding.

Compared to the 2018-based SNF market basket, the Wages and Salaries cost weight and the Employee Benefits cost weight as calculated directly from the Medicare cost reports each decreased by 0.8 percentage point. The Contract Labor cost weight increased 2.6 percentage points and so in aggregate, the Compensation cost weight increased 1.0 percentage point from 60.2 percent to 61.2 percent.

b. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2022 Medicare cost report data into more detailed cost categories, we are proposing to use the 2017 Benchmark I–O ''The Use Table (Supply-Use Framework)'' for Nursing and Community Care Facilities industry (NAICS 623A00), published by the Census Bureau's, Bureau of Economic Analysis (BEA). These data are publicly available at *https://www.bea.gov/industry/input-output-accounts-data.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years with 2017 being the most recent year for which data are available. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts; therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[1] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates are less comprehensive and provide less detail than benchmark data. Additionally, the annual I–O data are subject to revision once benchmark data become available. For these reasons, we propose to inflate the 2017 Benchmark I–O data aged forward to 2022 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data. Next, the relative shares of the cost shares that each cost category represents to the total residual I–O costs are calculated. These resulting 2022 cost shares of the I–O data are applied to the ''All Other'' residual cost weight to obtain detailed cost weights for the residual costs for the proposed 2022-based SNF market basket. For example, the cost for Food: Direct Purchases represents 12.8 percent of the sum of the ''All Other'' 2017 Benchmark I–O Expenditures inflated to 2022. Therefore, the Food: Direct Purchases cost weight is 2.8 percent of the proposed 2022-based SNF market basket (12.8 percent × 22.2 percent = 2.8 percent). For the 2018-based SNF market basket (86 FR 42449), we used a similar methodology utilizing the 2012 Benchmark I–O data (aged to 2018).

Using this methodology, we are proposing to derive 19 detailed SNF market basket cost category weights from the proposed 2022-based SNF market basket ''All Other'' residual cost weight (22.2 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity and Other Non-Fuel Utilities; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments and Supplies; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Apparel; (10) Machinery and Equipment; (11) Miscellaneous Products; (12) Professional Fees: Labor-Related; (13) Administrative and Facilities Support Services; (14) Installation, Maintenance, and Repair Services; (15) All Other: Labor-Related Services; (16) Professional Fees: Nonlabor-Related; (17) Financial Services; (18) Telephone Services; and (19) All Other: Nonlabor-Related Services. These are the same detailed cost categories as those that were used in the 2018-based SNF market basket.

We note that the machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are accounted for in the capital component of the proposed 2022-based SNF market basket (described in section V.A.1.c. of this proposed rule).

c. Derivation of the Detailed Capital Cost Weights

Similar to the 2018-based SNF market basket, we further divided the Capital-related cost weight into: Depreciation, Interest, Lease and Other Capital-related cost weights.

We calculated the depreciation cost weight (that is, depreciation costs excluding leasing costs) using depreciation costs from Worksheet S–2, column 1, lines 20 and 21. Since the depreciation costs reflect the entire SNF facility (Medicare and non-Medicare-allowable units), we used total facility capital costs (Worksheet B, Part I, column 18, line 100) as the denominator. This methodology assumes that the depreciation of an asset is the same regardless of whether the asset was used for Medicare or non-Medicare patients. This methodology yielded depreciation costs as a percent of capital costs of 22.6 percent for 2022. We then apply this percentage to the proposed 2022-based SNF market basket Medicare-allowable Capital-related cost weight of 8.3 percent, yielding a proposed Medicare-allowable depreciation cost weight (excluding leasing expenses, which is described in more detail below) of 1.9 percent for 2022. To further disaggregate the Medicare-allowable depreciation cost weight into fixed and movable depreciation, we are proposing to use the 2022 SNF Medicare cost report data for end-of-the-year capital asset balances as reported on Worksheet A–7. The 2022 SNF Medicare cost report data showed a fixed/movable split of 86/14. The 2018-based SNF market basket, which utilized the same data from the 2018 Medicare cost reports, also had a fixed/movable split of 86/14.

We derived the interest expense share of capital-related expenses from 2022 SNF Medicare cost report data, specifically from Worksheet A, column 2, line 81. Similar to the depreciation cost weight, we calculated the interest cost weight using total facility capital costs. This methodology yielded interest costs as a percent of capital costs of 17.7 percent for 2022. We then apply this percentage to the proposed 2022-based

[1] *https://www.bea.gov/resources/methodologies/concepts-methods-io-accounts.*

SNF market basket Medicare-allowable Capital-related cost weight of 8.3 percent, yielding a Medicare-allowable interest cost weight (excluding leasing expenses) of 1.5 percent. As done with the last rebasing (86 FR 42450), we are proposing to determine the split of interest expense between for-profit and not-for-profit facilities based on the distribution of long-term debt outstanding by type of SNF (for-profit or not-for-profit/government) from the 2022 SNF Medicare cost report data. We estimated the split between for-profit and not-for-profit interest expense to be 30/70 percent compared to the 2018-based SNF market basket with 25/75 percent.

Because the detailed data were not available in the Medicare cost reports, we used the most recent 2021 Census Bureau Service Annual Survey (SAS) data to derive the capital-related expenses attributable to leasing and other capital-related expenses. The 2018-based SNF market basket used the 2017 SAS data.

Based on the 2021 SAS data, we determined that leasing expenses are 65 percent of total leasing and capital-related expenses costs. In the 2018-based SNF market basket, leasing costs represent 62 percent of total leasing and capital-related expenses costs. We then apply this percentage to the proposed 2022-based SNF market basket residual Medicare-allowable capital costs of 4.9 percent derived from subtracting the Medicare-allowable depreciation cost weight and Medicare-allowable interest cost weight from the proposed 2022-based SNF market basket of total Medicare-allowable capital cost weight (8.3 percent − 1.9 percent − 1.5 percent = 4.9 percent). This produces the proposed 2022-based SNF Medicare-allowable leasing cost weight of 3.2 percent and all-other capital-related cost weight of 1.7 percent.

Lease expenses are not broken out as a separate cost category in the SNF market basket, but are distributed among the cost categories of depreciation, interest, and other capital-related expenses, reflecting the assumption that the underlying cost structure and price movement of leasing expenses is similar to capital costs in general. As was done with past SNF market baskets and other PPS market baskets, we assumed 10 percent of lease expenses are overhead and assigned them to the other capital-related expenses cost category. This is based on the assumption that leasing expenses include not only depreciation, interest, and other capital-related costs but also additional costs paid to the lessor. We distributed the remaining lease expenses to the three cost categories based on the proportion of depreciation, interest, and other capital-related expenses to total capital costs, excluding lease expenses.

Table 13 shows the capital-related expense distribution (including expenses from leases) in the proposed 2022-based SNF market basket and the 2018-based SNF market basket.

TABLE 13—COMPARISON OF THE CAPITAL-RELATED EXPENSE DISTRIBUTION OF THE PROPOSED 2022-BASED SNF MARKET BASKET AND THE 2018-BASED SNF MARKET BASKET

Cost category	Proposed 2022-based SNF market basket	2018-Based SNF market basket
Capital-related Expenses	8.3	8.2
Total Depreciation	3.0	3.0
Total Interest	2.3	2.7
Other Capital-related Expenses	3.0	2.6

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal; therefore, the detailed capital cost weights may not add to the total capital-related expenses cost weight due to rounding.

Table 14 presents the proposed 2022-based SNF market basket and the 2018-based SNF market basket cost categories and cost weights.

TABLE 14—PROPOSED 2022-BASED SNF MARKET BASKET AND 2018-BASED SNF MARKET BASKET COST CATEGORIES AND COST WEIGHTS

Cost category	Proposed 2022-based SNF market basket	2018-Based SNF market basket
Total	100.0	100.0
Compensation	61.2	60.2
Wages and Salaries [1]	51.8	50.4
Employee Benefits [1]	9.3	9.9
Utilities	2.7	1.5
Electricity and Other Non-Fuel Utilities	1.8	1.0
Fuel: Oil and Gas	0.8	0.4
Professional Liability Insurance	1.3	1.1
All Other	26.5	29.0
Other Products	16.1	17.6
Pharmaceuticals	6.4	7.5
Food: Direct Purchases	2.9	2.5
Food: Contract Services	3.4	4.3
Chemicals	0.2	0.2
Medical Instruments and Supplies	0.4	0.6
Rubber and Plastics	1.0	0.7
Paper and Printing Products	0.5	0.5
Apparel	0.4	0.5
Machinery and Equipment	0.7	0.5

TABLE 14—PROPOSED 2022-BASED SNF MARKET BASKET AND 2018-BASED SNF MARKET BASKET COST CATEGORIES AND COST WEIGHTS—Continued

Cost category	Proposed 2022-based SNF market basket	2018-Based SNF market basket
Miscellaneous Products	0.2	0.3
All Other Services	10.5	11.5
Labor-Related Services	6.5	6.4
Professional Fees: Labor-Related	3.6	3.5
Installation, Maintenance, and Repair Services	0.4	0.6
Administrative and Facilities Support	0.5	0.4
All Other: Labor-Related Services	2.0	1.9
Non Labor-Related Services	4.0	5.1
Professional Fees: Nonlabor-Related	1.8	2.0
Financial Services	0.5	1.3
Telephone Services	0.4	0.3
All Other: Nonlabor-Related Services	1.3	1.5
Capital-Related Expenses	8.3	8.2
Total Depreciation	3.0	3.0
Building and Fixed Equipment	2.5	2.5
Movable Equipment	0.4	0.4
Total Interest	2.3	2.7
For-Profit SNFs	0.7	0.7
Government and Nonprofit SNFs	1.6	2.0
Other Capital-Related Expenses	3.0	2.6

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal, and therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

2. Price Proxies Used To Measure Operating Cost Category Growth

After developing the 27 cost weights for the proposed 2022-based SNF market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of change for each cost category. With four exceptions (three for the capital-related expenses cost categories and one for PLI), we base the wage and price proxies on Bureau of Labor Statistics (BLS) data, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe that the CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 19 lists all price proxies for the proposed 2022-based SNF market basket. Below is a detailed explanation of the price proxies we are proposing to use for each operating cost category.

a. Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities

(NAICS 6231; BLS series code CIU2026231000000I) to measure price growth of this category. NAICS 623 includes facilities that provide a mix of health and social services, with many of the health services requiring some level of nursing services. Within NAICS 623 is NAICS 6231, which includes nursing care facilities primarily engaged in providing inpatient nursing and rehabilitative services. These facilities, which are most comparable to Medicare-certified SNFs, provide skilled nursing and continuous personal care services for an extended period of time, and, therefore, have a permanent core staff of registered or licensed practical nurses. This is the same index used in the 2018-based SNF market basket.

b. Employee Benefits

We are proposing to use the ECI for Benefits for Nursing Care Facilities (NAICS 6231) to measure price growth of this category. The ECI for Benefits for Nursing Care Facilities is calculated using BLS's total compensation (BLS series ID CIU2016231000000I) for nursing care facilities series and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section. This is the same index used in the 2018-based SNF market basket.

c. Electricity and Other Non-Fuel Utilities

We are proposing to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category as Electricity costs account for 93 percent of these expenses. This is the same index used for the Electricity cost category in the 2018-based SNF market basket.

d. Fuel: Oil and Gas

We are proposing to use a blended proxy composed of the PPI Industry for Petroleum Refineries (NAICS 324110) (BLS series code PCU32411–32411), the PPI Commodity for Natural Gas (NAICS 221200)(BLS series code WPU0531), and the PPI for Other Petroleum and Coal Products manufacturing (NAICS 324190)(BLS series code PCU32419–32419).

Our analysis of 2017 Benchmark I–O data for Nursing and Community Care Facilities found that these three NAICS industries account for approximately 93 percent of SNF Fuel: Oil and Gas expenses. The remaining 7 percent of SNF Fuel: Oil and Gas expenses are for two other incidental NAICS industries including Coal Mining and Petrochemical Manufacturing. We are proposing to create a blended index based on the three NAICS Fuel: Oil and Gas expenses listed above that account for 93 percent of SNF Fuel: Oil and Gas expenses. We propose to create this blend based on each NAICS' expenses as a share of their sum. These expenses as a share of their sum are listed in Table 15.

The 2018-based SNF market basket used a blended Fuel: Oil and Gas proxy that was based on 2012 Benchmark I–O data. We believe our proposed Fuel: Oil and Gas blended index for the proposed 2022-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 16 provides the weights for the 2022- and 2018-based blended Fuel: Oil and Gas index.

TABLE 15—FUEL: OIL AND GAS BLENDED INDEX WEIGHTS

NAICS	Price proxy	Proposed 2022-based index (%)	2018-Based index (%)
221200	PPI Commodity for Natural Gas	7	7
324110	PPI Industry for Petroleum Refineries	72	61
324190	PPI for Other Petroleum and Coal Products manufacturing	21	32
Total		100	100

e. Professional Liability Insurance

We are proposing to use the CMS Hospital Professional Liability Insurance Index to measure price growth of this category. We were unable to find a reliable data source that collects SNF-specific PLI data. Therefore, we propose to use the CMS Hospital Professional Liability Index, which tracks price changes for commercial insurance premiums for a fixed level of coverage, holding non-price factors constant (such as a change in the level of coverage). This is the same index used in the 2018-based SNF market basket. We believe this is an appropriate proxy to measure the price growth associated of SNF PLI as it captures the price inflation associated with other medical institutions that serve Medicare patients.

f. Pharmaceuticals

We are proposing to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

g. Food: Direct Purchases

We are proposing to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

h. Food: Contract Services

We are proposing to use the CPI All Urban for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

i. Chemicals

For measuring price change in the Chemicals cost category, we are proposing to use a blended PPI composed of the Industry PPIs for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561), and All Other Chemical Product and Preparation Manufacturing (NAICS 3259A0) (BLS series code PCU325998325998).

Using the 2017 Benchmark I–O data, we found that these three NAICS industries accounted for approximately 95 percent of SNF chemical expenses. The remaining 5 percent of SNF chemical expenses are for three other incidental NAICS chemicals industries

such as Paint and Coating Manufacturing. We are proposing to create a blended index based on the three NAICS chemical expenses listed above that account for 95 percent of SNF chemical expenses. We propose to create this blend based on each NAICS' expenses as a share of their sum. These expenses as a share of their sum are listed in Table 16.

The 2018-based SNF market basket used a blended chemical proxy that was based on 2012 Benchmark I–O data. We believe our proposed chemical blended index for the proposed 2022-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 16 provides the weights for the proposed 2022-based blended chemical index and the 2018-based blended chemical index.

TABLE 16—CHEMICAL BLENDED INDEX WEIGHTS

NAICS	Price proxy	Proposed 2022-based index (%)	2018-Based index (%)
325190	PPI for Other Basic Organic Chemical Manufacturing	49	34
325610	PPI for Soap and Cleaning Compound Manufacturing	9	21
325998	PPI for Other Miscellaneous Chemical Product Manufacturing	42	45
Total		100	100

j. Medical Instruments and Supplies

For measuring price change in the Medical Instruments and Supplies cost category, we are proposing to use a blended proxy. The 2017 Benchmark I–O data shows 62 percent of medical instruments and supply costs are for Surgical and medical instrument manufacturing costs (NAICS 339112) and 38 percent are for Surgical appliance and supplies manufacturing costs (NAICS 339113). To proxy the price changes associated with NAICS 339112, we propose using the PPI—Commodity—Surgical and medical instruments (BLS series code WPU1562). To proxy the price changes associated with NAICS 339113, we propose to use 50 percent for the PPI—Commodity—Medical and surgical appliances and supplies (BLS series code WPU1563) and 50 percent for the PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (BLS series code WPU1571). The latter price proxy would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2017 Benchmark I–O data does not provide specific expenses for personal protective equipment (which would be reflected in the NAICS 339113 expenses); however, we recognize that this category reflects costs faced by SNFs. In absence of any specific cost data on personal protective equipment, we propose to include the PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (BLS series code WPU1571) in the blended proxy for Medical Instruments and Supplies cost category with a weight of 19 percent (that is, 50 percent of the NAICS 339113 expenses as a percent of the sum of NAICS 339113 and NAICS 339112 expenses from the I–O).

The 2018-based SNF market basket used a blended Medical Instruments and Supplies proxy that was based on 2012 Benchmark I–O data. We believe our proposed blended index for the proposed 2022-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 17 provides the proposed Medical Instruments and Supplies cost weight blended price proxy.

TABLE 17—MEDICAL INSTRUMENTS AND SUPPLIES BLENDED INDEX WEIGHTS

NAICS	Price proxy	Proposed 2022-based index (%)	2018-Based index (%)
339112	PPI—Commodity—Surgical and medical instruments (WUI1562)	62	46
339113	PPI—Commodity—Medical and surgical appliances and supplies (WPU1563)	19	27
	PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (WPU1571).	19	27
Total		100	100

k. Rubber and Plastics

We are proposing to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

l. Paper and Printing Products

We are proposing to use a 86/14 blend of the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) and the PPI Commodity for Publications Printed Matter and Printing Material (BLS Series Code WPU094) to measure the price growth of this cost category. The 2017 Benchmark I–O data shows that 86 percent of paper and printing expenses are for paper manufacturing (NAICS 322) and the remaining expenses are for Printing (NAICS 323110). The 2018-based SNF market basket used the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category.

m. Apparel

We are proposing to use the PPI Commodity for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

n. Machinery and Equipment

We are proposing to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

o. Miscellaneous Products

For measuring price change in the Miscellaneous Products cost category, we are proposing to use the PPI Commodity for Finished Goods less Food and Energy (BLS series code WPUFD4131). Both food and energy are already adequately represented in separate cost categories and should not also be reflected in this cost category. This is the same index used in the 2018-based SNF market basket.

p. Professional Fees: Labor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the 2018-based SNF market basket.

q. Administrative and Facilities Support Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same index used in the 2018-based SNF market basket.

r. Installation, Maintenance and Repair Services

We are proposing to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU10100004300001) to measure the price growth of this new cost category. This is the same index used in the 2018-based SNF market basket.

s. All Other: Labor-Related Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

t. Professional Fees: Non-Labor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the 2018-based SNF market basket.

u. Financial Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

v. Telephone Services

We are proposing to use the CPI All Urban for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

w. All Other: Non-Labor-Related Services

We are proposing to use the CPI All Urban for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same index used in the 2018-based SNF market basket.

3. Price Proxies Used To Measure Capital Cost Category Growth

We are proposing to apply the same capital price proxies as were used in the 2018-based SNF market basket, and below is a detailed explanation of the price proxies used for each capital cost category. We are also proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2018-based SNF market basket and is described below.

- Depreciation—Building and Fixed Equipment: We are proposing to use the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. This is the same index used in the 2018-based SNF market basket.
- Depreciation—Movable Equipment: We are proposing to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by SNFs, including but not limited to medical equipment, communication equipment, and computers. This is the same index used in the 2018-based SNF market basket.
- Nonprofit Interest: We are proposing to use the average yield on Municipal Bonds (Bond Buyer 20-bond index). This is the same index used in the 2018-based SNF market basket.
- For-Profit Interest: For the For-Profit Interest cost category, we are proposing to use the iBoxx AAA Corporate Bond Yield index. This is the same index used in the 2018-based SNF market basket.
- Other Capital: Since this category includes fees for insurances, taxes, and other capital-related costs, we are proposing to use the CPI for Rent of Primary Residence (BLS series code CUUS0000SEHA), which would reflect the price growth of these costs. This is the same index used in the 2018-based SNF market basket.

We believe that these price proxies are the most appropriate proxies for SNF capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

As stated above, we are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. To capture the long-term nature, the price proxies are vintage-weighted and the vintage weights are calculated using a two-step process. First, we determine the expected useful life of capital and debt instruments held by SNFs. Second, we identify the proportion of expenditures within a cost category that is attributable to each individual year over the useful life of the relevant capital assets, or the vintage weights.

We rely on Bureau of Economic Analysis (BEA) fixed asset data to derive the useful lives of both fixed and movable capital, which is the same data source used to derive the useful lives for the 2018-based SNF market basket. The specifics of the data sources used are explained below.

a. Calculating Useful Lives for Movable and Fixed Assets

Estimates of useful lives for movable and fixed assets for the proposed 2022-based SNF market basket are 9 and 27 years, respectively. These estimates are based on three data sources from the BEA: (1) current-cost average age; (2) historical-cost average age; and (3) industry-specific current cost net stocks of assets.

BEA current-cost and historical-cost average age data by asset type are not available by industry but are published at the aggregate level for all industries. The BEA does publish current-cost net capital stocks at the detailed asset level for specific industries. There are 64 detailed movable assets (including intellectual property) and there are 32 detailed fixed assets in the BEA

estimates. Since we seek aggregate useful life estimates applicable to SNFs, we developed a methodology to approximate movable and fixed asset ages for nursing and residential care services (NAICS 623) using the published BEA data. For the proposed 2022-based SNF market basket, we use the current-cost average age for each asset type from the BEA fixed assets Table 2.9 for all assets and weight them using current-cost net stock levels for each of these asset types in the nursing and residential care services industry, NAICS 6230. For example, nonelectro medical equipment current-cost net stock (accounting for about 29 percent of total movable equipment current-cost net stock in 2022 is multiplied by an average age of 4.8 years for nonelectro medical equipment for all industries. Current-cost net stock levels are available for download from the BEA website at *https://apps.bea.gov/iTable/index_FA.cfm.* We then aggregate the ''weighted'' current-cost net stock levels (average age multiplied by current-cost net stock) into movable and fixed assets for NAICS 6230. We then adjust the average ages for movable and fixed assets by the ratio of historical-cost average age (Table 2.10) to current-cost average age (Table 2.9).

This produces historical cost average age data for fixed (structures) and movable (equipment and intellectual property) assets specific to NAICS 6230 of 13.6 and 4.4 years for 2022, respectively. This reflects the average age of an asset at a given point in time, whereas we want to estimate a useful life of the asset. To do this, we multiply each of the average age estimates by two to convert to average useful lives with the assumption that the average age reflects the midpoint of useful life and is normally distributed (about half of the assets are below the average at a given point in time, and half above the average at a given point in time). This produces estimates of likely useful lives of 27.2 and 8.8 years for fixed and movable assets, which we round to 27 and 9 years, respectively. We are proposing an interest vintage weight time span of 25 years, obtained by weighting the fixed and movable vintage weights (27 years and 9 years, respectively) by the fixed and movable split (86 percent and 14 percent, respectively). This is the same methodology used for the 2018-based SNF market basket, which had useful lives of 26 years and 9 years for fixed and movable assets, respectively.

b. Constructing Vintage Weights

Given the expected useful life of capital (fixed and movable assets) and debt instruments, we must determine the proportion of capital expenditures attributable to each year of the expected useful life for each of the three asset types: building and fixed equipment, movable equipment, and interest. These proportions represent the vintage weights. We were not able to find a historical time series of capital expenditures by SNFs. Therefore, we approximated the capital expenditure patterns of SNFs over time using alternative SNF data sources. For building and fixed equipment, we used the stock of beds in nursing homes from the National Nursing Home Survey (NNHS) conducted by the National Center for Health Statistics (NCHS) for 1962 through 1999. For 2000 through 2018, we extrapolated the 1999 bed data forward using measurements of the moving average rate of growth in the number of beds as reported in SNF Medicare cost report data on Worksheet S–3, part I, column 1, line 8. A more detailed discussion of this methodology was published in the FY 2022 SNF final rule (86 FR 42457). We are proposing to continue this methodology for the proposed 2022-based SNF market basket by extrapolating the 2018 bed data forward using the average growth in the number of beds over the 2019 to 2022 time period. We then propose to use the change in the stock of beds each year to approximate building and fixed equipment purchases for that year. This procedure assumes that bed growth reflects the growth in capital-related costs in SNFs for building and fixed equipment. We believe that this assumption is reasonable because the number of beds reflects the size of a SNF, and as a SNF adds beds, it also likely adds fixed capital.

As was done for the 2018-based SNF market basket (as well as prior market baskets), we are proposing to estimate movable equipment purchases based on the ratio of ancillary costs to routine costs. The time series of the ratio of ancillary costs to routine costs for SNFs measures changes in intensity in SNF services, which are assumed to be associated with movable equipment purchase patterns. The assumption here is that as ancillary costs increase compared to routine costs, the SNF caseload becomes more complex and would require more movable equipment. The lack of movable equipment purchase data for SNFs over time required us to use alternative SNF data sources. A more detailed discussion of this methodology was published in the FY 2008 SNF final rule (72 FR 43428). We believe the resulting two time series, determined from beds and the ratio of ancillary to routine costs, reflect real capital purchases of building and fixed equipment and movable equipment over time.

To obtain nominal purchases, which are used to determine the vintage weights for interest, we converted the two real capital purchase series from 1963 through 2022 determined above to nominal capital purchase series using their respective price proxies (the BEA Chained Price Index for Nonresidential Construction for Hospitals & Special Care Facilities and the PPI for Machinery and Equipment). We then combined the two nominal series into one nominal capital purchase series for 1963 through 2022. Nominal capital purchases are needed for interest vintage weights to capture the value of debt instruments.

Once we created these capital purchase time series for 1963 through 2022, we averaged different periods to obtain an average capital purchase pattern over time: (1) for building and fixed equipment, we averaged 34, 27-year periods; (2) for movable equipment, we averaged 52, 9-year periods; and (3) for interest, we averaged 36, 25-year periods. We calculate the vintage weight for a given year by dividing the capital purchase amount in any given year by the total amount of purchases during the expected useful life of the equipment or debt instrument.

The vintage weights for the proposed 2022-based SNF market basket and the 2018-based SNF market basket are presented in Table 18.

TABLE 18—PROPOSED 2022-BASED VINTAGE WEIGHTS AND 2018-BASED VINTAGE WEIGHTS

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	Proposed 2022-based 27 years	2018-based 26 years	Proposed 2022-based 9 years	2018-based 9 years	Proposed 2022-based 25 years	2018-based 24 years
1	0.049	0.049	0.106	0.135	0.026	0.027
2	0.048	0.050	0.121	0.140	0.027	0.028
3	0.048	0.049	0.119	0.128	0.028	0.029
4	0.046	0.047	0.103	0.112	0.030	0.031
5	0.045	0.045	0.117	0.119	0.031	0.032
6	0.043	0.043	0.124	0.111	0.033	0.034
7	0.042	0.041	0.101	0.084	0.035	0.036
8	0.042	0.040	0.093	0.080	0.038	0.037
9	0.039	0.037	0.115	0.091	0.041	0.038
10	0.037	0.035	.....	.....	0.043	0.040
11	0.038	0.036	.....	.....	0.045	0.043
12	0.039	0.036	.....	.....	0.045	0.047
13	0.038	0.036	.....	.....	0.044	0.049
14	0.038	0.036	.....	.....	0.044	0.051
15	0.038	0.035	.....	.....	0.045	0.050
16	0.036	0.036	.....	.....	0.045	0.048
17	0.034	0.036	.....	.....	0.045	0.048
18	0.033	0.038	.....	.....	0.045	0.048
19	0.033	0.037	.....	.....	0.043	0.048
20	0.032	0.036	.....	.....	0.042	0.048
21	0.031	0.035	.....	.....	0.042	0.047
22	0.030	0.035	.....	.....	0.043	0.047
23	0.030	0.035	.....	.....	0.044	0.047
24	0.028	0.033	.....	.....	0.045	0.049
25	0.027	0.032	.....	.....	0.051	.....
26	0.027	0.032	.....	.....	.....	.....
27	0.027	.....	.....	.....	.....	.....
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: The vintage weights are calculated using thirteen decimals. For presentation purposes, we are displaying three decimals and therefore, the detail vintage weights may not add to 1.000 due to rounding.

[1] Year 1 represents the vintage weight applied to the farthest year while the vintage weight for year 27, for example, would apply to the most recent year.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table 18 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

Table 19 shows all the price proxies for the proposed 2022-based SNF market basket.

TABLE 19—PRICE PROXIES FOR THE PROPOSED 2022-BASED SNF MARKET BASKET

Cost category	Weight	Price proxy
Total	100.0	
Compensation	61.2	
Wages and Salaries [1]	51.8	ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities.
Employee Benefits [1]	9.3	ECI for Total Benefits for Private Industry Workers in Nursing Care Facilities.
Utilities	2.7	
Electricity and Other Non-Fuel Utilities	1.8	PPI Commodity for Commercial Electric Power.
Fuel: Oil and Gas	0.8	Blend of PPIs.
Professional Liability Insurance	1.3	CMS Professional Liability Insurance Premium Index.
All Other	26.5	
Other Products	16.1	
Pharmaceuticals	6.4	PPI Commodity for Pharmaceuticals for Human Use, Prescription.
Food: Direct Purchase	2.9	PPI Commodity for Processed Foods and Feeds.
Food: Contract Purchase	3.4	CPI for Food Away From Home (All Urban Consumers).
Chemicals	0.2	Blend of PPIs.
Medical Instruments and Supplies	0.4	Blend of PPIs.

TABLE 19—PRICE PROXIES FOR THE PROPOSED 2022-BASED SNF MARKET BASKET—Continued

Cost category	Weight	Price proxy
Rubber and Plastics	1.0	PPI Commodity for Rubber and Plastic Products.
Paper and Printing Products	0.5	Blend of PPIs.
Apparel	0.4	PPI Commodity for Apparel.
Machinery and Equipment	0.7	PPI Commodity for Machinery and Equipment.
Miscellaneous Products	0.2	PPI Commodity for Finished Goods Less Food and Energy.
All Other Services	10.5	
Labor-Related Services	6.5	
Professional Fees: Labor-Related	3.6	ECI for Total Compensation for Private Industry Workers in Professional and Related.
Installation, Maintenance, and Repair Services	0.4	ECI for Total Compensation for All Civilian workers in Installation, Maintenance, and Repair.
Administrative and Facilities Support	0.5	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.
All Other: Labor-Related Services	2.0	ECI for Total Compensation for Private Industry Workers in Service Occupations.
Non Labor-Related Services	4.0	
Professional Fees: Nonlabor-Related	1.8	ECI for Total Compensation for Private Industry Workers in Professional and Related.
Financial Services	0.5	ECI for Total Compensation for Private Industry Workers in Financial Activities.
Telephone Services	0.4	CPI for Telephone Services.
All Other: Nonlabor-Related Services	1.3	CPI for All Items Less Food and Energy.
Capital-Related Expenses	8.3	
Total Depreciation	3.0	
Building and Fixed Equipment	2.5	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care—vintage weighted 27 years.
Movable Equipment	0.4	PPI Commodity for Machinery and Equipment—vintage weighted 9 years.
Total Interest	2.3	
For-Profit SNFs	0.7	iBoxx—Average yield on Aaa bond—vintage weighted 25 years.
Government and Nonprofit SNFs	1.6	Bond Buyer—Average yield on Domestic Municipal Bonds—vintage weighted 25 years.
Other Capital-Related Expenses	3.0	CPI for Rent of Primary Residence.

Note: The cost weights are calculated using three decimal places. For presentation purposes, we are displaying one decimal, and therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

4. Labor-Related Share

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. Each year, we calculate a revised labor-related share based on the relative importance of labor-related cost categories in the input price index. Effective for FY 2025, we are proposing to revise and update the labor-related share to reflect the relative importance of the proposed 2022-based SNF market basket cost categories that we believe are labor-intensive and vary with, or are influenced by, the local labor market. For the proposed 2022-based SNF market basket these are: (1) Wages and Salaries (including allocated contract labor costs as described above); (2) Employee Benefits (including allocated contract labor costs as described above); (3) Professional Fees: Labor-Related; (4) Administrative and Facilities Support Services; (5) Installation, Maintenance, and Repair Services; (6) All Other: Labor-Related Services; and (7) a proportion of capital-related expenses. We propose to continue to include a proportion of capital-related expenses because a portion of these expenses are deemed to be labor-intensive and vary with, or are influenced by, the local labor market. For example, a proportion of construction costs for a medical building would be attributable to local construction workers' compensation expenses.

Consistent with previous SNF market basket revisions and rebasings, the All Other: Labor-related services cost category is mostly comprised of building maintenance and security services (including, but not limited to, landscaping services, janitorial services, waste management services services) and dry cleaning and laundry services. Because these services tend to be labor-intensive and are mostly performed at the SNF facility or in the local area (and therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

These are the same cost categories we have included in the LRS for the 2018-based SNF market basket rebasing (86 FR 42461), as well as the same categories included in the LRS for the 2021-based IRF market basket (88 FR 50984), and 2021-based IPF market basket (88 FR 51078).

As discussed in the FY 2022 SNF PPS final rule (86 FR 42462), in an effort to determine more accurately the share of nonmedical professional fees (included in the proposed 2022-based SNF market basket Professional Fees cost categories) that should be included in the labor-related share, we surveyed SNFs regarding the proportion of those fees that are attributable to local firms and the proportion that are purchased from national firms. Based on these weighted results, we determined that SNFs purchase, on average, the following portions of contracted professional services inside their local labor market:

- 78 percent of legal services.
- 86 percent of accounting and auditing services.

- 89 percent of architectural, engineering services.
- 87 percent of management consulting services.

Together, these four categories represent 3.6 percentage points of the total costs for the proposed 2022-based SNF market basket. We applied the percentages from this special survey to their respective SNF market basket weights to separate them into labor-related and nonlabor-related costs. As a result, we are designating 2.8 of the 3.6 percentage points total to the labor-related share, with the remaining 0.8 percentage point categorized as nonlabor-related.

In addition to the professional services as previously listed, for the proposed 2022-based SNF market basket, we propose to allocate a proportion of the Home Office/Related Organization Contract Labor cost weight, calculated using the Medicare cost reports as previously stated, into the Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We propose to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office, and, therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market.

Similar to the 2018-based SNF market basket, we propose for the proposed 2022-based SNF market basket to use the Medicare cost reports for SNFs to determine the home office labor-related percentages. The Medicare cost report requires a SNF to report information regarding its home office provider. Using information on the Medicare cost report, we compared the location of the SNF with the location of the SNF's home office. We propose to classify a SNF with a home office located in their respective labor market if the SNF and its home office are located in the same Metropolitan Statistical Area (MSA). Then we determine the proportion of the Home Office/Related Organization Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total Home Office/Related Organization Contract Labor costs for those SNFs that had home offices located in their respective local labor markets of total Home Office/Related Organization Contract Labor costs for SNFs with a home office. We determined a SNF's and its home office's MSA using their zip code information from the Medicare cost report.

Using this methodology, we determined that 25 percent of SNFs' Home Office/Related Organization Contract Labor costs were for home offices located in their respective local labor markets. Therefore, we propose to allocate 25 percent of the Home Office/Related Organization Contract Labor cost weight (0.1 percentage point = 0.6 percent × 25 percent) to the Professional Fees: Labor-Related cost weight and 75 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-Related cost weight (0.4 percentage point = 0.6 percent × 75 percent). The 2018-based SNF market basket used a similar methodology for allocating the Home Office/Related Organization Contract Labor cost weight to the labor-related share.

In summary, based on the two allocations mentioned earlier, we propose to apportion 2.9 percentage points into the Professional Fees: Labor-Related cost category consisting of the Professional Fees (2.8 percentage points) and Home Office/Related Organization Contract Labor (0.1 percentage point) cost weights. This amount was added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 0.6 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 3.6 percent.

Table 20 compares the FY 2025 labor-related share based on the proposed 2022-based SNF market basket relative importance and the FY 2024 labor-related share based on the 2018-based SNF market basket relative importance as finalized in the FY 2024 SNF final rule (88 FR 53213).

TABLE 20—FY 2024 AND FY 2025 SNF LABOR-RELATED SHARE

	Relative importance, labor-related share, FY 2024 23:2 forecast [1]	Relative importance, labor-related share, FY 2025 23:4 forecast [2]
Wages and Salaries [3]	52.5	53.2
Employee Benefits [3]	9.3	9.1
Professional Fees: Labor-Related	3.4	3.5
Administrative & Facilities Support Services	0.6	0.4
Installation, Maintenance & Repair Services	0.4	0.5
All other: Labor-Related services	2.0	2.0
Capital-Related (.391)	2.9	3.2
Total	71.1	71.9

[1] Published in the **Federal Register** (88 FR 53213); based on the second quarter 2023 IHS Global Inc. forecast of the 2018-based SNF market basket, with historical data through first quarter 2023.

[2] Based on the fourth quarter 2023 IHS Global Inc. forecast of the proposed 2022-based SNF market basket, with historical data through third quarter 2023.

[3] The Wages and Salaries and Employee Benefits cost weight reflect contract labor costs as described above.

The proposed FY 2025 SNF labor-related share is 0.8 percentage point higher than the FY 2024 SNF labor-related share (based on the 2018-based SNF market basket). The higher labor-related share is primarily due to incorporating the 2022 Medicare cost report data, which resulted in a higher Compensation cost weight, as well as higher relative importance of the Capital cost category.

5. Market Basket Estimate for the FY 2025 SNF PPS Update

As discussed previously in this proposed rule, beginning with the FY 2025 SNF PPS update, we are proposing to adopt the proposed 2022-based SNF market basket as the appropriate market basket of goods and services for the SNF PPS. Consistent with historical practice, we estimate the market basket update for the SNF PPS based on IHS Global Inc.'s (IGI) forecast. IGI is a nationally

recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and total factor productivity (TFP).

Based on IGI's fourth quarter 2023 forecast with historical data through the third quarter of 2023, the most recent estimate of the proposed 2022-based SNF market basket update for FY 2025 is 2.8 percent—which is 0.1 percentage point lower than the FY 2025 percent change of the 2018-based SNF market basket. We are also proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket and/or the TFP), we would use such data, if appropriate, to determine the FY 2025 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the SNF PPS final rule.

Table 21 compares the proposed 2022-based SNF market basket and the 2018-based SNF market basket percent changes. While there are slight differences of up to 0.2 percentage point in certain years, there is no difference in the average growth rates between the two market baskets in either the historical (FY 2020–FY 2023) or forecast period (FY 2024–FY 2026) when rounded to one decimal place.

TABLE 21—PROPOSED 2022-BASED SNF MARKET BASKET AND 2018-BASED SNF MARKET BASKET, PERCENT CHANGES: 2020–2026

Fiscal Year (FY)	Proposed 2022-based SNF market basket	2018-Based SNF market basket
Historical data:		
FY 2020	2.0	2.1
FY 2021	3.6	3.6
FY 2022	6.5	6.3
FY 2023	5.6	5.6
Average FY 2020–2023	4.4	4.4
Forecast:		
FY 2024	3.7	3.7
FY 2025	2.8	2.9
FY 2026	2.7	2.7
Average FY 2024–2026	3.1	3.1

Source: IHS Global, Inc. 4th quarter 2023 forecast with historical data through 3rd quarter 2023.

B. Proposed Changes to SNF PPS Wage Index

1. Core-Based Statistical Areas (CBSAs) for the FY 2025 SNF PPS Wage Index

a. Background

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2025, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data under the IPPS also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use, as the basis for the SNF PPS wage index, the IPPS hospital wage data, unadjusted for occupational mix, without taking into account geographic reclassifications under section 1886(d)(8) and (d)(10) of the Act, and without applying the rural floor under section 4410 of the BBA 1997 and the outmigration adjustment under section 1886(d)(13) of the Act. For FY 2025, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2020 and before October 1, 2021 (FY 2021 cost report data).

The applicable SNF PPS wage index value is assigned to a SNF on the basis of the labor market area in which the SNF is geographically located. In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for Metropolitan Statistical Area (MSA) and the creation of micropolitan statistical areas and combined statistical areas. In adopting the Core-Based Statistical Areas (CBSA) geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01

were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300). As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), and as we note in this proposed rule, this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. Subsequently, on September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.* While OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations, including some new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. OMB issued further revised CBSA delineations in OMB Bulletin No. 20–01, on March 6, 2020 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). However, we determined that the changes in OMB Bulletin No. 20–01 do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, CMS did not propose to adopt the revised OMB delineations identified in OMB Bulletin No. 20 01 for FY 2022 through FY 2024.

On July 21, 2023, OMB issued OMB Bulletin No. 23–01 (available at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*) which updates and supersedes OMB Bulletin No. 20–01 based upon the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards'') published by the Office of Management and Budget (OMB) on July 16, 2021 (86 FR 37770). OMB Bulletin No. 23–01 revised CBSA delineations which are comprised of counties and equivalent entities (for example, boroughs, a city and borough, and a municipality in Alaska, planning regions in Connecticut, parishes in Louisiana, municipios in Puerto Rico, and independent cities in Maryland, Missouri, Nevada, and Virginia). For FY 2025, we propose to adopt the revised OMB delineations identified in OMB Bulletin No. 23–01.

To implement these changes for the SNF PPS beginning in FY 2025, it is necessary to identify the revised labor market area delineation for each affected county and provider in the country. The revisions OMB published on July 21, 2023 contain a number of significant changes. For example, under the proposed revised OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would split apart. We discuss these changes in more detail later in this proposed rule.

b. Proposed Implementation of Revised Labor Market Area Delineations

We typically delay implementing revised OMB labor market area delineations to allow for sufficient time to assess the new changes. For example, as discussed in the FY 2014 SNF PPS proposed rule (78 FR 26448) and final rule (78 FR 47952), we delayed implementing the revised OMB statistical area delineations described in OMB Bulletin No. 13–01 to allow for sufficient time to assess the new changes. We believe it is important for the SNF PPS to use the latest labor market area delineations available as soon as is reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the delineations reflected in OMB Bulletin No. 23–01 would increase the integrity of the SNF PPS wage index system by creating a more accurate representation of geographic variations in wage levels. We have reviewed our findings and impacts relating to the revised OMB delineations set forth in OMB Bulletin No. 23–01 and find no compelling reason to further delay implementation. Because we believe we have broad authority under section 1888(e)(4)(G)(ii) of the Act to determine the labor market areas used for the SNF PPS wage index, and because we believe the delineations reflected in OMB Bulletin No. 23–01 better reflect the local economies and wage levels of the areas in which hospitals are currently located, we are proposing to implement the revised OMB delineations as described in the July 21, 2023 OMB Bulletin No. 23–01, for the SNF PPS wage index effective beginning in FY 2025. In addition, we will apply the permanent 5 percent cap policy in FY 2025 on decreases in a hospital's wage index compared to its wage index for the prior fiscal year (FY 2024) to assist providers in adapting to the revised OMB delineations (if we finalize the implementation of such delineations for the SNF PPS wage index beginning in FY 2025). This policy is discussed in more detail later in this proposed rule. We invite comments on these proposals.

(1) Micropolitan Statistical Areas

As discussed in the FY 2006 SNF PPS proposed rule (70 FR 29093 through 29094) and final rule (70 FR 45041), we considered how to use the Micropolitan Statistical Area definitions in the calculation of the wage index. OMB defines a ''Micropolitan Statistical Area'' as a CBSA ''associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000'' (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's SNF PPS rural wage index (see 70 FR 29094 and 70 FR 45040 through 45041)).

Thus, the SNF PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in non-MSA areas, and the statewide rural wage index is assigned to SNFs located in those areas. Because Micropolitan Areas tend to encompass smaller population centers and contain fewer hospitals than MSAs, we determined that if Micropolitan Areas were to be treated as separate labor market areas, the SNF PPS wage index would have included significantly more single-provider labor market areas. As we explained in the FY 2006 SNF PPS proposed rule (70 FR 29094), recognizing Micropolitan Areas as independent labor markets would generally increase the potential for dramatic shifts in year-to-year wage index values because a single hospital (or group of hospitals) could have a disproportionate effect on the wage index of an area. Dramatic shifts in an area's wage index from year-to-year are problematic and create instability in the payment levels from year-to-year, which could make fiscal planning for SNFs difficult if we adopted this approach. For these reasons, we adopted a policy

to include Micropolitan Areas in the state's rural wage area for purposes of the SNF PPS wage index and have continued this policy through the present.

We believe that the best course of action would be to continue the policy established in the FY 2006 SNF PPS final rule and include Micropolitan Areas in each state's rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000 to 49,999). We do not believe it would be appropriate to calculate a separate wage index for areas that typically may include only a few hospitals for the reasons discussed in the FY 2006 SNF PPS proposed rule, and as discussed earlier. Therefore, in conjunction with our proposal to implement the revised OMB labor market delineations beginning in FY 2025 and consistent with the treatment of Micropolitan Areas under the IPPS, we are proposing to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of the state's rural wage index.

(2) Urban Counties That Would Become Rural Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the new OMB statistical area delineations (based upon the 2020 decennial Census data) beginning in FY 2025 for the SNF PPS wage index. Our analysis shows that a total of 54 counties (and county equivalents) that are currently considered part of an urban CBSA would be considered located in a rural area, for SNF PPS payment beginning in FY 2025, if we adopt the new OMB delineations. Table 22 lists the 54 urban counties that would be rural if we finalize our proposal to implement the new OMB delineations.

TABLE 22—COUNTIES THAT WOULD TRANSITION FROM URBAN TO RURAL STATUS

FIPS county code	County name	State	Current CBSA	Current CBSA name
01129	Washington	AL	33660	Mobile, AL.
05025	Cleveland	AR	38220	Pine Bluff, AR.
05047	Franklin	AR	22900	Fort Smith, AR-OK.
05069	Jefferson	AR	38220	Pine Bluff, AR.
05079	Lincoln	AR	38220	Pine Bluff, AR.
09015	Windham	CT	49340	Worcester, MA-CT.
10005	Sussex	DE	41540	Salisbury, MD-DE.
13171	Lamar	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA.
16077	Power	ID	38540	Pocatello, ID.
17057	Fulton	IL	37900	Peoria, IL.
17077	Jackson	IL	16060	Carbondale-Marion, IL.
17087	Johnson	IL	16060	Carbondale-Marion, IL.
17183	Vermilion	IL	19180	Danville, IL.
17199	Williamson	IL	16060	Carbondale-Marion, IL.
18121	Parke	IN	45460	Terre Haute, IN.
18133	Putnam	IN	26900	Indianapolis-Carmel-Anderson, IN.
18161	Union	IN	17140	Cincinnati, OH-KY-IN.
21091	Hancock	KY	36980	Owensboro, KY.
21101	Henderson	KY	21780	Evansville, IN-KY.
22045	Iberia	LA	29180	Lafayette, LA.
24001	Allegany	MD	19060	Cumberland, MD-WV.
24047	Worcester	MD	41540	Salisbury, MD-DE.
25011	Franklin	MA	44140	Springfield, MA.
26155	Shiawassee	MI	29620	Lansing-East Lansing, MI.
27075	Lake	MN	20260	Duluth, MN-WI.
28031	Covington	MS	25620	Hattiesburg, MS.
31051	Dixon	NE	43580	Sioux City, IA-NE-SD.
36123	Yates	NY	40380	Rochester, NY.
37049	Craven	NC	35100	New Bern, NC.
37077	Granville	NC	20500	Durham-Chapel Hill, NC.
37085	Harnett	NC	22180	Fayetteville, NC.
37087	Haywood	NC	11700	Asheville, NC.
37103	Jones	NC	35100	New Bern, NC.
37137	Pamlico	NC	35100	New Bern, NC.
42037	Columbia	PA	14100	Bloomsburg-Berwick, PA.
42085	Mercer	PA	49660	Youngstown-Warren-Boardman, OH-PA.
42089	Monroe	PA	20700	East Stroudsburg, PA.
42093	Montour	PA	14100	Bloomsburg-Berwick, PA.
42103	Pike	PA	35084	Newark, NJ-PA.
45027	Clarendon	SC	44940	Sumter, SC.
48431	Sterling	TX	41660	San Angelo, TX.
49003	Box Elder	UT	36260	Ogden-Clearfield, UT.
51113	Madison	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV.
51175	Southampton	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC.
51620	Franklin City	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC.
54035	Jackson	WV	16620	Charleston, WV.
54043	Lincoln	WV	16620	Charleston, WV.
54057	Mineral	WV	19060	Cumberland, MD-WV.
55069	Lincoln	WI	48140	Wausau-Weston, WI.
72001	Adjuntas	PR	38660	Ponce, PR.
72055	Guanica	PR	49500	Yauco, PR.

TABLE 22—COUNTIES THAT WOULD TRANSITION FROM URBAN TO RURAL STATUS—Continued

FIPS county code	County name	State	Current CBSA	Current CBSA name
72081	Lares	PR	10380	Aguadilla-Isabela, PR.
72083	Las Marias	PR	32420	Mayagüez, PR.
72141	Utuado	PR	10380	Aguadilla-Isabela, PR.

We are proposing that, for purposes of determining the wage index under the SNF PPS, the wage data for all hospitals located in the counties listed in Table 22 would be considered rural when calculating their respective state's rural wage index under the SNF PPS. We recognize that rural areas typically have lower area wage index values than urban areas, and SNFs located in these counties may experience a negative impact in their SNF PPS payment due to the proposed adoption of the revised OMB delineations. Furthermore, for SNF providers currently located in an urban county that would be considered rural should this proposal be finalized, we would utilize the rural unadjusted per diem rates, found in Table 4, as the basis for determining payment rates for these facilities beginning on October 1, 2024.

(3) Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the revised OMB statistical area delineations based upon OMB Bulletin No. 18–04 beginning in FY 2025. Analysis of these OMB statistical area delineations shows that a total of 54 counties (and county equivalents) that are currently located in rural areas would be located in urban areas if we finalize our proposal to implement the revised OMB delineations.

Table 23 lists the 54 rural counties that would be urban if we finalize this proposal.

TABLE 23—COUNTIES THAT WOULD TRANSITION FROM RURAL TO URBAN STATUS

FIPS county code	County	State	Proposed CBSA	Proposed CBSA name
01087	Macon	AL	12220	Auburn-Opelika, AL.
01127	Walker	AL	13820	Birmingham, AL.
12133	Washington	FL	37460	Panama City-Panama City Beach, FL.
13187	Lumpkin	GA	12054	Atlanta-Sandy Springs-Roswell, GA.
15005	Kalawao	HI	27980	Kahului-Wailuku, HI.
17053	Ford	IL	16580	Champaign-Urbana, IL.
17127	Massac	IL	37140	Paducah, KY-IL.
18159	Tipton	IN	26900	Indianapolis-Carmel-Greenwood, IN.
18179	Wells	IN	23060	Fort Wayne, IN.
20021	Cherokee	KS	27900	Joplin, MO-KS.
21007	Ballard	KY	37140	Paducah, KY-IL.
21039	Carlisle	KY	37140	Paducah, KY-IL.
21127	Lawrence	KY	26580	Huntington-Ashland, WV-KY-OH.
21139	Livingston	KY	37140	Paducah, KY-IL.
21145	Mc Cracken	KY	37140	Paducah, KY-IL.
21179	Nelson	KY	31140	Louisville/Jefferson County, KY-IN.
22053	Jeffrson Davis	LA	29340	Lake Charles, LA.
22083	Richland	LA	33740	Monroe, LA.
26015	Barry	MI	24340	Grand Rapids-Wyoming-Kentwood, MI.
26019	Benzie	MI	45900	Traverse City, MI.
26055	Grand Traverse	MI	45900	Traverse City, MI.
26079	Kalkaska	MI	45900	Traverse City, MI.
26089	Leelanau	MI	45900	Traverse City, MI.
27133	Rock	MN	43620	Sioux Falls, SD-MN.
28009	Benton	MS	32820	Memphis, TN-MS-AR.
28123	Scott	MS	27140	Jackson, MS.
30007	Broadwater	MT	25740	Helena, MT.
30031	Gallatin	MT	14580	Bozeman, MT.
30043	Jefferson	MT	25740	Helena, MT.
30049	Lewis And Clark	MT	25740	Helena, MT.
30061	Mineral	MT	33540	Missoula, MT.
32019	Lyon	NV	39900	Reno, NV.
37125	Moore	NC	38240	Pinehurst-Southern Pines, NC.
38049	Mchenry	ND	33500	Minot, ND.
38075	Renville	ND	33500	Minot, ND.
38101	Ward	ND	33500	Minot, ND.
39007	Ashtabula	OH	17410	Cleveland, OH.
39043	Erie	OH	41780	Sandusky, OH.
41013	Crook	OR	13460	Bend, OR.
41031	Jefferson	OR	13460	Bend, OR.
42073	Lawrence	PA	38300	Pittsburgh, PA.
45087	Union	SC	43900	Spartanburg, SC.
46033	Custer	SD	39660	Rapid City, SD.
47081	Hickman	TN	34980	Nashville-Davidson-Murfreesboro-Franklin, TN.

TABLE 23—COUNTIES THAT WOULD TRANSITION FROM RURAL TO URBAN STATUS—Continued

FIPS county code	County	State	Proposed CBSA	Proposed CBSA name
48007	Aransas	TX	18580	Corpus Christi, TX.
48035	Bosque	TX	47380	Waco, TX.
48079	Cochran	TX	31180	Lubbock, TX.
48169	Garza	TX	31180	Lubbock, TX.
48219	Hockley	TX	31180	Lubbock, TX.
48323	Maverick	TX	20580	Eagle Pass, TX.
48407	San Jacinto	TX	26420	Houston-Pasadena-The Woodlands, TX.
51063	Floyd	VA	13980	Blacksburg-Christiansburg-Radford, VA.
51181	Surry	VA	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC.
55123	Vernon	WI	29100	La Crosse-Onalaska, WI-MN.

We are proposing that, for purposes of calculating the area wage index under the SNF PPS, the wage data for hospitals located in the counties listed in Table 23 would be included in their new respective urban CBSAs. Typically, SNFs located in an urban area would receive a wage index value higher than or equal to SNFs located in their state's rural area. Furthermore, for SNFs currently located in a rural county that would be considered urban should this proposal be finalized, we would utilize the urban unadjusted per diem rates found in Table 3, as the basis for determining the payment rates for these facilities beginning October 1, 2024.

(4) Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the new OMB delineations. In other cases, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs.

In one type of change, an entire CBSA would be subsumed by another CBSA. For example, CBSA 31460 (Madera, CA) currently is a single county (Madera, CA) CBSA. Madera County would be a part of CBSA 23420 (Fresno, CA) under the new OMB delineations.

In another type of change, some CBSAs have counties that would split off to become part of, or to form, entirely new labor market areas. For example, CBSA 29404 (Lake County-Kenosha County, IL-WI) currently is comprised of two counties (Lake County, IL and Kenosha County, WI). Under the new OMB delineations, Kenosha county would split off and form the new CBSA 28450 (Kenosha, WI), while Lake county would remain in CBSA 29404.

Finally, in some cases, a CBSA would lose counties to another existing CBSA if we adopt the new OMB delineations. For example, Meade County, KY, would move from CBSA 21060 (Elizabethtown-Fort Knox, KY) to CBSA 31140 (Louisville/Jefferson County, KY-IN). CBSA 21060 would still exist in the new labor market delineations with fewer constituent counties. Table 24 lists the urban counties that would move from one urban CBSA to another urban CBSA under the new OMB delineations.

TABLE 24—COUNTIES THAT WOULD CHANGE TO A DIFFERENT CBSA

FIPS county code	County name	State	Current CBSA	Proposed CBSA
06039	Madera	CA	31460	23420
11001	The District	DC	47894	47764
12053	Hernando	FL	45300	45294
12057	Hillsborough	FL	45300	45294
12101	Pasco	FL	45300	45294
12103	Pinellas	FL	45300	41304
12119	Sumter	FL	45540	48680
13013	Barrow	GA	12060	12054
13015	Bartow	GA	12060	31924
13035	Butts	GA	12060	12054
13045	Carroll	GA	12060	12054
13057	Cherokee	GA	12060	31924
13063	Clayton	GA	12060	12054
13067	Cobb	GA	12060	31924
13077	Coweta	GA	12060	12054
13085	Dawson	GA	12060	12054
13089	De Kalb	GA	12060	12054
13097	Douglas	GA	12060	12054
13113	Fayette	GA	12060	12054
13117	Forsyth	GA	12060	12054
13121	Fulton	GA	12060	12054
13135	Gwinnett	GA	12060	12054
13143	Haralson	GA	12060	31924
13149	Heard	GA	12060	12054
13151	Henry	GA	12060	12054
13159	Jasper	GA	12060	12054
13199	Meriwether	GA	12060	12054

TABLE 24—COUNTIES THAT WOULD CHANGE TO A DIFFERENT CBSA—Continued

FIPS county code	County name	State	Current CBSA	Proposed CBSA
13211	Morgan	GA	12060	12054
13217	Newton	GA	12060	12054
13223	Paulding	GA	12060	31924
13227	Pickens	GA	12060	12054
13231	Pike	GA	12060	12054
13247	Rockdale	GA	12060	12054
13255	Spalding	GA	12060	12054
13297	Walton	GA	12060	12054
18073	Jasper	IN	23844	29414
18089	Lake	IN	23844	29414
18111	Newton	IN	23844	29414
18127	Porter	IN	23844	29414
21163	Meade	KY	21060	31140
22103	St. Tammany	LA	35380	43640
24009	Calvert	MD	47894	30500
24017	Charles	MD	47894	47764
24033	Prince Georges	MD	47894	47764
24037	St. Marys	MD	15680	30500
25015	Hampshire	MA	44140	11200
34009	Cape May	NJ	36140	12100
34023	Middlesex	NJ	35154	29484
34025	Monmouth	NJ	35154	29484
34029	Ocean	NJ	35154	29484
34035	Somerset	NJ	35154	29484
36027	Dutchess	NY	39100	28880
36071	Orange	NY	39100	28880
37019	Brunswick	NC	34820	48900
39035	Cuyahoga	OH	17460	17410
39055	Geauga	OH	17460	17410
39085	Lake	OH	17460	17410
39093	Lorain	OH	17460	17410
39103	Medina	OH	17460	17410
39123	Ottawa	OH	45780	41780
47057	Grainger	TN	34100	28940
51013	Arlington	VA	47894	11694
51043	Clarke	VA	47894	11694
51047	Culpeper	VA	47894	11694
51059	Fairfax	VA	47894	11694
51061	Fauquier	VA	47894	11694
51107	Loudoun	VA	47894	11694
51153	Prince William	VA	47894	11694
51157	Rappahannock	VA	47894	11694
51177	Spotsylvania	VA	47894	11694
51179	Stafford	VA	47894	11694
51187	Warren	VA	47894	11694
51510	Alexandria City	VA	47894	11694
51600	Fairfax City	VA	47894	11694
51610	Falls Church City	VA	47894	11694
51630	Fredericksburg City	VA	47894	11694
51683	Manassas City	VA	47894	11694
51685	Manassas Park City	VA	47894	11694
53061	Snohomish	WA	42644	21794
54037	Jefferson	WV	47894	11694
55059	Kenosha	WI	29404	28450
72023	Cabo Rojo	PR	41900	32420
72059	Guayanilla	PR	49500	38660
72079	Lajas	PR	41900	32420
72111	Penuelas	PR	49500	38660
72121	Sabana Grande	PR	41900	32420
72125	San German	PR	41900	32420
72153	Yauco	PR	49500	38660

If providers located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values.

In other cases, adopting the revised OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19430 (Dayton-Kettering, OH) would experience a change to its name and become CBSA 19430 (Dayton-Kettering-Beavercreek, OH), while all of its three constituent counties would remain the same. We consider these proposed

changes (where only the CBSA name and/or number would change) to be inconsequential changes with respect to the SNF PPS wage index. Table 25 sets forth a list of such CBSAs where there would be a change in CBSA name and/or number only if we adopt the revised OMB delineations.

TABLE 25—URBAN CBSAS WITH CHANGE TO NAME AND/OR NUMBER

Current CBSA	Current CBSA name	Proposed CBSA	Proposed CBSA name
10380	Aguadilla-Isabela, PR	10380	Aguadilla, PR.
10540	Albany-Lebanon, OR	10540	Albany, OR.
12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA.
12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA.
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock-San Marcos, TX.
12540	Bakersfield, CA	12540	Bakersfield-Delano, CA.
13820	Birmingham-Hoover, AL	13820	Birmingham, AL.
13980	Blacksburg-Christiansburg, VA	13980	Blacksburg-Christiansburg-Radford, VA.
14860	Bridgeport-Stamford-Norwalk, CT	14860	Bridgeport-Stamford-Danbury, CT.
15260	Brunswick, GA	15260	Brunswick-St. Simons, GA.
15680	California-Lexington Park, MD	30500	Lexington Park, MD.
16540	Chambersburg-Waynesboro, PA	16540	Chambersburg, PA.
16984	Chicago-Naperville-Evanston, IL	16984	Chicago-Naperville-Schaumburg, IL.
17460	Cleveland-Elyria, OH	17410	Cleveland, OH.
19430	Dayton-Kettering, OH	19430	Dayton-Kettering-Beavercreek, OH.
19740	Denver-Aurora-Lakewood, CO	19740	Denver-Aurora-Centennial, CO.
21060	Elizabethtown-Fort Knox, KY	21060	Elizabethtown, KY.
21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN.
21780	Evansville, IN-KY	21780	Evansville, IN.
21820	Fairbanks, AK	21820	Fairbanks-College, AK.
22660	Fort Collins, CO	22660	Fort Collins-Loveland, CO.
23224	Frederick-Gaithersburg-Rockville, MD	23224	Frederick-Gaithersburg-Bethesda, MD.
23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN.
24340	Grand Rapids-Kentwood, MI	24340	Grand Rapids-Wyoming-Kentwood, MI.
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Greer, SC.
25540	Hartford-East Hartford-Middletown, CT	25540	Hartford-West Hartford-East Hartford, CT.
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Port Royal, SC.
26380	Houma-Thibodaux, LA	26380	Houma-Bayou Cane-Thibodaux, LA.
26420	Houston-The Woodlands-Sugar Land, TX	26420	Houston-Pasadena-The Woodlands, TX.
26900	Indianapolis-Carmel-Anderson, IN	26900	Indianapolis-Carmel-Greenwood, IN.
27900	Joplin, MO	27900	Joplin, MO-KS.
27980	Kahului-Wailuku-Lahaina, HI	27980	Kahului-Wailuku, HI.
29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI.
29404	Lake County-Kenosha County, IL-WI	29404	Lake County, IL.
29820	Las Vegas-Henderson-Paradise, NV	29820	Las Vegas-Henderson-North Las Vegas, NV.
31020	Longview, WA	31020	Longview-Kelso, WA.
31460	Madera, CA	23420	Fresno, CA.
34100	Morristown, TN	28940	Knoxville, TN.
34740	Muskegon, MI	34740	Muskegon-Norton Shores, MI.
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	34820	Myrtle Beach-Conway-North Myrtle Beach, SC.
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	48900	Wilmington, NC.
35084	Newark, NJ-PA	35084	Newark, NJ.
35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ.
35300	New Haven-Milford, CT	35300	New Haven, CT.
35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville-Covington, LA.
35840	North Port-Sarasota-Bradenton, FL	35840	North Port-Bradenton-Sarasota, FL.
35980	Norwich-New London, CT	35980	Norwich-New London-Willimantic, CT.
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Fremont-Berkeley, CA.
36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ.
36260	Ogden-Clearfield, UT	36260	Ogden, UT.
36540	Omaha-Council Bluffs, NE-IA	36540	Omaha, NE-IA.
37460	Panama City, FL	37460	Panama City-Panama City Beach, FL.
39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY.
39340	Provo-Orem, UT	39340	Provo-Orem-Lehi, UT.
39540	Racine, WI	39540	Racine-Mount Pleasant, WI.
41540	Salisbury, MD-DE	41540	Salisbury, MD.
41620	Salt Lake City, UT	41620	Salt Lake City-Murray, UT.
41900	San Germán, PR	32420	Mayagüez, PR.
42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA.
42680	Sebastian-Vero Beach, FL	42680	Sebastian-Vero Beach-West Vero Corridor, FL.
42700	Sebring-Avon Park, FL	42700	Sebring, FL.
43620	Sioux Falls, SD	43620	Sioux Falls, SD-MN.
44140	Springfield, MA	11200	Amherst Town-Northampton, MA.
44420	Staunton, VA	44420	Staunton-Stuarts Draft, VA.
44700	Stockton, CA	44700	Stockton-Lodi, CA.
45300	Tampa-St. Petersburg-Clearwater, FL	41304	St. Petersburg-Clearwater-Largo, FL.
45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL.

TABLE 25—URBAN CBSAS WITH CHANGE TO NAME AND/OR NUMBER—Continued

Current CBSA	Current CBSA name	Proposed CBSA	Proposed CBSA name
45540	The Villages, FL	48680	Wildwood-The Villages, FL.
45780	Toledo, OH	41780	Sandusky, OH.
47220	Vineland-Bridgeton, NJ	47220	Vineland, NJ.
47260	Virginia Beach-Norfolk-Newport News, VA-NC	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC.
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV.
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD.
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD.
48140	Wausau-Weston, WI	48140	Wausau, WI.
48300	Wenatchee, WA	48300	Wenatchee-East Wenatchee, WA.
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL.
49340	Worcester, MA-CT	49340	Worcester, MA.
49500	Yauco, PR	38660	Ponce, PR.
49660	Youngstown-Warren-Boardman, OH-PA	49660	Youngstown-Warren, OH.

5. Change to County-Equivalents in the State of Connecticut

The June 6, 2022 Census Bureau Notice (87 FR 34235–34240), OMB Bulletin No. 23–01 replaced the 8 counties in Connecticut with 9 new ''Planning Regions.'' Planning regions now serve as county-equivalents within the CBSA system. We are proposing to adopt the planning regions as county equivalents for wage index purposes. We believe it is necessary to adopt this migration from counties to planning region county-equivalents in order to maintain consistency with OMB updates. We are providing the following crosswalk with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

TABLE 26—CONNECTICUT COUNTIES TO PLANNING REGIONS

FIPS	Current county	Current CBSA	Proposed FIPS	Proposed planning region area (county equivalent)	Proposed CBSA
9001	Fairfield	14860	9190	Western Connecticut	14860
9001	Fairfield	14860	9120	Greater Bridgeport	14860
9003	Hartford	25540	9110	Capitol	25540
9005	Litchfield	7	9160	Northwest Hills	7
9007	Middlesex	25540	9130	Lower Connecticut River Valley	25540
9009	New Haven	35300	9170	South Central Connecticut	35300
9009	New Haven	35300	9140	Naugatuck Valley	47930
9011	New London	35980	9180	Southeastern Connecticut	35980
9013	Tolland	25540	9110	Capitol	25540
9015	Windham	49340	9150	Northeastern Connecticut	7

2. Transition Policy for FY 2025 Wage Index Changes

Overall, we believe that implementing the new OMB delineations would result in wage index values being more representative of the actual costs of labor in a given area. We recognize that some SNFs (43 percent) would experience decreases in their area wage index values as a result of this proposal, though less than 1 percent of providers would experience a significant decrease (that is, greater than 5 percent) in their area wage index value. We also realize that many SNFs (57 percent) would have higher area wage index values after adopting the revised OMB delineations.

CMS recognizes that SNFs in certain areas may experience reduced payment due to the proposed adoption of the revised OMB delineations and has finalized transition policies to mitigate negative financial impacts and provide stability to year-to-year wage index variations. In FY 2023, the 5 percent cap policy was made permanent for all SNFs. This 5 percent cap on reductions policy is discussed in further detail in FY 2023 final rule at 87 FR 47521 through 47523. It is CMS's long held opinion that revised labor market delineations should be adopted as soon as is possible to maintain the integrity the wage index system. We believe the 5 percent cap policy will sufficiently mitigate significant disruptive financial impacts on SNFs negatively affected by the proposed adoption of the revised OMB delineations. We do not believe any additional transition is necessary considering that the current cap on wage index decreases, which was not in place when implementing prior decennial census updates in FY 2006 and FY 2015, ensures that a SNF's wage index would not be less than 95 percent of its final wage index for the prior year.

Furthermore, consistent with the requirement at section 1888(e)(4)(G)(ii) of the Act that wage index adjustments must be made in a budget neutral manner, the applied 5 percent cap on the decrease in an SNF's wage index would not result in any change in estimated aggregate SNF PPS payments by applying a budget neutrality factor to the unadjusted Federal per diem rates. The methodology for calculating this budget neutrality factor is discussed below in section III.D of this proposed rule.

We invite comments on our proposed implementation of revised labor market area delineations. The proposed wage index applicable to FY 2025 is set forth in Table A available on the CMS website at *http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* Table A provides a crosswalk between the FY 2024 wage index for a provider using the current OMB delineations in effect in FY 2024 and the FY 2025 wage index using the proposed revised OMB delineations.

C. Technical Updates to the PDPM ICD–10 Mappings

1. Background

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the Patient Driven Payment Model (PDPM), effective October 1, 2019. The PDPM utilizes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM, hereafter referred to as ICD–10) codes in several ways, including using the patient's primary diagnosis to assign patients to clinical categories under several PDPM components, specifically the PT, OT, SLP, and NTA components. While other ICD–10 codes may be reported as secondary diagnoses and designated as additional comorbidities, the PDPM does not use secondary diagnoses to assign patients to clinical categories. The PDPM ICD–10 code to clinical category mapping, ICD–10 code to SLP comorbidity mapping, and ICD–10 code to NTA comorbidity mapping (hereafter collectively referred to as the PDPM ICD–10 code mappings) are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.*

In the FY 2020 SNF PPS final rule (84 FR 38750), we outlined the process by which we maintain and update the PDPM ICD–10 code mappings, as well as the SNF Grouper software and other such products related to patient classification and billing, to ensure that they reflect the most up to date codes. Beginning with the updates for FY 2020, we apply non-substantive changes to the PDPM ICD–10 code mappings through a sub-regulatory process consisting of posting the updated PDPM ICD–10 code mappings on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.* Such nonsubstantive changes are limited to those specific changes that are necessary to maintain consistency with the most current PDPM ICD–10 code mappings.

On the other hand, substantive changes that go beyond the intention of maintaining consistency with the most current PDPM ICD–10 code mappings, such as changes to the assignment of a code to a clinical category or comorbidity list, would be through notice and comment rulemaking because they are changes that affect policy. We note that, in the case of any diagnoses that are either currently mapped to Return to Provider or that we are finalizing to classify into this category, this is not intended to reflect any judgment on the importance of recognizing and treating these conditions. Rather, we believe that there are more specific or appropriate diagnoses that would better serve as the primary diagnosis for a Part-A covered SNF stay.

2. Clinical Category Changes for New ICD–10 Codes for FY 2025

Each year, we review the clinical category assigned to new ICD–10 diagnosis codes and propose changing the assignment to another clinical category if warranted. This year, we are proposing changing the clinical category assignment for the following four new codes that were effective on October 1, 2023.

- E88.10 *Metabolic Syndrome* was initially mapped to the clinical category of Medical Management. The National Institutes of Health (NIH) as the presence of at least three of the following traits: Large waist, elevated triglyceride levels, reduced high-density lipoprotein (HDL) cholesterol, increased blood pressure, and/or elevated fasting blood glucose. Metabolic syndrome is a cluster of metabolic risk factors for cardiovascular diseases and type 2 diabetes mellitus. The root causes of metabolic syndrome are overweight/obesity, physical inactivity, and genetic factors. Given this, treatment for Metabolic Syndrome typically occurs outside of a Part A SNF stay and we do not believe it would serve appropriately as the primary diagnosis for a Part A-covered SNF stay. For this reason, we propose to change the mapping of this code from Medical Management to the clinical category of Return to Provider.
- E88.811 *Insulin Resistance Syndrome, Type A* was initially mapped to the clinical category of Medical Management. Type A insulin resistance syndrome (TAIRS) is a rare disorder characterized by severe insulin resistance due to defects in insulin receptor signaling and treatment typically occurs outside of a Part A SNF stay. For this reason, we propose to change the mapping of this code from Medical Management to the clinical category of Return to Provider.
- E88.818 *Other Insulin Resistance* was initially mapped to the clinical category of Medical Management. Other Insulin Resistance is used to specify a medical diagnosis of other insulin resistance such as Insulin resistance, Type B. Treatment typically occurs outside of a Part A SNF stay. For this reason, we propose to change the mapping of this code from Medical Management to the clinical category of Return to Provider.
- E88.819 *Insulin Resistance, Unspecified* was initially mapped to the clinical category of Medical Management and is utilized to indicate when a specific type of insulin resistance has not been specifically identified. Treatment typically occurs outside of a Part A SNF stay. For this reason, we propose to change the mapping of this code from Medical Management to the clinical category of Return to Provider.

We solicit comments on the proposed substantive changes to the PDPM ICD–10 code mappings discussed in this section, as well as comments on additional substantive and non-substantive changes that commenters believe are necessary.

D. Request for Information: Update to PDPM Non-Therapy Ancillary Component

1. Background

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the PDPM, effective October 1, 2019. Under the PDPM, payment is determined through the combination of six payment components. Five of the components (PT, OT, SLP, NTA, and nursing) are case-mix adjusted. Additionally, there is a non-case-mix adjusted component to cover utilization of SNF resources that do not vary according to patient characteristics.

The NTA component utilizes a comorbidity score to assign the patient to an NTA component case-mix group, which is determined by the presence of conditions or the use of extensive services (henceforth also referred to as comorbidities) that were found to be correlated with increases in NTA costs for SNF patients. The presence of these conditions and extensive services is reported by providers on certain items of the Minimum Data Set (MDS) resident assessment, with some conditions and extensive services being identified by ICD–10–CM codes (hereafter referred to as ICD–10 codes) that are coded in Item I8000 of the MDS. MDS Item I8000 is an open-ended item on the MDS assessment where the provider can fill in additional active diagnoses for the patient that are either not explicitly on the MDS, or are more severe or specific diagnoses, in the form of ICD–10 codes. For conditions and extensive services where the source is indicated as MDS item I8000, CMS posts an NTA Comorbidity to ICD–10 Mapping, available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/skilled-nursing-facility-snf/patient-driven-model,* that provides a crosswalk between the listed condition and the ICD–10 codes that may be coded to

qualify that condition to serve as part of the patient's NTA classification.

During the development of PDPM, CMS identified a list of 50 conditions and extensive services that were associated with increases in NTA costs. Each of the 50 comorbidities used under PDPM for NTA classification is assigned a certain number of points based on its relative costliness. To determine the patient's NTA comorbidity score, a provider would identify all the comorbidities for which a patient would qualify and then add the points for each comorbidity together. The resulting sum represents the patient's NTA comorbidity score, which is then used to classify the patient into an NTA component classification group. More information about the creation of the NTA component scoring method can be found in Section 3.7 of the SNF PDPM Technical Report, available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/skilled-nursing-facility-snf/pps-model-research*.

In response to stakeholder comments, CMS stated in the FY 2019 SNF PPS final rule that we would consider revisiting both the list of included NTA comorbidities and the points assigned to each condition or extensive service based on changes in the patient population and care practices over time (83 FR 39224). This request for information (RFI) solicits comment on the methodology CMS is currently considering for updating the NTA component.

2. Updates to the Study Population and Methodology

We are considering several changes to the NTA study population as a foundation upon which to update the NTA component. First, we are considering updating the years used for data corresponding to Medicare Part A SNF stays, including claims, assessments, and cost reports. To develop PDPM, CMS used a study population of Medicare Part A SNF stays with admissions from FY 2014 through FY 2017 (see FY 2019 SNF PPS final rule, 83 FR 39220). This methodology is described in more detail in Section 3.2.1 of the SNF PDPM technical report, available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/skilled-nursing-facility-snf/pps-model-research*. The updated study population will instead use Medicare Part A SNF stays with admissions from FY 2019 through FY 2022. However, as discussed in the FY 2023 SNF PPS final rule (87 FR 47526 through 47528), data from much of this time period was affected by the national COVID–19 PHE with significant impacts on nursing homes. We are therefore considering using the same subset population used for the PDPM parity adjustment recalibration by excluding stays with either a COVID–19 diagnosis or stays using a COVID–19 PHE-related modification under section 1812(f) of the Act.

Next, we are considering making certain methodological changes to reflect more accurate and reliable coding of NTA conditions and extensive services on SNF Part A claims and the MDS after PDPM implementation. We had taken a broad approach when creating the initial PDPM NTA list to predict what NTA coding practices would be after PDPM implementation, given the absence of analogous data in the previous Resource Utilization Groups, Version IV (RUG–IV) payment model. The NTA list was therefore created using data from a variety of different sources, including using Medicare inpatient, outpatient, and Part B claims to identify the presence of condition categories from the Medicare Parts C and D risk adjustment models (hereafter referred to as CCs and RxCCs, respectively). More information about this methodology can be found in Section 3.7 of the SNF PDPM Technical Report, available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/skilled-nursing-facility-snf/pps-model-research*. Given that we now have several years of post-PDPM implementation data, we believe it would more accurately reflect the coding of conditions and extensive services under PDPM to rely exclusively upon SNF PPS Part A claims and the MDS. We are therefore considering updating the methodology to only utilize SNF Part A claims and the MDS, and not claim types from other Medicare settings.

Additionally, we are considering modifying the overlap methodology to rely more upon the MDS items that use a checkbox to record the presence of conditions and extensive services whenever possible, while allowing for potentially more severe or specific diagnoses to be indicated on MDS item I8000 when it would be useful for more accurate patient classification under PDPM. During the development of the NTA component, CMS included both MDS items and ICD–10 diagnoses from the Medicare Part C CCs and Part D RxCCs. Because the CCs were developed to predict utilization of Medicare Part C services, while the RxCCs were developed to predict Medicare Part D drug costs, the largest component of NTA costs, we stated in the FY 2019 SNF PPS final rule that we believed using both sources allowed us to define the conditions and extensive services potentially associated with NTA utilization more comprehensively (83 FR 39220). In cases where there was considerable overlap between an MDS item and its CC or RxCC definition, to ensure accurate estimation of statistically significant regression results, we chose the CC or RxCC definition if it had higher average NTA cost per day than the MDS item before running the final regression analysis. More information about this methodology can be found in Section 3.7 of the SNF PDPM Technical Report, available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/skilled-nursing-facility-snf/pps-model-research*.

Since the implementation of PDPM, we believe patient conditions and extensive services are now more accurately and reliably reported by providers using MDS items. We are therefore considering prioritizing the reporting of conditions on the MDS by raising the cost threshold for selecting the overlapping CC or RxCC definitions from any additional cost to 5 dollars in average NTA cost per day, which is the amount that we observe to be generally associated with a 1-point NTA increase. Specifically, since any dollar amount less than 5 dollars would render the two options indistinguishable from each other in the point assignment when comparing relative costliness, choosing MDS items over CC/RxCCs will not lead to any loss of the most expensive representations of the conditions and services in the regression model.

3. Updates to Conditions and Extensive Services Used for NTA Classification

Table 27 provides the list of conditions and extensive services that would be used for NTA classification following the various changes we are considering to the methodology outlined above. For each condition or extensive service, we have also included the frequency of stays, the average NTA cost per day, the ordinary least squares (OLS) estimate of its impact on NTA costs per day, and the assigned number of points based on its relative impact on a patient's NTA costs. Conditions and extensive services with a greater impact on NTA costs were assigned more points, while those with less of an impact were assigned fewer points. More information about this methodology can be found in Section 3.7 of the SNF PDPM Technical Report, available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/skilled-nursing-facility-snf/pps-model-research*.

TABLE 27—CONDITIONS AND EXTENSIVE SERVICES USED FOR NTA CLASSIFICATION

NTA comorbidity	% of stays	Avg NTA costs	OLS estimate	PDPM points
DGN: HIV/AIDS	0.3	$128	$71.01	7
RxCC: Lung Transplant Status	0.0	117	49.29	5
O0100H2: Special Treatments/Programs: Intravenous Medication Post-admit Code	8.6	105	46.99	5
MDS: Parenteral IV feeding: Level high	0.3	120	46.27	5
RxCC: Cystic Fibrosis	0.0	99	31.10	3
RxCC: Major Organ Transplant Status, Except Lung	0.5	85	21.66	2
CC: Cirrhosis of Liver	2.0	77	18.92	2
RxCC: Chronic Myeloid Leukemia	0.1	75	17.81	2
DGN: Endocarditis	0.5	97	17.46	2
RxCC: Opportunistic Infections	0.3	85	16.91	2
I2900: Active Diagnoses: Diabetes Mellitus (DM) Code	38.2	66	15.67	2
O0100I2: Special Treatments/Programs: Transfusion Post-admit Code	0.2	80	14.65	1
MDS: Parenteral IV feeding: Level Low	0.0	82	14.26	1
CC: Bone/Joint/Muscle Infections/Necrosis—Except: RxCC: Aseptic Necrosis of Bone	2.9	97	14.23	1
I6200: Active Diagnoses: Asthma COPD Chronic Lung Disease Code	29.2	66	13.72	1
O0100D2: Special Treatments/Programs: Suctioning Post-admit Code	0.8	86	13.11	1
RxCC: Psoriatic Arthropathy and Systemic Sclerosis	0.2	72	12.87	1
RxCC: Chronic Pancreatitis	0.3	75	12.64	1
RxCC: Specified Hereditary Metabolic/Immune Disorders	0.0	74	10.36	1
I5200: Active Diagnoses: Multiple Sclerosis Code	0.9	63	9.84	1
O0100F2: Special Treatments/Programs: Ventilator Post-admit Code	0.3	99	9.79	1
RxCC: Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.6	65	9.16	1
M1040B: Other Foot Skin Problems: Diabetic Foot Ulcer Code	1.6	87	9.07	1
RxCC: Narcolepsy and Cataplexy	0.1	68	9.01	1
RxCC: Venous Thromboembolism	4.4	64	8.86	1
B0100: Comatose	0.0	87	8.64	1
M0300X1: Highest Stage of Unhealed Pressure Ulcer—Stage 4	1.6	80	8.48	1
I1300: Active Diagnoses: Ulcerative Colitis, Crohn's Disease, or Inflammatory Bowel Disease	2.3	63	7.77	1
RxCC: Atrial Arrhythmias	26.4	60	7.35	1
RxCC: Sickle Cell Anemia	0.0	65	7.27	1
RxCC: Myelodysplastic Syndromes and Myelofibrosis	0.4	65	7.11	1
I2500: Wound Infection Code	2.1	84	6.96	1
RxCC: Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	2.5	62	6.94	1
RxCC: Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease—Except: CC: Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.3	64	6.60	1
CC: Complications of Specified Implanted Device or Graft	0.3	75	6.39	1
I6100: Active Diagnoses: Post Traumatic Stress Disorder	0.6	67	5.94	1
RxCC: Aplastic Anemia and Other Significant Blood Disorders	0.4	64	5.90	1
O0100M2: Special Treatments/Programs: Isolation Post-admit Code	2.0	68	5.77	1
I0600: Active Diagnoses: Heart Failure	29.5	63	5.72	1
H0100D: Bladder and Bowel Appliances: Intermittent catheterization	0.8	59	5.39	1
I6300: Active Diagnoses: Respiratory Failure	12.5	67	5.10	1
RxCC: Morbid Obesity	6.7	69	5.02	1
I5700: Active Diagnoses: Anxiety Disorder	22.4	59	4.89	1
CC: Disorders of Immunity—Except: RxCC: Immune Disorders	0.9	65	4.76	1
G0600D: Mobility Devices: Limb prosthesis	0.4	68	4.65	1
RxCC: Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	2.4	61	4.62	1
I1700: Active Diagnoses: Multi-Drug Resistant Organism (MDRO) Code	2.7	84	4.57	1
M1040E: Other Skin Problems: Surgical Wound(s) Code	25.7	57	4.05	1
I5900: Active Diagnoses: Bipolar Disorder	3.5	61	4.02	1
RxCC: Chronic Viral Hepatitis, Except Hepatitis C	0.1	71	3.90	1

We invite comments on the updates that we are considering for the NTA component of PDPM.

VI. Skilled Nursing Facility Quality Reporting Program (SNF QRP)

A. Background and Statutory Authority

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-critical access hospital (CAH) swing-bed rural hospitals. Section 1888(e)(6)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual market basket percentage increase described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year (FY), after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for that FY. Section 1890A of the Act requires that the Secretary establish and

follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the SNF QRP. We have codified our program requirements in our regulations at § 413.360.

We are proposing to require SNFs to collect and submit through the Minimum Data Set (MDS) four new items and modify one item on the MDS as described in section VI.C. of this proposed rule. In section VI.E.3. of this proposed rule, we are proposing to adopt a similar validation process for the SNF QRP that we adopted for the SNF VBP, and to amend regulation text at § 413.360 to implement the validation process we propose. We are also seeking information on future measure concepts for the SNF QRP in section VI.D. of this proposed rule.

B. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we use for the selection of SNF QRP quality, resource use, or other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

1. Quality Measures Currently Adopted for the SNF QRP

The SNF QRP currently has 15 adopted measures, which are listed in Table 28. For a discussion of the factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to § 413.360(b)(2).

TABLE 28—QUALITY MEASURES CURRENTLY ADOPTED FOR THE SNF QRP

Short name	Measure name & data source
Resident Assessment Instrument Minimum Data Set (Assessment-Based)	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients.
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
TOH-Provider	Transfer of Health (TOH) Information to the Provider Post-Acute Care (PAC).
TOH-Patient	Transfer of Health (TOH) Information to the Patient Post-Acute Care (PAC).
DC Function	Discharge Function Score.
Patient/Resident COVID–19 Vaccine	COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date.
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
SNF HAI	SNF Healthcare-Associated Infections (HAI) Requiring Hospitalization.
National Healthcare Safety Network	
HCP COVID–19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP).
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (HCP).

We are not proposing to adopt any new measures for the SNF QRP.

C. Proposal To Collect Four New Items as Standardized Patient Assessment Data Elements and To Modify One Item Collected as a Standardized Patient Assessment Data Element Beginning With the FY 2027 SNF QRP

In this proposed rule, we are proposing to require SNFs to report the following four new items [2] as standardized patient assessment data elements under the social determinants of health (SDOH) category: one item for Living Situation; two items for Food; and one item for Utilities. We are also proposing to modify one of the current items collected as a standardized patient assessment data element under the SDOH category (the Transportation item), as described in section VI.C.5. of this proposed rule.[3]

1. Definition of Standardized Patient Assessment Data

Section 1888(e)(6)(B)(i)(III) of the Act requires SNFs to submit standardized patient assessment data required under section 1899B(b)(1) of the Act. Section 1899B(b)(1)(A) of the Act requires post-acute care (PAC) providers to submit standardized patient assessment data under applicable reporting provisions (which, for SNFs, is the SNF QRP) with respect to the admission and discharge of an individual (and more frequently as the Secretary deems appropriate) using a standardized patient assessment instrument. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including SNFs, to submit standardized patient assessment data under the Medicare program. SNFs are currently required to report standardized patient assessment data through the patient

[2] Items may also be referred to as ''data elements.''

[3] As noted in section VI.C.3, hospitals are required to report whether they have screened patients for five standardized SDOH categories: housing instability, food insecurity, utility difficulties, transportation needs, and interpersonal safety.

assessment instrument, referred to as the MDS. Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

2. Social Determinants of Health Collected as Standardized Patient Assessment Data Elements

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect standardized patient assessment data elements with respect to other categories deemed necessary and appropriate. Accordingly, we finalized the creation of the SDOH category of standardized patient assessment data elements in the FY 2020 SNF PPS final rule (84 FR 38805 through 38817), and defined SDOH as the socioeconomic, cultural, and environmental circumstances in which individuals live that impact their health.[4] According to the World Health Organization, research shows that the SDOH can be more important than health care or lifestyle choices in influencing health, accounting for between 30 to 55 percent of health outcomes.[5] This is part of a growing body of research that highlights the importance of SDOH on health outcomes. Subsequent to the FY 2020 SNF PPS final rule, we expanded our definition of SDOH: SDOH are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[6] [7] [8] This expanded definition aligns our definition of SDOH with the definition used by HHS agencies, including OASH, the Centers for Disease Control and Prevention (CDC) and the White House Office of Science and Technology Policy.[9] [10] We currently collect seven items in this SDOH category of standardized patient assessment data elements: ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation (84 FR 38805 through 38817).[11]

In accordance with our authority under section 1899B(b)(1)(B)(vi) of the Act, we similarly finalized the creation of the SDOH category of standardized patient assessment data elements for Inpatient Rehabilitation Facilities (IRFs) in the FY 2020 IRF PPS final rule (84 FR 39149 through 39161), for Long-Term Care Hospitals (LTCHs) in the FY 2020 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (84 FR 42577 through 84 FR 42588), and for Home Health Agencies (HHAs) in the Calendar Year (CY) 2020 HH PPS final rule (84 60597 through 60608). We also collect the same seven SDOH items in these PAC providers' respective patient assessment instruments (84 FR 39161, 84 FR 42590, and 84 FR 60610, respectively).

Access to standardized data relating to SDOH on a national level permits us to conduct periodic analyses, and to assess their appropriateness as risk adjustors or in future quality measures. Our ability to perform these analyses relies on existing data collection of SDOH items from PAC settings. We adopted these SDOH items using common standards and definitions across the four PAC providers to promote interoperable exchange of longitudinal information among these PAC providers, including SNFs, and other providers. We believe this information may facilitate coordinated care, continuity in care planning, and the discharge planning process from PAC settings.

We noted in our FY 2020 SNF PPS final rule that each of the items we were adopting at that time was identified in the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report as impacting care use, cost and outcomes for Medicare beneficiaries (84 FR 38806). At that time, we acknowledged that other items may also be useful to understand. The SDOH items we are now proposing to adopt as standardized patient assessment data elements under the SDOH category in this proposed rule were also identified in the 2016 NASEM report [12] or the 2020 NASEM report [13] as impacting care use, cost and outcomes for Medicare beneficiaries. The items have the capacity to take into account treatment preferences and care goals of residents and their caregivers, to inform our understanding of resident complexity and SDOH that may affect care outcomes, and ensure that SNFs are in a position to impact them through the provision of services and supports, such as connecting residents and their caregivers with identified needs with social support programs.

Health-related social needs (HRSNs) are individual-level, adverse social conditions that negatively impact a person's health or health care,[14] and are the resulting effects of SDOH. Examples of HRSNs include lack of access to food, housing, or transportation, and have been associated with poorer health outcomes, greater use of emergency departments and hospitals, and higher health care costs.[15] Certain HRSNs can directly influence an individual's physical, psychosocial, and functional status. This is particularly true for food

[4] FY 2020 SNF PPS final rule (84 FR 38805).

[5] World Health Organization. Social determinants of health. Available at *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1*.

[6] Using Z Codes: The Social Determinants of Health (SDOH). Data Journey to Better Outcomes.

[7] Improving the Collection of Social Determinants of Health (SDOH) Data with ICD–10–CM Z Codes. *https://www.cms.gov/files/document/cms-2023-omh-z-code-resource.pdf*.

[8] *CMS.gov*. Measures Management System (MMS). CMS Focus on Health Equity. Health Equity Terminology and Quality Measures. *https://mmshub.cms.gov/about-quality/quality-at-CMS/goals/cms-focus-on-health-equity/health-equity-terminology*.

[9] Centers for Disease Control and Prevention. Social Determinants of Health (SDOH) and PLACES Data.

[10] ''U.S. Playbook To Address Social Determinants Of Health'' from the White House Office Of Science And Technology Policy (November 2023).

[11] These SDOH data are also collected for purposes outlined in section 2(d)(2)(B) of the Improving Medicare Post-Acute Care Transitions Act (IMPACT Act). For a detailed discussion on SDOH data collection under section 2(d)(2)(B) of the IMPACT Act, see the FY 2020 SNF PPS final rule (84 FR 38805 through 38817).

[12] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858*.

[13] National Academies of Sciences, Engineering, and Medicine. 2020. Leading Health Indicators 2030: Advancing Health, Equity, and Well-Being. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25682*.

[14] Centers for Medicare & Medicaid Services. ''A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights.'' August 2022. Available at *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion*.

[15] Berkowitz, S.A., T.P. Baggett, and S.T. Edwards, ''Addressing Health-Related Social Needs: Value-Based Care or Values-Based Care?'' Journal of General Internal Medicine, vol. 34, no. 9, 2019, pp. 1916–1918, *https://doi.org/10.1007/s11606-019-05087-3*.

security, housing stability, utilities security, and access to transportation.[16]

We are proposing to require SNFs to collect and submit four new items in the MDS as standardized patient assessment data elements under the SDOH category because these items would collect information not already captured by the current SDOH items. Specifically, we believe the ongoing identification of SDOH would have three significant benefits. First, promoting screening for these SDOH could serve as evidence-based building blocks for supporting healthcare providers in actualizing their commitment to address disparities that disproportionately impact underserved communities. Second, screening for SDOH improves health equity through identifying potential social needs so the SNF may address those with the resident, their caregivers, and community partners during the discharge planning process, if indicated.[17] Third, these SDOH items could support our ongoing SNF QRP initiatives by providing data with which to stratify SNF's performance on measures and or in future quality measures.

Additional collection of SDOH items would permit us to continue developing the statistical tools necessary to maximize the value of Medicare data and improve the quality of care for all beneficiaries. For example, we recently developed and released the Health Equity Confidential Feedback Reports, which provided data to SNFs on whether differences in quality measure outcomes are present for their residents by dual-enrollment status and race and ethnicity.[18] We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars [19] and a Biden-Harris Administration priority.[20]

3. Proposal To Collect Four New Items as Standardized Patient Assessment Data Elements Beginning With the FY 2027 SNF QRP

We are proposing to require SNFs to collect and submit four new items as standardized patient assessment data elements under the SDOH category using the MDS: one item for Living Situation, as described in section VI.C.3.(a) of this proposed rule; two items for Food, as described in section VI.C.3.(b) of this proposed rule; and one item for Utilities, as described in section VI.C.3.(c) of this proposed rule.

We selected the proposed SDOH items from the Accountable Health Communities (AHC) HRSN Screening Tool developed for the AHC Model. The AHC HRSN Screening Tool is a universal, comprehensive screening for HRSNs that addresses five core domains as follows: (1) housing instability (for example, homelessness, poor housing quality); (2) food insecurity; (3) transportation difficulties; (4) utility assistance needs; and (5) interpersonal safety concerns (for example, intimate-partner violence, elder abuse, child maltreatment).[21]

We believe that requiring SNFs to report the Living Situation, Food, Utilities, and Transportation items that are currently included in the AHC HRSN Screening Tool would further standardize the screening of SDOH across quality programs. For example, our proposal would align, in part, with the requirements of the Hospital Inpatient Quality Reporting (IQR) Program and the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. As of January 2024, hospitals are required to report whether they have screened patients for the standardized SDOH categories of housing instability, food insecurity, utility difficulties, transportation needs, and interpersonal safety to meet the Hospital IQR Program requirements.[22] Additionally, beginning January 2025, IPFs will also be required to report whether they have screened patients for the same set of SDOH categories.[23] As we continue to standardize data collection across PAC settings, we believe using common standards and definitions for new items is important to promote interoperable exchange of longitudinal information between SNFs and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process.

Below we describe each of the four proposed items in more detail.

(a) Living Situation

Healthy People 2030 prioritizes economic stability as a key SDOH, of which housing stability is a component.[24] [25] Lack of housing stability encompasses several challenges, such as having trouble paying rent, overcrowding, moving frequently, or spending the bulk of household income on housing.[26] These experiences may negatively affect one's physical health and access to health care. Housing instability can also lead to homelessness, which is housing deprivation in its most severe form.[27] On a single night in 2023, roughly 653,100 people, or 20 out of every 10,000 people in the United States, were experiencing homelessness.[28] Studies also found that people who are homeless have an increased risk of

[16] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/*.

[17] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf*.

[18] In October 2023, we released two new annual Health Equity Confidential Feedback Reports to SNFs: The Discharge to Community (DTC) Health Equity Confidential Feedback Report and the Medicare Spending Per Beneficiary (MSPB) Health Equity Confidential Feedback Report. The PAC Health Equity Confidential Feedback Reports stratified the DTC and MSPB measures by dual-enrollment status and race/ethnicity. For more information on the Health Equity Confidential Feedback Reports, please refer to the Education and Outreach materials available on the SNF QRP Training web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training*.

[19] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go from Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*.

[20] The Biden-Harris Administration's strategic approach to addressing health related social needs can be found in The U.S. Playbook to Address Social Determinants of Health (SDOH) (2023): *https://www.whitehouse.gov/wp-content/uploads/2023/11/SDOH-Playbook-3.pdf*.

[21] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf*.

[22] Centers for Medicare & Medicaid Services, FY2023 IPPS/LTCH PPS final rule (87 FR 49202 through 49215).

[23] Centers for Medicare & Medicaid Services, FY2024 Inpatient Psychiatric Prospective Payment System—Rate Update (88 FR 51107 through 51121).

[24] Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2030 | Priority Areas: Social Determinants of Health. Retrieved from U.S. Department of Health and Human Services: *https://health.gov/healthypeople/priority-areas/social-determinants-health*.

[25] Healthy People 2030 is a long-term, evidence-based effort led by the U.S. Department of Health and Human Services (HHS) that aims to identify nationwide health improvement priorities and improve the health of all Americans.

[26] Kushel, M.B., Gupta, R., Gee, L., & Haas, J.S. (2006). Housing instability and food insecurity as barriers to health care among low-income Americans. *Journal of General Internal Medicine, 21*(1), 71–77. doi: *10.1111/j.1525-1497.2005.00278.x*.

[27] Homelessness is defined as ''lacking a regular nighttime residence or having a primary nighttime residence that is a temporary shelter or other place not designed for sleeping.'' Crowley, S. (2003). The affordable housing crisis: Residential mobility of poor families and school mobility of poor children. Journal of Negro Education, 72(1), 22–38. *https://doi.org/10.2307/3211288*.

[28] The 2023 Annual Homeless Assessment Report (AHAR) to Congress. The U.S. Department of Housing and Urban Development 2023. *https://www.huduser.gov/portal/sites/default/files/pdf/2023-AHAR-Part-1.pdf*.

premature death and experience chronic disease more often than among the general population.[29] We believe that SNFs can use information obtained from the Living Situation item during a resident's discharge planning. For example, SNFs could work in partnership with community care hubs and community-based organizations to establish new care transition workflows, including referral pathways, contracting mechanisms, data sharing strategies, and implementation training that can track HRSNs to ensure unmet needs, such as housing, are successfully addressed through closed loop referrals and follow-up.[30] SNFs could also take action to help alleviate a resident's other related costs of living, like food, by referring the resident to community-based organizations that would allow the resident's additional resources to be allocated towards housing without sacrificing other needs.[31] Finally, SNFs could use the information obtained from the Living Situation item to better coordinate with other healthcare providers, facilities, and agencies during transitions of care, so that referrals to address a resident's housing stability are not lost during vulnerable transition periods.

Due to the potential negative impacts housing instability can have on a resident's health, we are proposing to adopt the Living Situation item as a new standardized patient assessment data element under the SDOH category. The proposed Living Situation item is based on the Living Situation item currently collected in the AHC HRSN Screening Tool,[32] [33] and was adapted from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) tool.[34] The proposed Living Situation item asks, ''What is your living situation today?'' The proposed response options are: (0) I have a steady place to live; (1) I have a place to live today, but I am worried about losing it in the future; (2) I do not have a steady place to live; (7) Resident declines to respond; and (8) Resident unable to respond. A draft of the Living Situation item proposed as a standardized patient assessment data element under the SDOH category can be found in the Downloads section of the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality/snf-quality-reporting-program/measures-and-technical-information*.

(b) Food

The U.S. Department of Agriculture, Economic Research Service defines a lack of food security as a household-level economic and social condition of limited or uncertain access to adequate food.[35] Adults who are food insecure may be at an increased risk for a variety of negative health outcomes and health disparities. For example, a study found that food-insecure adults may be at an increased risk for obesity.[36] Another study found that food-insecure adults have a significantly higher probability of death from any cause or cardiovascular disease in long-term follow-up care, in comparison to adults that are food secure.[37]

While having enough food is one of many predictors for health outcomes, a diet low in nutritious foods is also a factor.[38] The United States Department of Agriculture (USDA) defines nutrition security as ''consistent and equitable access to healthy, safe, affordable foods essential to optimal health and well-being.'' [36] Nutrition security builds on and complements long standing efforts to advance food security. Studies have shown that older adults struggling with food insecurity consume fewer calories and nutrients and have lower overall dietary quality than those who are food secure, which can put them at nutritional risk.[39] Older adults are also at a higher risk of developing malnutrition, which is considered a state of deficit, excess, or imbalance in protein, energy, or other nutrients that adversely impacts an individual's own body form, function, and clinical outcomes.[40] About 50 percent of older adults are affected by malnutrition, which is further aggravated by a lack of food security and poverty.[41] These facts highlight why the Biden-Harris Administration launched the White House Challenge to End Hunger and Build Health Communities.[42]

We believe that adopting items to collect and analyze information about a resident's food security at home could provide additional insight to their health complexity and help facilitate coordination with other healthcare providers, facilities, and agencies during transitions of care, so that referrals to address a resident's food security are not lost during vulnerable transition periods. For example, a SNF's dietitian or other clinically qualified nutrition professional could work with the

[29] Baggett, T.P., Hwang, S.W., O'Connell, J.J., Porneala, B.C., Stringfellow, E.J., Orav, E.J., Singer, D.E., & Rigotti, N.A. (2013). Mortality among homeless adults in Boston: Shifts in causes of death over a 15-year period. JAMA Internal Medicine, 173(3), 189–195. *https://doi.org/10.1001/jamainternmed.2013.1604*. Schanzer, B., Dominguez, B., Shrout, P.E., & Caton, C.L. (2007). Homelessness, health status, and health care use. American Journal of Public Health, 97(3), 464–469. doi: *https://doi.org/10.2105/ajph.2005.076190*.

[30] U.S. Department of Health & Human Services (HHS), Call to Action, ''Addressing Health Related Social Needs in Communities Across the Nation.'' November 2023. *https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf*.

[31] Henderson, K.A., Manian, N., Rog, D.J., Robison, E., Jorge, E., AlAbdulmunem, M. ''Addressing Homelessness Among Older Adults'' (Final Report). Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. October 26, 2023.

[32] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf*.

[33] The AHC HRSN Screening Tool Living Situation item includes two questions. In an effort to limit SNF burden, we are only proposing the first question.

[34] National Association of Community Health Centers and Partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. ''PRAPARE.'' 2017. *https://prapare.org/the-prapare-screening-tool/*.

[35] U.S. Department of Agriculture, Economic Research Service. (n.d.). *Definitions of food security*. Retrieved March 10, 2022, from *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/definitions-of-food-security/*.

[36] Hernandez, D.C., Reesor, L.M., & Murillo, R. (2017). Food insecurity and adult overweight/obesity: Gender and race/ethnic disparities. *Appetite, 117,* 373–378.

[37] Banerjee, S., Radak, T., Khubchandani, J., & Dunn, P. (2021). Food Insecurity and Mortality in American Adults: Results From the NHANES-Linked Mortality Study. Health promotion practice, 22(2), 204–214. *https://doi.org/10.1177/1524839920945927*.

[38] National Center for Health Statistics. (2022, September 6). Exercise or Physical Activity. Retrieved from Centers for Disease Control and Prevention: *https://www.cdc.gov/nchs/fastats/exercise.htm*.

[39] Ziliak, J.P., & Gundersen, C. (2019). The State of Senior Hunger in America 2017: An Annual Report. Prepared for Feeding America. Available at *https://www.feedingamerica.org/research/senior-hunger-research/senior*.

[40] The Malnutrition Quality Collaborative. (2020). National Blueprint: Achieving Quality Malnutrition Care for Older Adults, 2020 Update. Washington, DC: Avalere Health and Defeat Malnutrition Today. Available at *https://defeatmalnutrition.today/advocacy/blueprint/*.

[41] Food Research & Action Center (FRAC). ''Hunger is a Health Issue for Older Adults: Food Security, Health, and the Federal Nutrition Programs.'' December 2019. *https://frac.org/wp-content/uploads/hunger-is-a-health-issue-for-older-adults-1.pdf*.

[42] The White House Challenge to End Hunger and Build Health Communities (Challenge) was a nationwide call-to-action released on March 24, 2023 to stakeholders across all of society to make commitments to advance President Biden's goal to end hunger and reduce diet-related diseases by 2030—all while reducing disparities. More information on the White House Challenge to End Hunger and Build Health Communities can be found: *https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/24/fact-sheet-biden-harris-administration-launches-the-white-house-challenge-to-end-hunger-and-build-healthy-communities-announces-new-public-private-sector-actions-to-continue-momentum-from-hist/*.

resident and their caregiver to plan healthy, affordable food choices prior to discharge.[43] SNFs could also refer a resident that indicates lack of food security to government initiatives such as the Supplemental Nutrition Assistance Program (SNAP) and food pharmacies (programs to increase access to healthful foods by making them affordable), two initiatives that have been associated with lower health care costs and reduced hospitalization and emergency department visits.[44]

We are proposing to adopt two Food items as new standardized patient assessment data elements under the SDOH category. These proposed items are based on the Food items currently collected in the AHC HRSN Screening Tool and were adapted from the USDA 18-item Household Food Security Survey (HFSS).[45] The first proposed Food item states, ''Within the past 12 months, you worried that your food would run out before you got money to buy more.'' The second proposed Food item States, ''Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.'' We propose the same response options for both items: (0) Often true; (1) Sometimes true; (2) Never True; (7) Resident to declines to respond; and (8) Resident unable to respond. A draft of the Food items proposed to be adopted as standardized patient assessment data elements under the SDOH category can be found in the Downloads section of the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality/snf-quality-reporting-program/measures-and-technical-information.*

(c) Utilities

A lack of energy (utility) security can be defined as an inability to adequately meet basic household energy needs.[46] According to the United States Department of Energy, one in three households in the U.S. are unable to adequately meet basic household energy needs.[47] The consequences associated with a lack of utility security are represented by three primary dimensions: economic; physical; and behavioral. Residents with low incomes are disproportionately affected by high energy costs, and they may be forced to prioritize paying for housing and food over utilities.[48] Some residents may face limited housing options, and therefore, are at increased risk of living in lower-quality physical conditions with malfunctioning heating and cooling systems, poor lighting, and outdated plumbing and electrical systems.[49] Residents with a lack of utility security may use negative behavioral approaches to cope, such as using stoves and space heaters for heat.[50] In addition, data from the Department of Energy's U.S. Energy Information Administration confirm that a lack of energy security disproportionately affects certain populations, such as low-income and African American households.[51] The effects of a lack of utility security include vulnerability to environmental exposures such as dampness, mold, and thermal discomfort in the home, which have a direct impact on a person's health.[52] For example, research has shown associations between a lack of energy security and respiratory conditions as well as mental health–related disparities and poor sleep quality in vulnerable populations such as the elderly, children, the socioeconomically disadvantaged, and the medically vulnerable.[53]

We believe adopting an item to collect information about a resident's utility security would facilitate the identification of residents who may not have utility security and who may benefit from engagement efforts. For example, SNFs may be able to use the information on utility security to help connect some residents in need to programs that can help older adults pay for their home energy (heating/cooling) costs, like the Low-Income Home Energy Assistance Program (LIHEAP).[54] SNFs may also be able to partner with community care hubs and community-based organizations to assist the resident in applying for these and other local utility assistance programs, as well as helping them navigate the enrollment process.[55]

We are proposing to adopt a new item, Utilities, as a new standardized patient assessment data element under the SDOH category. This proposed item is based on the Utilities item currently collected in the AHC HRSN Screening Tool, and was adapted from the Children's Sentinel Nutrition Assessment Program (C–SNAP) survey.[56] The proposed Utilities item asks, ''In the past 12 months, has the electric, gas, oil, or water company threatened to shut off services in your home?'' The proposed response options are: (0) Yes; (1) No; (2) Already shut off; (7) Resident declines to respond; and (8) Resident unable to respond. A draft of the Utilities item proposed as a standardized patient assessment data element under the SDOH category can be found in the Downloads section of the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality/snf-quality-reporting-program/measures-and-technical-information.*

4. Interested Parties Input

We developed our proposal to add these items after considering feedback we received in response to our request

[43] Schroeder K., Smaldone A. Food Insecurity: A Concept Analysis. Nurse Forum. 2015 Oct–Dec;50(4):274–84. doi: 10.1111/nuf.12118. Epub 2015 Jan 21. PMID: 25612146; PMCID: PMC4510041.

[44] Tsega M., Lewis C., McCarthy D., Shah T., Coutts K. Review of Evidence for Health-Related Social Needs Interventions. July 2019. The Commonwealth Fund. *https://www.commwealthfund.org/sites/default/files/2019-07/ROI-evidence-review-final-version.pdf.*

[45] More information about the HFSS tool can be found at *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/survey-tools/.*

[46] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc Sci Med. 2016 Oct; 167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub 2016 Aug 21. PMID: 27592003; PMCID: PMC5114037.

[47] US Energy Information Administration. ''One in Three U.S. Households Faced Challenges in Paying Energy Bills in 2015.'' 2017 Oct 13. *https://www.eia.gov/consumption/residential/reports/2015/energybills/.*

[48] Hernández D. ''Understanding 'energy insecurity' and why it matters to health.'' Soc Sci Med. 2016; 167:1–10.

[49] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc Sci Med. 2016 Oct;167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub 2016 Aug 21. PMID: 27592003; PMCID: PMC5114037.

[50] Hernández D. ''What 'Merle' Taught Me About Energy Insecurity and Health.'' Health Affairs, VOL.37, NO.3: Advancing Health Equity Narrative Matters. March 2018. *https://doi.org/10.1377/hlthaff.2017.1413.*

[51] US Energy Information Administration. ''One in Three U.S. Households Faced Challenges in Paying Energy Bills in 2015.'' 2017 Oct 13. *https://www.eia.gov/consumption/residential/reports/2015/energybills/.*

[52] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc Sci Med. 2016 Oct;167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub 2016 Aug 21. PMID: 27592003; PMCID: PMC5114037.

[53] Hernández D, Siegel E. Energy insecurity and its ill health effects: A community perspective on the energy-health nexus in New York City. Energy Res Soc Sci. 2019 Jan;47:78–83. *doi: 10.1016/j.erss.2018.08.011.* Epub 2018 Sep 8. PMID: 32280598; PMCID: PMC7147484.

[54] U.S. Department of Health & Human Services. Office of Community Services. Low Income Home Energy Assistance Program (LIHEAP). *https://www.acf.hhs.gov/ocs/programs/liheap.*

[55] National Council on Aging (NCOA). ''How to Make It Easier for Older Adults to Get Energy and Utility Assistance.'' Promising Practices Clearinghouse for Professionals. Jan 13, 2022. *https://www.ncoa.org/article/how-to-make-it-easier-for-older-adults-to-get-energy-and-utility-assistance.*

[56] This validated survey was developed as a clinical indicator of household energy security among pediatric caregivers. Cook, J.T., D.A. Frank., P.H. Casey, R. Rose-Jacobs, M.M. Black, M. Chilton, S. Ettinger de Cuba, et al. ''A Brief Indicator of Household Energy Security: Associations with Food Security, Child Health, and Child Development in US Infants and Toddlers.'' Pediatrics, vol. 122, no. 4, 2008, pp. e874–e875. *https://doi.org/10.1542/peds.2008-0286.*

for information (RFI) on Principles for Selecting and Prioritizing SNF QRP Quality Measures and Concepts Under Consideration for Future Years in the FY 2024 SNF PPS final rule (88 FR 53265 through 53267). This RFI sought to obtain input on a set of principles to identify SNF QRP measures, as well as additional thoughts about measurement gaps, and suitable measures for filling these gaps. In response to this solicitation, commenters stated that the inclusion of a malnutrition screening and intervention measures would promote both quality and health equity. Other measures and measurement concepts included health equity, psychosocial issues, and caregiver status. The FY 2024 SNF PPS final rule includes a summary of the public comments that we received in response to the RFI and our responses to those comments (88 FR 53265 through 53267).

We also considered comments received in response to our Health Equity Update in the FY 2024 SNF PPS final rule. Comments were generally supportive of CMS' efforts to develop ways to measure and mitigate health inequities. One commenter referenced their belief that collection of SDOH would enhance holistic care, call attention to impairments that might be mitigated or resolved, and facilitate clear communication between residents and SNFs. While there were commenters who urged CMS to balance reporting requirements so as not to create undue administrative burden, another commenter suggested CMS incentivize collection of data on SDOH such as housing stability and food security. The FY 2024 SNF PPS final rule (88 FR 53268 through 53269) includes a summary of the public comments that we received in response to the Health Equity Update and our responses to those comments.

Additionally, we considered feedback we received when we proposed the creation of the SDOH category of standardized patient assessment data elements in the FY 2020 SNF PPS proposed rule (84 FR 17671 through 17679). Commenters were generally in favor of the concept of collecting SDOH items and stated that, if implemented appropriately, the data could be useful in identifying and addressing health care disparities, as well as refining the risk adjustment of outcome measures. The FY 2020 SNF PPS final rule (84 FR 38805 through 38818) includes a summary of the public comments that we received and our responses to those comments. We incorporated this input into the development of this proposal.

We invite comment on the proposal to adopt four new items as standardized patient assessment data elements under the SDOH category beginning with the FY 2027 SNF QRP: one Living Situation item; two Food items; and one Utilities item.

5. Proposal To Modify the Transportation Item Beginning With the FY 2027 SNF QRP

Beginning October 1, 2023, SNFs began collecting seven items adopted as standardized patient assessment data elements under the SDOH category on the MDS.[57] One of these items, A1250. Transportation, collects data on whether a lack of transportation has kept a resident from getting to and from medical appointments, meetings, work, or from getting things they need for daily living. This item was adopted as a standardized patient assessment data element under the SDOH category in the FY 2020 SNF PPS final rule (84 FR 38805 through 38809). As we discussed in the FY 2020 SNF PPS final rule (84 FR 38814 through 42588), we continue to believe that access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management and that the collection of a Transportation item would facilitate the connection to programs that can address identified needs (84 FR 38815 through 42588).

As part of our routine item and measure monitoring work, we continually assess the implementation of the new SDOH items. We have identified an opportunity to improve the data collection for A1250. Transportation in the MDS by aligning it with the Transportation category collected in our other programs.[58] Specifically, we are proposing to modify the current Transportation item in the MDS so that it aligns with a Transportation item collected on the AHC HRSN Screening Tool, one of the potential tools the IPFQR and Hospital IQR Programs may select for data collection.

A1250. Transportation currently collected in the MDS asks: ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The response options are: (A) Yes, it has kept me from medical appointments or from getting my medications; (B) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; (C) No; (X) Resident unable to respond; and (Y) Resident declines to respond. The Transportation item collected in the AHC HRSN Screening Tool asks, ''In the past 12 months, has lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?'' The two response options are: Yes; and No. Consistent with the AHC HRSN Screening Tool and adapted from the PRAPARE tool, we are proposing to modify the A1250. Transportation item currently collected in the SNF MDS in two ways: (1) revise the look-back period for when the resident experienced lack of reliable transportation; and (2) simplify the response options.

First, the proposed modification of the Transportation item would use a defined 12-month look back period, while the current Transportation item uses a look back period of six to 12 months. We believe the distinction of a 12-month look back period would reduce ambiguity for both residents and clinicians, and therefore, improve the validity of the data collected. Second, we are proposing to simplify the response options. Currently, SNFs separately collect information on whether a lack of transportation has kept the patient from medical appointments or from getting medications, and whether a lack of transportation has kept the resident from non-medical meetings, appointments, work, or from getting things they need. Although transportation barriers can directly affect a person's ability to attend medical appointments and obtain medications, a lack of transportation can also affect a person's health in other ways, including accessing goods and services, obtaining adequate food and clothing, and social activities.[59] The proposed modified Transportation item would collect information on whether a lack of reliable transportation has kept the resident from medical appointments, meetings, work or from getting things needed for daily living, rather than collecting the information separately. As discussed previously, we believe reliable transportation services are fundamental to a person's overall

[57] The seven SDOH items are ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation (84 FR 38805 through 38818).

[58] Centers for Medicare & Medicaid Services, FY2024 Inpatient Psychiatric Prospective Payment System—Rate Update (88 FR 51107 through 51121).

[54] Centers for Medicare & Medicaid Services, FY2023 IPPS/LTCH PPS final rule (87 FR 49202 through 49215).

[59] Victoria Transport Policy Institute. (2016, August 25). Basic access and basic mobility: Meeting society's most important transportation needs. Retrieved from *http://www.vtpi.org/tdm/tdm103.htm*.

health, and as a result, the burden of collecting this information separately outweighs its potential benefit.

For the reasons stated previously, we are proposing to modify A1250. Transportation based on the Transportation item adopted for use in the AHC HRSN Screening Tool and adapted from the PRAPARE tool. The proposed Transportation item asks, ''In the past 12 months, has a lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?'' The proposed response options are: (0) Yes; (1) No; (7) Resident declines to respond; and (8) Resident unable to respond. A draft of the proposed modified Transportation item can be found in the Downloads section of the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality/snf-quality-reporting-program/measures-and-technical-information.*

We invite comment on the proposal to modify the current Transportation item previously adopted as a standardized patient assessment data element under the SDOH category beginning with the FY 2027 SNF QRP.

D. SNF QRP Quality Measure Concepts Under Consideration for Future Years—Request for Information (RFI)

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the concepts under consideration listed in Table 29 for future years in the SNF QRP. In the FY 2024 SNF PPS proposed rule (88 FR 21353 through 21355), we published a request for information (RFI) on a set of principles for selecting and prioritizing SNF QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. Within this proposed rule, we also sought input on data available to develop measures, approaches for data collection, perceived challenges or barriers, and approaches for addressing identified challenges. We refer readers to the FY 2024 SNF PPS final rule (88 FR 53265 through 53267) for a summary of the public comments we received in response to the RFI.

Subsequently, our measure development contractor convened a Technical Expert Panel (TEP) on December 15, 2023 to obtain expert input on the future measure concepts that could fill the measurement gaps identified in our FY 2024 RFI.[60] The TEP also discussed the alignment of PAC and Hospice measures with CMS' ''Universal Foundation'' of quality measures.[61] The Universal Foundation aims to focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for comparisons across programs, and help identify measurement gaps.

In consideration of the feedback we have received through these activities, we are seeking input on four concepts for the SNF QRP. One is a composite of vaccinations,[62] which could represent overall immunization status of residents such as the Adult Immunization Status measure[63] in the Universal Foundation. A second concept on which we are seeking feedback is the concept of depression for the SNF QRP, which may be similar to the Clinical Screening for Depression and Follow-up measure[64] in the Universal Foundation. Finally, we are seeking feedback on the concepts of pain management and patient experience of care/patient satisfaction for the SNF QRP.

TABLE 29—FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE SNF QRP

Quality measure concepts
Vaccination Composite.
Pain Management.
Depression.
Patient Experience of Care/Patient Satisfaction.

While we will not be responding to specific comments in response to this RFI in the FY 2025 SNF PPS final rule, we intend to use this input to inform our future measure development efforts.

E. Form, Manner, and Timing of Data Submission Under the SNF QRP

1. Background

We refer readers to the current regulatory text at § 413.360(b) for information regarding the policies for reporting specified data for the SNF QRP.

2. Proposed Reporting Schedule for the Proposed New Standardized Patient Assessment Data Elements, and the Modified Transportation Data Element, Beginning October 1, 2025 for the FY 2027 SNF QRP

As discussed in section VI.C.3. and VI.C.5. of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category (one Living Situation item, two Food items, and one Utilities item) and to modify the Transportation standardized patient assessment data element previously adopted under the SDOH category beginning with the FY 2027 SNF QRP.

We are proposing that SNFs would be required to report these new items and the modified Transportation item using the MDS beginning with residents admitted on October 1, 2025 through December 31, 2025 for purposes of the FY 2027 SNF QRP. Starting in CY 2026, SNFs would be required to submit data for the entire calendar year for each program year.

We are also proposing that SNFs that submit the Living Situation, Food, and Utilities items proposed for adoption as standardized patient assessment data elements under the SDOH category with respect to admission only would be deemed to have submitted those items with respect to both admission and discharge. We propose that SNFs would be required to submit these items at admission only (and not at discharge) because it is unlikely that the assessment of those items at admission would differ from the assessment of the same item at discharge. This would align the data collection for these proposed items with other SDOH items (that is, Race, Ethnicity, Preferred Language, and Interpreter Services) which are only collected at admission.[65] A draft of the proposed items is available in the Downloads section of the SNF QRP Measures and Technical Information web page at *https://www.cms.gov/medicare/quality/snf-quality-reporting-program/measures-and-technical-information.*

As we noted in section VI.C.5 of this proposed rule, we continually assess the

[60] The Post-Acute Care (PAC) and Hospice Quality Reporting Program Cross-Setting TEP summary report will be published in early summer or as soon as technically feasible. SNFs can monitor the Partnership for Quality Measurement website at *https://mmshub.cms.gov/get-involved/technical-expert-panel/updates* for updates.

[61] Centers for Medicare & Medicaid Services. Aligning Quality Measures Across CMS—the Universal Foundation. November 17, 2023. *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.*

[62] A composite measure can summarize multiple measures through the use of one value or piece of information. More information can be found at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/mms/downloads/composite-measures.pdf.*

[63] CMS Measures Inventory Tool. Adult immunization status measure found at *https://cmit.cms.gov/cmit/#/FamilyView?familyId=26.*

[64] CMS Measures Inventory Tool. Clinical Depression Screening and Follow-Up measure found at *https://cmit.cms.gov/cmit/#/FamilyView?familyId=672.*

[65] FY 2020 SNF PPS final rule (84 FR 38817 through 38818).

implementation of the new SDOH items, including A1250. Transportation, as part of our routine item and measure monitoring work. We received feedback from interested parties in response to the FY 2020 SNF PPS proposed rule (84 FR 17676 through 17678) noting their concern with the burden of collecting the Transportation item at admission and discharge. Specifically, commenters stated that a resident's access to transportation is unlikely to change between admission and discharge. We analyzed the data SNFs reported from October 1, 2023 through December 31, 2023 (Quarter 4 of CY 2023) and found that residents' responses do not significantly change from admission to discharge.[66] Specifically, the proportion of residents [67] who responded ''Yes'' to the Transportation item at admission versus at discharge differed by only 0.60 percentage points during this period. We find these results convincing, and therefore are proposing to require SNFs to collect and submit the proposed modified standardized patient assessment data element, Transportation, at admission only.

We invite public comment on our proposal to collect data on the following items proposed as standardized patient assessment data elements under the SDOH category at admission only beginning with October 1, 2025 SNF admissions: (1) Living Situation as described in section VI.C.3(a) of this proposed rule; (2) Food as described in section VI.C.3(b) of this proposed rule; and (3) Utilities as described in section VI.C.3(c) of this proposed rule. We also invite comment on our proposal to collect the proposed modified standardized patient assessment data element, Transportation, at admission only beginning with October 1, 2025 SNF admissions as described in section VI.C.5 of this proposed rule.

3. Proposal To Participate in a Validation Process Beginning With the FY 2027 SNF QRP

Section 1888(h)(12)(A) of the Act (as added by section 111(a)(4) of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)) requires the Secretary to apply a process to validate data submitted under the SNF QRP. Accordingly, we are proposing to require SNFs to participate in a validation process that would apply to data submitted using the MDS and SNF Medicare fee-for-service claims as a SNF QRP requirement beginning with the FY 2027 SNF QRP. We are also proposing to amend the regulation text at § 413.360.

We are also considering additional validation methods that may be appropriate to include in the future for the current measures submitted through the National Healthcare Safety Network (NHSN), as well as for other new measures we may consider for the program. Any updates to specific program requirements related to the validation process would be addressed through separate and future notice-and-comment rulemaking, as necessary.

(a) Proposal To Participate in a Validation Process for Assessment-Based Measures

The MDS is a resident assessment instrument that SNFs must complete for all residents in a Medicare or Medicaid certified nursing facility, and for residents whose stay is covered under SNF PPS in a non-critical access hospital swing bed facility. The MDS includes the resident in the assessment process, and uses standard protocols used in other settings to improve clinical assessment and support the credibility of programs that rely on MDS, like the SNF QRP.[68]

We are proposing to adopt a similar validation process for the SNF QRP that we have adopted for the SNF Value-Based Purchasing (VBP) program in the FY 2024 SNF PPS final rule (88 FR 53323 through 53325) beginning with the FY 2027 SNF QRP. This method would closely align with the validation process we have adopted for the SNF VBP program and would have the following elements:

- We propose that our validation contractor would select, on an annual basis, up to 1,500 SNFs that submit at least one MDS record in the calendar year (CY) 3 years prior to the applicable FY SNF QRP. For example, for the FY 2027 SNF QRP, we would choose up to 1,500 SNFs that submitted at least one MDS record in CY 2024. We are also proposing that the SNFs that are selected to participate in the SNF QRP validation for a program year would be the same SNFs that are randomly selected to participate in the SNF VBP validation process for the corresponding SNF VBP program year.
- We propose that our validation contractor would request up to 10 medical records from each of the selected SNFs. Each SNF selected would only be required to submit records once in a fiscal year, for a maximum of 10 records for each SNF selected. To decrease the burden for the selected SNF, we are proposing that the validation contractor would request that the SNFs submit the same medical records, at the same time, that are required from the same SNFs for purposes of the SNF VBP validation.
- We propose that the selected SNFs would have the option to submit digital or paper copies of the requested medical records to the validation contractor and would be required to submit the medical records within 45 days of the date of the request (as documented on the request). If the validation contractor has not received the medical records within 30 days of the date of the request, the validation contractor would send the SNF a reminder in writing to inform the SNF that it must submit the requested medical records within 45 days of the date of the initial request.

We propose that if a SNF does not submit the requested number of medical records within 45 days of the initial request, we would, under section 1888(e)(6)(A) of the Act, reduce the SNF's otherwise applicable annual market basket percentage update by 2 percent. The reduction would be applied to the payment update 2 fiscal years after the fiscal year for which the validation contractor requested records. For example, if the validation contractor requested records for FY 2027, and the SNF did not send them, we would reduce the SNF's otherwise applicable annual market basket percentage update by 2 percent for the FY 2029 SNF QRP.

We also intend to propose in future rulemaking the process by which we would evaluate the submitted medical records against the MDS to determine the accuracy of the MDS data that the SNF reported and that CMS used to calculate the measure results. We invite public comment on what that process could include.

We solicit public comments on our proposal to require SNFs who participate in the SNF QRP to participate in a validation process for assessment-based measures beginning with the FY 2027 SNF QRP.

(b) Proposal To Apply the Existing Validation Process for Claims-Based Measures Reported in the SNF QRP

Beginning with the FY 2027 SNF QRP, we are proposing to apply the process we currently use to ensure the accuracy of the Medicare fee-for-service claims to validate claims-based measures under the SNF QRP. Specifically, information reported

[66] Due to data availability of SNF SDOH standardized patient assessment data elements, this is based on one quarter of Transportation data.

[67] The analysis is limited to residents who responded to the Transportation item at both admission and discharge.

[68] Centers for Medicare and Medicaid Services (CMS). (2023, March 29). Minimum Data Set (MDS) 3.0 for Nursing Homes and Swing Bed Providers. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/nhqimds30.*

through Medicare Part A fee-for-service claims are validated for accuracy by Medicare Administrative Contractors (MACs) to ensure accurate Medicare payments. MACs use software to determine whether billed services are medically necessary and should be covered by Medicare, review claims to identify any ambiguities or irregularities, and use a quality assurance process to help ensure quality and consistency in claim review and processing. They conduct prepayment and post-payment audits of Medicare claims, using both random selection and targeted reviews based on analyses of claims data.

We use data to calculate claims-based measures for the SNF QRP. We believe that adopting the MAC's existing process of validating claims for medical necessity through targeted and random audits would satisfy the statutory requirement to adopt a validation process for data submitted under the SNF QRP for claims-based measures at section 1888(h)(12)(A) of the Act (as added by section 111(a)(4) of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)).

We solicit public comment on our proposal to apply the MAC's existing validation process for the SNF QRP claims-based measures beginning with the FY 2027 program year.

(c) Proposal To Amend the Regulation Text at § 413.360

We propose to amend our regulation at § 413.360 to reflect these proposed policies. Specifically, we propose to add (g) to our regulation at § 413.360, which will incorporate the procedural requirements we are proposing for these validation processes for SNF QRP under these sections VI.E.3(a) and VI.E.3(b). We also propose to add paragraph (f)(1)(iv) to our regulation at § 413.360 to establish that, if the SNF is selected for the validation process, the SNF must submit up to 10 medical records requested, in their entirety. Finally, we propose minor technical amendments for our regulation at § 413.360(f)(3) to apply to all data completion thresholds implemented in § 413.360(f)(1).

We solicit public comments on our proposal to amend our regulation at § 413.360.

F. Policies Regarding Public Display of Measure Data for the SNF QRP

We are not proposing any new policies regarding the public display of measure data at this time. For a discussion about our policies regarding public display of SNF QRP measure data and procedures for the SNF's opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

VII. Proposed Updates to the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program

A. Statutory Background

Through the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program, we award incentive payments to SNFs to encourage improvements in the quality of care provided to Medicare beneficiaries. The SNF VBP Program is authorized by section 1888(h) of the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing bed rural hospitals. We believe the SNF VBP Program has helped to transform how Medicare payment is made for SNF care, moving increasingly towards rewarding better value and outcomes instead of merely rewarding volume. Our codified policies for the SNF VBP Program can be found in our regulations at 42 CFR 413.337(f) and 413.338.

1. Spotlight on the CMS National Quality Strategy

As part of the CMS National Quality Strategy,[69] we are committed to aligning measures across our quality programs and ensuring we measure quality across the entire care continuum in a way that promotes the best, safest, and most equitable care for all individuals.

We believe that improving alignment of measures across the CMS quality programs will reduce provider burden while also improving the effectiveness of quality programs. However, we also recognize that a one-size-fits-all approach would fail to capture important aspects of quality in our healthcare system across populations and care settings.

To move towards a more streamlined approach that does not lose sight of important aspects of quality, we are implementing a building-block approach: a ''Universal Foundation'' of quality measures across as many of our quality reporting and value-based care programs as possible, with additional measures added on depending on the population or setting (''add-on sets'').[70]

Our goal with the Universal Foundation is to focus provider attention on measures that are the most meaningful for patients and patient outcomes, reduce provider burden by streamlining and aligning measures, allow for consistent stratification of measures to identify disparities in care between and among populations, accelerate the transition to interoperable, digital quality measures, and allow for comparisons across quality and value-based care programs to better understand what drives quality improvement and what does not.

We select measures for the Universal Foundation that are of high national impact, can be benchmarked nationally and globally, are applicable to multiple populations and settings, are appropriate for stratification to identify disparity gaps, have scientific acceptability, support the transition to digital measurement, and have no anticipated unintended consequences with widespread measure implementation.

We believe that the creation of this Universal Foundation will result in higher quality care for the more than 150 million Americans covered by our programs and will serve as an alignment standard for the rest of the healthcare system. We continue to collect feedback from interested parties through listening sessions, requests for information and proposed rulemaking, and other interactions to refine our approach as we work to implement the Universal Foundation across our quality programs. As we continue building the SNF VBP measure set, we intend to align with the measures in the Universal Foundation, as well as the post-acute care add-on measure set, to the extent feasible.

B. Proposed Regulation Text Technical Updates

We are proposing to make several technical updates to our regulation text. First, we are proposing to update § 413.337(f) to correct the cross-references in that section to § 413.338(a). Second, we are proposing to update the definition of ''SNF readmission measure'' in § 413.338(a) by replacing the references to the Skilled Nursing Facility Potentially Preventable Readmissions (SNFPPR) measure with a reference to the Skilled Nursing Facility Within-Stay Potentially Preventable Readmission (SNF WS PPR) measure, by clarifying that we specified both measures under section 1888(g) of the Act, and by clarifying that the SNF readmission measure will be the SNF WS PPR beginning October 1, 2027.

This change would align the definition of ''SNF readmission measure'' with policies we have previously finalized for SNF VBP, including that we will not use the SNFPPR and that we will replace the SNFRM with the SNF WS PPR beginning October 1, 2027. In addition,

[69] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[70] *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.*

we are proposing to redesignate the term ''performance score'' at § 413.338(a) with the term ''SNF performance score'' for consistency with the terminology we are now using in the Program, and to make conforming edits to the last sentence of § 413.337(f). We are also proposing to replace the references to ''program year'' with ''fiscal year'' in the definitions of ''health equity adjustment (HEA) bonus points,'' ''measure performance scaler'', ''top tier performing SNF'', and ''underserved multiplier'' to align the terminology with that used in the remainder of that section.

We are also proposing to update § 413.338(f) to redesignate paragraphs (f)(1) through (4) as paragraphs (f)(2) through (5), respectively. We are also proposing to add a new paragraph (f)(1) and to revise the newly redesignated paragraphs (f)(2) and (3).

In addition, we are proposing to update § 413.338(j)(3) to include additional components of the MDS validation process that we finalized in the FY 2024 SNF PPS final rule (88 FR 53324). In particular, we are proposing to include the SNF selection, medical record request, and medical record submission processes for MDS validation.

Further, we are proposing to remove § 413.338(d)(5) from the regulation text because the only measure that will be in the SNF VBP Program until the FY 2026 program year is the SNFRM, and to add new paragraph (l)(1) which would state that the SNF VBP measure set for each year includes the statutorily-required SNF readmission measure, and beginning with the FY 2026 program year, up to nine additional measures specified by CMS.

We welcome public comment on these proposed technical updates to our regulation text.

C. SNF VBP Program Measures

1. Background

We refer readers to the FY 2024 SNF PPS final rule for background on the measures we have adopted for the SNF VBP Program (88 FR 53276 through 53297).

Table 30 lists the measures that have been adopted for the SNF VBP Program, along with their timeline for inclusion.

TABLE 30—SNF VBP PROGRAM MEASURES AND TIMELINE FOR INCLUSION IN THE PROGRAM

Measure	FY 2025 program year	FY 2026 program year	FY 2027 program year	FY 2028 program year
Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)	Included	Included	Included.	
Skilled Nursing Facility Healthcare Associated Infections Requiring Hospitalization (SNF HAI) measure.		Included	Included	Included.
Total Nursing Hours per Resident Day (Total Nurse Staffing) measure		Included	Included	Included.
Total Nursing Staff Turnover (Nursing Staff Turnover) measure		Included	Included	Included.
Discharge to Community—Post-Acute Care Measure for Skilled Nursing Facilities (DTC PAC SNF measure).			Included	Included.
Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (Falls with Major Injury (Long-Stay)) measure.			Included	Included.
Discharge Function Score for SNFs (DC Function Measure)			Included	Included.
Number of Hospitalizations per 1,000 Long Stay Resident Days (Long Stay Hospitalization) measure.			Included	Included.
Skilled Nursing Facility Within-Stay Potentially Preventable Readmissions (SNF WS PPR) measure.				Included.

2. Proposal To Adopt a Measure Selection, Retention, and Removal Policy Beginning With the FY 2026 SNF VBP Program Year

Section 1888(h)(2) of the Act requires the Secretary to apply the measure specified under subsection (g)(1) (currently the SNFRM) and replace that measure, as soon as practicable, with the measure specified under subsection (g)(2) (currently the SNF WS PPR measure). That section also allows the Secretary to apply, as appropriate, up to nine additional measures to the SNF VBP Program, in addition to the statutorily required SNF Readmission Measure. We have now adopted seven additional measures for the Program (see the FY 2023 SNF PPS final rule (87 FR 47564 through 47580) and the FY 2024 SNF PPS final rule (88 FR 53280 through 53296)).

Now that the SNF VBP Program includes measures in addition to the SNFRM (which will be replaced with the SNF WS PPR measure beginning with the FY 2028 program year), we believe it is appropriate to adopt a policy that governs the retention of measures in the Program, as well as criteria we would use to consider whether a measure should be removed from the Program. These policies would help ensure that the Program's measure set remains focused on the best and most appropriate metrics for assessing care quality in the SNF setting. We also believe that the measure removal policy, as described later in this section, would streamline the rulemaking process by providing a sub-regulatory process that we could utilize to remove measures from the Program that raise safety concerns while also providing sufficient opportunities for the public to consider, and provide input on, future proposals to remove a measure.

Other CMS quality reporting programs, including the SNF QRP and Hospital Inpatient Quality Reporting (IQR) Program, have adopted similar policies. For example, in the FY 2016 SNF PPS final rule (80 FR 46431 through 46432), the SNF QRP adopted 7 removal factors and, in the FY 2019 SNF PPS final rule (83 FR 39267 through 39269), the SNF QRP adopted an additional measure removal factor, such that a total of eight measure removal factors are now used to determine whether a measure should be removed. The SNF QRP also codified those factors at § 413.360(b)(2).

For the purposes of the SNF VBP Program, we are proposing to adopt the following measure selection, retention, and removal policy beginning with the FY 2026 SNF VBP program year. This proposed policy would apply to all SNF VBP measures except for the SNF readmission measure because we are statutorily required to retain that measure in the measure set.

First, we are proposing that when we adopt a measure for the SNF VBP Program for a particular program year, that measure would be automatically retained for all subsequent program years unless we propose to remove or replace the measure. We believe that this policy would make clear that when we adopt a measure for the SNF VBP Program, we intend to include that measure in all subsequent program

years. This policy would also avoid the need to continuously propose a measure for subsequent program years.

Second, we are proposing that we would use notice and comment rulemaking to remove or replace a measure in the SNF VBP Program to allow for public comment. We are also proposing that we would use the following measure removal factors to determine whether a measure should be considered for removal or replacement:

(1) SNF performance on the measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made;

(2) Performance and improvement on a measure do not result in better resident outcomes;

(3) A measure no longer aligns with current clinical guidelines or practices;

(4) A more broadly applicable measure for the particular topic is available;

(5) A measure that is more proximal in time to the desired resident outcomes for the particular topic is available;

(6) A measure that is more strongly associated with the desired resident outcomes for the particular topic is available;

(7) The collection or public reporting of a measure leads to negative unintended consequences other than resident harm; and

(8) The costs associated with a measure outweigh the benefit of its continued use in the Program.

Each of these measure removal factors represent instances where the continued use of a measure in the Program would not support the Program's objective, which is to incentivize improvements in quality of care by linking SNF payments to performance on quality measures. Therefore, we believe that these are appropriate criteria for determining whether a measure should be removed or replaced.

Third, upon a determination by CMS that the continued requirement for SNFs to submit data on a measure raises specific resident safety concerns, we are proposing that we may elect to immediately remove the measure from the SNF VBP measure set. Upon removal of the measure, we would provide notice to SNFs and the public, along with a statement of the specific patient safety concerns that would be raised if SNFs continued to submit data on the measure. We would also provide notice of the removal in the **Federal Register**.

We are proposing to codify this policy at § 413.338(l)(2) and (l)(3) of our regulations.

We invite public comment on the proposed measure selection, retention, and removal policy. We also invite public comment on our proposal to codify this policy at § 413.338(l)(2) and (3).

3. Future Measure Considerations

Section 1888(h)(2) of the Act allows the Secretary to apply, as appropriate, up to nine additional measures to the SNF VBP Program, in addition to the statutorily required SNF Readmission Measure. These measures may include measures of functional status, patient safety, care coordination, or patient experience.

In the FY 2022 SNF PPS proposed rule (86 FR 20009 through 20011), we requested public comment on potential future measures to include in the expanded SNF VBP Program. After considering the public input we received, we adopted three new measures in the FY 2023 SNF PPS final rule (87 FR 47564 through 47580). Two of those measures will be scored beginning with the FY 2026 program year: SNF HAI and Total Nurse Staffing measures; and the third measure will be scored beginning with the FY 2027 program year: DTC PAC SNF measure. In the FY 2024 SNF PPS final rule (88 FR 53280 through 53296), we adopted four additional measures. One of those measures, the Nursing Staff Turnover measure, will be scored beginning with the FY 2026 program year, while the other three measures will be scored beginning with the FY 2027 program year: Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalizations measures.

With the adoption of those seven measures, in addition to the statutorily-required SNF Readmission Measure, the SNF VBP Program will include eight measures that cover a range of quality measure topics important for assessing the quality of care in the SNF setting. Therefore, as permitted under section 1888(h)(2)(A)(ii) of the Act, we can add up to two additional measures in the Program.

As part of our efforts to build a robust measure set for the SNF VBP Program, we are considering several options related to new measures and other measure set adjustments. First, we recognize that gaps remain in the current measure set and therefore, we are considering which measures are best suited to fill those gaps. Specifically, we are assessing several resident experience measures to determine their appropriateness and feasibility for inclusion in the Program. We are also testing the appropriateness of measures that address other CMS priorities, such as interoperability and health equity/social determinants of health.

Beyond the adoption of new measures, we are also considering other measure set adjustments. For example, we are assessing the feasibility of a staffing composite measure that would combine the two previously adopted staffing measures. We are also considering whether measure domains and domain weighting are appropriate for the SNF VBP Program.

While we are not proposing any new measures or measure set adjustments in this proposed rule, we will continue to assess and determine which, if any, of these options would help us maximize the impact of the SNF VBP Program measure set and further incentivize quality of care improvements in the SNF setting. We welcome commenters' continuing feedback on potential new measure topics and other measure set adjustments.

D. SNF VBP Performance Standards

1. Background

We refer readers to the FY 2024 SNF PPS final rule (88 FR 53299 through 53300) for a detailed history of our performance standards policies.

In the FY 2024 SNF PPS final rule (88 FR 53300), we adopted the final numerical values for the FY 2026 performance standards and the final numerical values for the FY 2027 performance standards for the DTC PAC SNF measure.

2. Estimated Performance Standards for the FY 2027 Program Year

In the FY 2024 SNF PPS final rule (88 FR 53300), we adopted the final numerical values for the FY 2027 performance standards for the DTC PAC SNF measure.

To meet the requirements at section 1888(h)(3)(C) of the Act, we are providing estimated numerical performance standards for the remaining measures applicable for the FY 2027 program year: SNFRM, SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, Falls with Major Injury (Long-Stay), Long Stay Hospitalization, and DC Function measures. In accordance with our previously finalized methodology for calculating performance standards (81 FR 51996 through 51998), the estimated numerical values for the FY 2027 program year performance standards are shown in Table 31.

TABLE 31—ESTIMATED FY 2027 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure short name	Achievement threshold	Benchmark
SNFRM	0.78800	0.82971
SNF HAI Measure	0.92315	0.95004
Total Nurse Staffing Measure	3.18523	5.70680
Nursing Staff Turnover Measure	0.35912	0.72343
Falls with Major Injury (Long-Stay) Measure	0.95327	0.99956
Long Stay Hospitalization Measure	0.99777	0.99964
DC Function Measure	0.40000	0.79764

3. Estimated Performance Standards for the FY 2028 Program Year

In the FY 2024 SNF PPS final rule (88 FR 53280 through 53281), we finalized that the SNF WS PPR measure will replace the SNFRM beginning with the FY 2028 program year. In that final rule (88 FR 53299 through 53300), we also finalized that the baseline and performance periods for the SNF WS PPR measure would each be 2 consecutive years, and that FY 2025 and FY 2026 would be the performance period for the SNF WS PPR measure for the FY 2028 program year.

To meet the requirements at section 1888(h)(3)(C) of the Act, we are providing estimated numerical performance standards for the FY 2028 program year for the SNF WS PPR measure as well as the DTC PAC SNF measure. In accordance with our previously finalized methodology for calculating performance standards (81 FR 51996 through 51998), the estimated numerical values for the FY 2028 program year performance standards for the DTC PAC SNF and SNF WS PPR measures are shown in Table 32.

We note that we will provide the estimated numerical performance standards values for the remaining measures applicable in the FY 2028 program year in the FY 2026 SNF PPS proposed rule.

TABLE 32—ESTIMATED FY 2028 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure short name	Achievement threshold	Benchmark
DTC PAC SNF Measure	0.42946	0.66370
SNF WS PPR Measure	0.86756	0.92527

4. Proposed Policy for Incorporating Technical Measure Updates Into Measure Specifications and for Subsequent Updates to SNF VBP Performance Standards Beginning With the FY 2025 Program Year

We are required under section 1888(h)(3) of the Act to establish performance standards for SNF VBP measures for a performance period for a fiscal year. Under that section, we are also required to establish performance standards that include levels of achievement and improvement, the higher of which is used to calculate the SNF performance score, and to announce those performance standards no later than 60 days prior to the beginning of the performance period for the applicable fiscal year. We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for details on our previously finalized performance standards methodology.

In the FY 2019 SNF PPS final rule (83 FR 39276 through 39277), we finalized a policy that allows us to update the numerical values of the performance standards for a fiscal year if we discover an error in the performance standards calculations. Under this policy, if we discover additional errors with respect to that fiscal year, we will not further update the numerical values for that fiscal year.

In this proposed rule, we are proposing to adopt a policy that would allow us to update previously finalized SNF VBP measure specifications using subregulatory processes to incorporate technical measure updates. We are also proposing to use sub-regulatory processes to update the numerical values of the performance standards for a measure if that measure's specifications have been technically updated.

We currently calculate performance standards for SNF VBP measures using baseline period data, which are then used, in conjunction with performance period data, to calculate performance scores for SNFs on each measure for the applicable program year. However, during the long interval between the time we finalize the performance standards for the measures and the time that we calculate the achievement and improvement scores for those measures based on actual SNF performance, one or more of the measures may have been technically updated in a way that inhibits our ability to ensure that we are making appropriate comparisons between the baseline and performance period. We believe that to calculate the most accurate achievement and improvement scores for a measure, we should calculate the performance standards, baseline period measure results, and performance period measure results using the same measure specifications.

Therefore, we are proposing to incorporate technical measure updates into the measure specifications we have adopted for the SNF VBP Program so that these measures remain up-to-date and ensure that we can make fair comparisons between the baseline and performance periods that we adopt under the Program. Further, we are proposing that we would incorporate these technical measure updates in a sub-regulatory manner and that we would inform SNFs of any technical measure updates for any measure through postings on our SNF VBP website, listservs, and through other educational outreach efforts to SNFs. These types of technical measure updates do not substantively affect the measure rate calculation methodology. We also recognize that some updates to measures are substantive in nature and may not be appropriate to adopt without further rulemaking. In those instances, we would continue to use rulemaking to adopt substantive updates to SNF VBP measures.

With respect to what constitutes substantive versus non-substantive (technical) measure changes, we would make this determination on a case-by-case basis. Examples of technical measure changes may include, but are not limited to, updates to the case-mix or risk adjustment methodology, changes in exclusion criteria, or updates required to accommodate changes in the content and availability of assessment data. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure.

We are also proposing to expand our performance standards correction policy beginning with the FY 2025 program year such that we would be able to update the numerical values for the performance standards for a measure for a program year if a measure's specifications were technically updated between the time that we published the performance standards for a measure and the time that we calculate SNF performance on that measure at the conclusion of the applicable performance period. Any update we would make to the numerical values would be announced via the SNF VBP website, listservs, and through other educational outreach efforts to SNFs. In addition, this proposal would have the effect of superseding the performance standards that we establish prior to the start of the performance period for the affected measures, but we believe them to be necessary to ensure that the performance standards in the SNF VBP Program's scoring calculations enable the fairest comparison of measure performance between the baseline and performance period.

We note that these proposals align with the Technical Updates Policy for Performance Standards that we adopted for the Hospital VBP Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077 through 50079).

Further, we are proposing to codify these proposals in our regulations. Specifically, we are proposing to codify our proposed policy to incorporate technical measure updates into previously finalized SNF VBP measure specifications in a subregulatory manner by adding a new paragraph (l)(4) to our regulations at § 413.338. Our current performance standards policies are codified at § 413.338(d)(6) of our regulations. However, we are proposing to redesignate that paragraph as new § 413.338(n) of our regulations and to include in paragraph (n) both the existing performance standards policies and this newly proposed expansion of our performance standards correction policy.

We invite public comment on these proposals.

E. SNF VBP Performance Scoring Methodology

1. Background

We refer readers to the FY 2024 SNF PPS final rule (88 FR 53300 through 53304) for a detailed history of our performance scoring methodology. Our performance scoring methodology is codified at §§ 413.338(d) and (e) of our regulations. We have also codified the Health Equity Adjustment (HEA) at § 413.338(k) of our regulations.

2. Proposed Measure Minimum Policies

a. Background

We refer readers to the FY 2024 SNF PPS final rule (88 FR 53301 through 53303) for details on our previously adopted case minimums and measure minimums. Our case minimum and measure minimum policies are also codified at § 413.338(b) of our regulations. In this proposed rule, we are proposing to apply the previously finalized FY 2027 measure minimum to the FY 2028 program year and subsequent years. We are not proposing any changes to our previously finalized case minimums.

b. Proposal To Apply the FY 2027 Measure Minimum to the FY 2028 SNF VBP Program Year and Subsequent Years

In the FY 2024 SNF PPS final rule (88 FR 53301 through 53303), we adopted an updated measure minimum for the FY 2027 program year. Specifically, we finalized that for a SNF to receive a SNF performance score and value-based incentive payment for the FY 2027 program year, SNFs must report the minimum number of cases for four of the eight measures during the applicable performance period. As discussed below, we are proposing to apply this measure minimum to the FY 2028 program year and subsequent years, such that SNFs must report the minimum number of cases for at least four measures during the applicable performance period. SNFs that do not meet this measure minimum requirement would be excluded from the applicable program year and would receive their adjusted Federal per diem rate for that fiscal year.

Based on our analyses for the FY 2028 program year, which are also applicable to subsequent program years for which we use the same measure set, we estimate that, under the proposed measure minimum, approximately 6 percent of SNFs would be excluded from the Program compared to the approximately 8 percent of SNFs that we estimate would be excluded from the Program in FY 2027. This represents fewer SNFs being excluded from the FY 2028 program year than our estimated number of SNFs that would be excluded from the FY 2027 program year, due to the SNF WS PPR measure replacing the SNFRM beginning in FY 2028. We also assessed the consistency of incentive payment multipliers (IPMs), or value-based incentive payment adjustment factors, between FY 2027 and FY 2028 as a proxy for SNF performance score reliability. We found that applying the FY 2027 measure minimum to the FY 2028 program year would have minimal impact on the percentage of SNFs that would receive a net-positive IPM between those two fiscal years, which indicates that the reliability of the SNF performance score would be minimally impacted if we applied the FY 2027 measure minimum to the FY 2028 program year. Based on these testing results for FY 2028, we believe that applying the FY 2027 measure minimum to the FY 2028 program year and subsequent years best balances SNF performance score reliability with our desire to ensure that as many SNFs as possible can receive a SNF performance score. We note that if we propose in future years to revise the total number of measures in the Program, we would reassess this measure minimum policy to ensure it continues to meet our previously stated goals. If needed, we would propose updates in future rulemaking.

We invite public comment on our proposal to apply the FY 2027 measure minimum in which SNFs must report the minimum number of cases for at least four measures during the performance period to the FY 2028 SNF VBP program year and subsequent years.

3. Potential Next Steps for Health Equity in the SNF VBP Program

In the FY 2024 SNF PPS final rule (88 FR 53304 through 53318), we adopted a Health Equity Adjustment (HEA) that allows SNFs that provide high quality care and care for high proportions of SNF residents who are underserved to earn bonus points. We refer readers to that final rule for an overview of our definition of health equity, current disparities in quality of care in the SNF setting, our commitment to advancing health equity, and the details of the HEA.

In the FY 2024 SNF PPS proposed rule (88 FR 21393 through 21396), we also included a request for information

(RFI) entitled ''Health Equity Approaches Under Consideration for Future Program Years,'' where we noted that significant disparities in quality of care persist in the SNF setting. We stated that the goal of explicitly incorporating health equity-focused components into the Program was to both measure and incentivize equitable care in SNFs. Although the HEA rewards high performing SNFs that care for high proportions of SNF residents with underserved populations, it does not explicitly measure or reward high provider performance among the disadvantaged or underserved population. We remain committed to achieving equity in health outcomes for residents by promoting SNF accountability for addressing health disparities, supporting SNFs' quality improvement activities to reduce these disparities, and incentivizing better care for all residents. Through the RFI, we solicited public comment on possible health equity advancement approaches to incorporate into the Program in future program years that could supplement or replace the HEA. We refer readers to the FY 2024 SNF PPS final rule (88 FR 53322) for a summary of the public comments we received in response to the health equity RFI. We are considering these comments as we continue to develop policies, quality measures, and measurement strategies on this important topic.

We are currently exploring the feasibility of proposing future health equity-focused metrics for the Program. Specifically, we are considering different ways of measuring health equity that could be incorporated into the program as either a new measure, combined to form a composite measure, or as an opportunity for SNFs to earn bonus points on their SNF performance score. These performance metrics described in more detail later in this section of the proposed rule would utilize the existing SNF HAI, DC Function, DTC PAC SNF, and SNF WS PPR measures that we adopted in the Program. We are considering the development of health-equity-focused versions of these measures because they are either cross-setting or could be implemented in multiple programs. The health-equity focused measures or metrics for bonus points include:

- A high-social risk factor (SRF) measure that utilizes an existing Program measure where the denominator of the measure only includes residents with a given SRF, which would allow for comparisons of care for underserved populations across SNFs;
- A worst-performing group measure that utilizes an existing Program measure and compares the quality of care among residents with and without a given SRF on that measure and places greater weight on the performance of the worst-performing group with the goal of raising the quality floor at every facility; and
- A within-provider difference measure that assesses performance differences between residents (those with and without a given SRF) within a SNF on an existing Program measure, creating a new measure of disparities within SNFs.

We are testing these various measure concepts to determine where current across- and within-provider disparities exist in performance, how we can best incentivize SNFs to improve their quality of care for all residents, including those who may be underserved, and the feasibility of incorporating a health equity-focused measure into the Program.

As we explore these and other options, we are focusing on approaches that:

- Include as many SNFs as possible and are feasible to implement;
- Integrate feedback from interested parties;
- Encourage high quality performance for all SNFs among all residents and discourage low quality performance;
- Are simple enough for SNFs to understand and can be used to guide SNFs in improvement; and
- Meet the goal of incentivizing equitable care to ensure all residents in all SNFs receive high quality care.

We are also exploring how constraints, such as sample size limitations, may impact our ability to effectively incorporate certain approaches into the Program. Lastly, we continue to explore opportunities to align with other CMS programs to minimize provider burden.

F. Proposed Updates to the SNF VBP Review and Correction Process

1. Background

We refer readers to the FY 2024 SNF PPS final rule (88 FR 53325 through 53326) and to § 413.338(f) of our regulations for details on the SNF VBP Program's public reporting requirements and the two-phase review and correction process that we have adopted for the Program. We also refer readers to the SNF VBP website (*https://www.cms.gov/medicare/quality/nursing-home-improvement/value-based-purchasing/confidential-feedback-reporting-review-and-corrections*) for additional details on our review and correction process. In Phase One of the review and correction process, we accept corrections for 30 days after distributing the following quarterly confidential feedback reports to SNFs: the two Full-Year Workbooks (one each for the baseline period and performance period), generally released in December and June, respectively. Corrections are limited to errors made by CMS or its contractors when calculating a measure rate. In the FY 2022 SNF PPS final rule (86 FR 42516 through 42517), we finalized that SNFs are not able to correct any of the underlying administrative claims data used to calculate a SNF's readmission measure rate during Phase One of the review and correction process. For corrections to the underlying administrative claims data to be reflected in the SNF VBP Program's quarterly confidential feedback reports, the SNF must submit the claims correction request to their MAC and the MAC must process the correction before the ''snapshot date.'' For the SNFRM, the quarterly confidential feedback reports will not reflect any claims corrections processed after the date of the claims snapshot, which is 3 months following the last index SNF admission in the applicable baseline period or performance period.

In Phase Two of the review and correction process, SNFs may submit corrections to SNF performance scores and rankings only. We accept Phase Two corrections for 30 days after distributing the Performance Score Report that we generally release in August of each year.

Under our current review and correction policy, the SNF must identify the error for which it is requesting correction, explain its reason for requesting the correction, and submit documentation or other evidence, if available, supporting the request. SNFs must submit correction requests to the SNF VBP Program Help Desk, which is currently available at *SNFVBP@rti.org,* and the requests must contain:

- The SNF's CMS Certification Number (CCN),
- The SNF's name,
- The correction requested, and
- The reason for requesting the correction, including any available evidence to support the request.

For all review and correction requests, we will review the requests and notify the requesting SNF of the final decision. We will also implement any approved corrections before the affected data becomes publicly available.

We are proposing to apply our existing Phase One of the review and correction process to all measures

adopted in the Program regardless of the data source for a particular measure. We are also proposing ''snapshot dates'' for the new SNF VBP measures and to codify those snapshot dates in revised § 413.338(f)(1). We are also proposing to redesignate current § 413.338(f)(1) as 413.338(f)(2) and to revise that paragraph to state that the underlying data used to calculate measure rates cannot be corrected by SNFs during the SNF VBP review and correction process.

2. Proposal To Apply the Existing Phase One Review and Correction Policy to All Claims-based Measures Beginning With the FY 2026 Program Year and Proposed ''Snapshot Dates'' for Recently Adopted SNF VBP Claims-based Measures

In the FY 2023 SNF PPS final rule, we adopted the SNF HAI measure beginning with the FY 2026 SNF VBP program year (87 FR 47564 through 47570), and the DTC PAC SNF measure beginning with the FY 2027 SNF VBP program year (87 FR 47576 through 47580). In the FY 2024 SNF PPS final rule, we adopted the Long-Stay Hospitalization measure beginning with the FY 2027 SNF VBP program year (88 FR 53293 through 53296), as well as the SNF WS PPR measure beginning with the FY 2028 SNF VBP program year (88 FR 53277 through 53280). Each of these measures is calculated using claims data.

We are proposing to apply our existing Phase One review and correction process to all SNF VBP Program measures calculated using claims data. That is, Phase One corrections for claims-based measures would be limited to errors made by CMS or its contractors when calculating the measure rates. For corrections to the underlying administrative claims data to be reflected in the SNF VBP Program's quarterly confidential feedback reports, the SNF must submit any claims correction requests to their MAC before the ''snapshot date'' to ensure that those corrections are reflected fully in measure calculations.

For the SNF HAI, DTC PAC SNF, and SNF WS PPR measures, we propose to define the ''snapshot date'' as 3 months following the last SNF discharge in the applicable baseline period or performance period to align with the ''snapshot date'' we previously adopted for the Program's Phase One review and correction process. We refer readers to the FY 2022 SNF PPS final rule (86 FR 42516 through 42517) where we explain our rationale for selecting 3 months as the ''snapshot date.'' Any corrections made to claims following the ''snapshot date'' would not be reflected in our subsequent scoring calculations.

For the Long Stay Hospitalization measure, we propose to define the ''snapshot date'' as 3 months following the final quarter of the applicable baseline period or performance period. For example, for the FY 2027 SNF VBP program year, the performance period is FY 2025. The final quarter of the performance period is July 1 through September 30, 2025. The ''snapshot date'' for this performance period would be December 31, 2025. Any corrections made to claims following the ''snapshot date'' would not be reflected in our subsequent scoring calculations.

We welcome public comment on this proposal.

3. Proposal To Apply the Existing Phase One Review and Correction Policy to PBJ-based Measures Beginning With the FY 2026 Program Year and Proposed ''Snapshot Dates'' for PBJ-Based Measures

In the FY 2023 SNF PPS final rule (87 FR 47570 through 47576), we adopted the Total Nurse Staffing measure beginning with the FY 2026 SNF VBP program year. Additionally, in the FY 2024 SNF PPS final rule (88 FR 53281 through 53286), we adopted the Nursing Staff Turnover measure beginning with the FY 2026 SNF VBP program year. Each of these measures is calculated using electronic staffing data submitted by each SNF for each quarter through the PBJ system, along with daily resident census information derived from MDS 3.0 standardized patient assessments in the case of the Total Nurse Staffing measure.

We are proposing to apply our existing Phase One review and correction process to SNF VBP Program measures calculated using PBJ data. That is, Phase One corrections would be limited to errors made by CMS or its contractors when calculating the measure rates for the PBJ-based measures applicable in the SNF VBP Program. For corrections to the underlying PBJ data to be reflected in the SNF VBP Program's quarterly confidential feedback reports, the SNF must make any corrections to the underlying data within the PBJ system before the ''snapshot date.'' Any corrections made to PBJ data following the ''snapshot date'' would not be reflected in our subsequent scoring calculations.

For measures calculated using PBJ data, we propose to define the ''snapshot date'' as 45 calendar days after the last day in each fiscal quarter. This deadline is consistent with the CMS Nursing Home Quality Improvement deadline, which requires that PBJ data submissions must be received by the end of the 45th calendar day (11:59 p.m. Eastern Time) after the last day in each fiscal quarter to be considered timely. We aim to align quality programs to the extent possible to reduce confusion and burden on providers. For more information about submitting PBJ data, we refer readers to the CMS Staffing Data Submission web page at *https://www.cms.gov/medicare/quality/nursing-home-improvement/staffing-data-submission.*

We welcome public comment on this proposal.

4. Proposal To Apply the Existing Phase One Review and Correction Policy to MDS-Based Measures Beginning With the FY 2027 Program Year and Proposed ''Snapshot Dates'' for the Recently Adopted SNF VBP MDS-Based Measures

In the FY 2024 SNF PPS final rule (88 FR 53286 through 53293), we adopted the Falls with Major Injury (Long-Stay) and DC Function measures, both beginning with the FY 2027 SNF VBP program year. These two measures are calculated using data reported by SNFs on the MDS 3.0.

We are proposing to apply our existing Phase One review and correction process to SNF VBP Program measures calculated using MDS data. That is, Phase One corrections would be limited to errors made by CMS or its contractors when calculating the measure rates for the MDS-based measures applicable in the SNF VBP Program. For corrections to the underlying MDS data to be reflected in the SNF VBP Program's quarterly confidential feedback reports, the SNF must make any corrections to the underlying data via the internet Quality Improvement Evaluation System (iQIES) before the ''snapshot date.''

For the DC Function and Falls with Major Injury (Long-Stay) measures, we propose that the ''snapshot date'' is the February 15th that is 4.5 months after the last day of the applicable baseline or performance period. However, if February 15th falls on a Friday, weekend, or Federal holiday, the data submission deadline is delayed until 11:59 p.m. ET on the next business day. For example, for the FY 2027 SNF VBP program year, the performance period is FY 2025 (October 1, 2024 through September 30, 2025). The ''snapshot date'' for this performance period would normally be February 15, 2026. However, since February 15, 2026 falls on a Sunday, the snapshot date would be extended until the next business day, which is Tuesday, February 17, 2026,

due to Monday, February 16, 2026 being a Federal holiday. This is consistent with the SNF QRP QM User's Manual available at *https://www.cms.gov/files/document/snf-qm-calculations-and-reporting-users-manual-v50.pdf-0.* Any corrections made to the MDS data following the ''snapshot date'' would not be reflected in our subsequent scoring calculations.

We welcome public comment on this proposal.

G. Proposed Updates to the SNF VBP Extraordinary Circumstances Exception Policy

1. Background

Our Extraordinary Circumstances Exception (ECE) policy, which allows SNFs to request an exception to the SNF VBP requirements for one or more calendar months when there are certain extraordinary circumstances beyond the control of the SNF, is currently codified at § 413.338(d)(4) of our regulations. We are proposing to redesignate that paragraph as new § 413.338(m) of our regulations to ensure the policy remains effective beyond FY 2025. We are also proposing to amend our existing ECE policy to include the proposed changes discussed later in this section, as well as to make other technical updates to enhance the clarity of the ECE policy in our regulations.

2. Proposal To Expand the Reasons a SNF May Submit an Extraordinary Circumstance Exception Request Beginning With the FY 2025 Program Year

Paragraph (d)(4)(ii) of our regulations currently states that a SNF may request an ECE if the SNF is able to demonstrate that an extraordinary circumstance affected the care provided to its residents and subsequent measure performance. We are proposing to expand this policy to also allow a SNF to request an ECE if the SNF can demonstrate that, as a result of the extraordinary circumstance, it cannot report SNF VBP data on one or more measures by the specified deadline. This expanded policy would avoid penalizing SNFs due to circumstances out of their control, and would also align the SNF VBP ECE policy with the ECE policies we have adopted for the SNF QRP and Home Health QRP.

If we grant an ECE to a SNF under the SNF VBP, we would, as previously finalized, calculate a SNF performance score that does not include the SNF's performance on the measure or measures during the months the SNF was affected by the extraordinary circumstance.

We welcome public comment on this proposal.

3. Proposed Updates to the Instructions for Requesting an Extraordinary Circumstance Exception Beginning With the FY 2025 Program Year

Under our current ECE policy, when a SNF requests an ECE, the SNF must complete an Extraordinary Circumstances Request form (available on *https://qualitynet.cms.gov*) and send the form, along with supporting documentation, to the SNF VBP Program Help Desk within 90 days of the date that the extraordinary circumstance occurred.

The most recent version of the ECE Request Form no longer includes information related to the SNF VBP Program. Although the previous form is still available, once it is no longer available, SNFs will no longer able to use this new version of the form when submitting an ECE request for the SNF VBP Program. Accordingly, we are proposing to update our policy to align with the current SNF QRP ECE request submission process, which does not require the completion of a form and instead requires SNFs to submit specific information via email to a Help Desk. Under our proposal, beginning with the FY 2025 program year, a SNF may request an ECE by sending an email with the subject line ''SNF VBP Extraordinary Circumstances Exception Request'' to the SNF VBP Program Help Desk with the following information:

- The SNF's CMS Certification Number (CCN);
- The SNF's business name and business address;
- Contact information for the SNF's CEO or CEO-designated personnel, including all applicable names, email addresses, telephone numbers, and the SNF's physical mailing address (not a PO Box);
- A description of the event, including the dates and duration of the extraordinary circumstance;
- Available evidence of the impact of the extraordinary circumstance on the care the SNF provided to its residents or the SNF's ability to report SNF VBP measure data, including, but not limited to, photographs, media articles, and any other materials that would aid CMS in determining whether to grant the ECE;
- A date when the SNF believes it will again be able to fully comply with the SNF VBP Program's requirements and a justification for the proposed date.

We welcome public comment on these proposed updates to the SNF VBP ECE policy.

VIII. Nursing Home Enforcement

A. Background

The Biden-Harris Administration is committed to ensuring that all residents living in nursing homes receive safe, high-quality care. This includes making certain that all Americans, including older Americans and people with disabilities, live in a society that is accessible, inclusive, and equitable. To ensure that residents are receiving high quality, and safe care, long-term care facilities that participate in the Medicare or Medicaid program, or both must be certified as meeting Federal participation requirements. Long-term care facilities are certified as a skilled nursing facility in Medicare and nursing facility in Medicaid, or dually-certified in both programs, as specified in sections 1819 and 1919 of the Act, respectively, and in regulations at 42 CFR part 483, subpart B.

Section 1864(a) of the Act authorizes the Secretary to enter into agreements with State survey agencies to conduct surveys (that is, inspections) to determine whether skilled nursing facilities meet the Federal participation requirements for Medicare. Section 1902(a)(33)(B) of the Act provides for state survey agencies to perform the same survey tasks for facilities participating or seeking to participate in the Medicaid program. The results of these surveys are used by CMS and the State Medicaid agency, respectively, as the basis for a decision to enter into, deny, or terminate a provider agreement with the facility. They are also used to determine whether one or more enforcement remedies should be imposed when noncompliance with requirements is identified. Surveyors observe the provision of care and services to residents, conduct interviews, and review facility and residents' documentation to determine compliance with federal requirements and ensure the residents' health and safety are adequately protected.

Under sections 1819(f)(1) and 1919(f)(1) of the Act, the Secretary must ensure that the enforcement of compliance with the participation requirements is adequate to protect the health, safety, welfare, and rights of the residents and to promote the effective use of public money. Additionally, criteria must be specified as to when and how enforcement remedies are applied, the amounts of any fines, and the severity of each remedy imposed. Criteria must also be designed to minimize the time between the identification of violations and the final imposition of the remedies. Sections 1819(h)(2)(B) and 1919(h)(3)(C) of the

Act. One of the Federal statutory enforcement remedies available to the Secretary and the States to address facility noncompliance with the requirements is a civil money penalty (CMP). Under sections 1819(h)(2)(B)(ii)(I) and 1919(h)(3)(C)(ii)(I) of the Act, CMPs may be imposed to remedy noncompliance at amounts not to exceed $10,000 for each day of noncompliance (as annually adjusted by inflation by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015). The statute additionally permits the Secretary and the States to impose a CMP for each day of noncompliance, even if a facility has since returned to substantial compliance as documented by an intervening standard survey (sections 1819(h)(2)(A) and 1919(h)(1) and (3) of the Act providing that if a facility is found to be in compliance with the requirements, ''. . . but, as of a previous period, did not meet such requirements, [the Secretary provide for] a civil money penalty . . . for the days in which he finds that the facility was not in compliance with such requirements''). The Secretary must follow the procedures set out in section 1128A of the Act in processing these CMP remedies.

The regulations that govern the imposition of CMPs and other remedies authorized by the statute were published on November 10, 1994 (59 FR 56116) and subsequently revised on September 28, 1995 (60 FR 50118), March 18, 1999 (64 FR 13354 through 13360), March 18, 2011 (76 FR 15106), and September 6, 2016 (81 FR 61538). The nursing home enforcement rules are set forth in 42 CFR part 488, subpart F, and the provisions directly affecting CMPs imposed for noncompliance with the requirements are set forth in §§ 488.430 to 488.444. In general, the severity of an enforcement action is based on the extent and/or severity of harm or potential for more than minimal harm to residents that results from the cited noncompliance. This is intended to ensure prompt compliance, incentivizing the facility to take appropriate actions to permanently correct their noncompliance and protect residents' health and safety in the future. For example, if residents experienced serious harm due to noncompliance (including death), a less impactful enforcement remedy may not compel the facility to take the appropriate actions to prevent a similar event from occurring in the future, leaving residents at risk for serious harm, injury, or death.

Under 42 CFR 488.438, the amount of CMPs increases based on the severity and/or extent of the harm, or potential for more than minimal harm that might result from noncompliance. Current regulations at § 488.408 allow for penalties to be assessed in the upper range for $3,050 to $10,000 per day (PD) or $1,000 to $10,000 per instance (PI), as annually adjusted for inflation, for noncompliance that constitutes immediate jeopardy (IJ) to resident health and safety, while penalties in the lower range of $50 to $3,000 PD or $1,000 to $10,000 PI of noncompliance, as annually adjusted for inflation, may be imposed where immediate jeopardy does not exist.

Under the current regulations, the State and/or CMS must decide whether to select either a PD or PI CMP when considering whether a CMP will be used as a remedy. A PD CMP is an amount that may be imposed for each day a facility is not in compliance until the facility corrects the noncompliance and achieves substantial compliance. A PI CMP is an amount that is imposed for each instance that a facility is not in substantial compliance. The current enforcement regulations at 42 CFR part 488, subpart F do not authorize the use of both types of CMPs during the same survey, nor do they allow for multiple PI CMPs to be imposed for multiple instances within the same noncompliance deficiency that occurred on different days during a survey.

While there is no statutory limitation of both a PI and PD being imposed on the same survey, we specified in the rulemaking that revised § 488.430(a) (published on March 18, 1999 (64 FR 13360)), that we would not impose both PD and PI CMPs during a survey. Instead, the 1999 rule required that, ''a concomitant decision must be made whether the civil money penalty will be based on a determination of per instance or per day'' (64 FR at 13356). Additionally, we noted that an ''instance'' means a singular event of noncompliance or single deficiency under a distinct regulatory area identified by an administrative ''F tag'' number used as reference on the CMS–2567, Statement of Deficiencies. (*Id.*) We are proposing revisions to this limitation to enable more types of CMPs to be imposed during a survey once a CMP remedy is selected, allowing for penalties to be better aligned with the noncompliance identified during the survey and for more consistency of CMP amount across the nation. PI CMPs are often imposed in certain circumstances, such as when noncompliance existed but was corrected prior to the survey, and for isolated instances of noncompliance unrelated to resident abuse. PI CMPs may also be imposed in cases where a deficiency is found, but the facility has not had any citations of actual or serious harm on any survey in the past three years. A PI CMP has typically not been imposed for findings of abuse or neglect, when there is continued noncompliance, or when the facility has a past history of the same type of noncompliance causing actual harm to residents. PD CMPs, however, are generally imposed when these scenarios do not exist and the facility has a history of similar noncompliance. For example, if a facility was found to be out of compliance with the requirements to prevent accidents where a resident was injured during a transfer from a wheelchair to the bed, and this was cited as an isolated instance of noncompliance that caused actual harm to a resident, a PI CMP may be imposed. We developed a Civil Money Penalty Analytic Tool to help determine CMP amounts when a CMP is one of the selected remedies, per section 1819(h)(2)(B)(ii) of the Act; 42 CFR 488.404 and 488.438.

The Biden-Harris Administration is committed to ensuring that all residents living in Medicare and Medicaid nursing homes receive safe, high-quality care. Specifically, In February 2022, alongside a suite of other reforms, CMS committed to expanding financial penalties and other enforcement sanctions to improve the safety and quality of care in the Nation's nursing homes.[68] As part of this effort, CMS examined the use of PD and PI CMPs and CMP impositions across states from January 1, 2022, to December 31, 2022. We found national variations in the length of time PD CMPs are imposed based on when the noncompliance occurred, when the survey was performed, and when the facility was found to have corrected the noncompliance. For example, from January 1, 2022–December 31, 2022, the State with the shortest average number of average days for PD CMP imposition was 1 day, and the longest average number of days in a State was 43 days. This results in vastly differing PD CMP amounts across the States based on the number of days of noncompliance, as well as the date the survey was conducted, rather than being more focused on the potential or actual harm that a deficiency may cause to residents. In other words, the same type of noncompliance may exist in two facilities, yet the PD CMP amounts would be different simply due to the number of days between the identification of noncompliance by the Surveyor and the date of correction by the facility. We believe that this results

in at least two problems. First, it could create a perception of inequity in the total amount calculated for a CMP. Second, it prevents us from holding some facilities responsible for failing to adequately protect the health, safety, and well-being of residents. Take, for example, a survey that finds noncompliance with the requirements of participation that increases the likelihood of serious injury, harm, impairment, or death to residents—such as when residents are susceptible to falls while not being monitored (even when no resident actually fell as a result of the failure to monitor). If this is identified to have started 100 days prior to the survey, a PD CMP would accrue for each of the 100 days and each additional day until the facility corrected its noncompliance, resulting in a very high CMP. Conversely, another facility's similar noncompliance might result in serious harm to a resident, when two residents fall due to failures to monitor, resulting in serious injury. But, If these falls are identified to have occurred one and two days prior to the survey, a PD CMP would only accrue for 2 days and each additional day until the noncompliance was corrected, resulting in a relatively low CMP that may not encourage prompt or lasting compliance.

These scenarios show how the timing of a survey can potentially result in a higher CMP for similar noncompliance that resulted in less harm to residents. As such, we want to ensure that CMS retains the authority to impose CMPs related to the nature of the harm that is caused by—or could be caused by—a facility's noncompliance and the length of such noncompliance, rather than the date that a standard survey was conducted or a finding of noncompliance was identified, even if the administration of imposing the CMP occurs after another survey has been conducted.

Therefore, as discussed later in this section, we propose to expand and strengthen our enforcement process by revising the regulations to increase CMS's flexibility when a CMP is the selected remedy and allow for multiple PI CMPs to be imposed for the same type of noncompliance, allow for both PD and PI CMPs to be imposed for noncompliance findings in the same survey, as well as ensure that the amount of a CMP does not depend solely on the date that the most recent standard survey is conducted or the date that a finding of noncompliance was identified by surveyors. With these proposed revisions, in certain circumstances, CMS or the State may use the survey start date when imposing a PD CMP instead of the beginning date of the noncompliance, which maintains the benefit of fines accruing to incentivize swift correction to protect existing residents' safety, and as a deterrent for future noncompliance to protect future residents' safety. In other words, by creating the ability to impose a PI CMP and PD CMP on the same survey, CMS or the State could impose a PI CMP to address the noncompliance that occurred in the past or prior to the survey, and a PD CMP beginning at the start of the survey and continuing until the facility has corrected its noncompliance. Additionally, if multiple instances of noncompliance occurred prior to the survey, CMS or the State could impose multiple PI CMPs, as well as a PD CMP. This helps ensure that similar types of noncompliance receive similar CMPs regardless of how many days prior to the survey it occurred, and ensures facilities are motivated to correct their noncompliance as soon as possible after the surveyors identify it.

These proposed revisions are not intended to expand the type of deficiencies that are subject to PD and PI CMPs. The States and CMS would continue to follow the existing criteria for imposing a PD CMP or PI CMP, including imposing a PD or PI CMP for noncompliance that occurred prior to the start of a survey. Rather, these proposed revisions would allow for more consistent CMP amounts imposed across the nation and expand the current enforcement to allow for additional CMPs that more closely align with the noncompliance that occurred. These actions will help to better ensure that compliance is quickly achieved and is lasting.

B. Provisions of the Proposed Regulations

1. Imposing Multiple per Instance Civil Money Penalties for the Same Type of Noncompliance

Sections 1819(h)(2)(B)(ii) and 1919 (h)(3)(C)(ii) of the Act authorize the Secretary to impose a CMP for each day of noncompliance. Section 1128A(d) of the Act further states that the Secretary shall consider (1) the nature of claims and the circumstances under which they were presented, (2) the degree of culpability, history of prior offenses and financial condition of the person presenting the claims, and (3) such other matters as justice may require when determining the amount or scope of any penalty. The regulations at § 488.454(d) state that, in the case of a CMP imposed for an instance of noncompliance, the remedy is the specific amount of the CMP imposed for the particular noncompliance deficiency. The meaning of an ''instance,'' therefore, focuses on a single deficiency citation of the applicable requirements of part 483, subpart B referenced on the facility's statement of deficiencies (Form CMS–2567)) and, under the current regulations, only one type of CMP can be imposed per F tag deficiency.

The statute grants the Secretary broad discretion to determine how appropriate CMPs should be enforced and only limits the imposition to a maximum daily amount. We propose to expand the circumstances in which a PI CMP can be imposed to allow for more than one PI CMP to be imposed when multiple occurrences, or ''instances'' of a specific noncompliance are identified during a survey, regardless of whether they are cited at the same regulatory deficiency tag number in the statement of deficiencies. For example, if a surveyor identifies during a survey several instances of noncompliance within a particular regulatory requirement (such as § 483.25, identified as tag F684—quality of care,) that occurred on different days, CMS or the State survey agency would be able to impose a PI CMP for each occurrence of that noncompliance for those days, as long as the total facility CMP liability did not exceed the statutory and regulatory maximum amount on any given day.

As previously mentioned, CMS imposes CMPs based on sections 1819(h)(2)(B)(ii) and 1919 (h)(3)(C)(ii) of the Act, §§ 488.404, and 488.438 which provides the amount of penalty, the ranges, basis for penalty amount, increase/decrease of penalty amounts, and factors affecting the amount. While we may impose various enforcement remedies, CMPs are frequently imposed for deficiencies that result in serious injury, harm, impairment, or death to nursing home residents. Currently, we can only impose PI CMPs for different types of noncompliance identified on a survey, while other instances of the same noncompliance would not receive a CMP due to current regulatory limitations. Since the PI CMP is limited to one broad regulatory occurrence, the amount of the PI CMP often is not sufficient to encourage sustained compliance and deter future noncompliance with the requirements of participation.

To strengthen our enforcement policies, we propose to revise § 488.401 to define ''instance'' or ''instance of noncompliance'' as a separate factual and temporal occurrence when a facility fails to meet a participation requirement. We further propose that

each instance of noncompliance would be sufficient to constitute a deficiency and that a deficiency may be comprised of multiple instances of noncompliance. This proposed revision will allow us and the States to impose multiple PI CMPs for the same type of noncompliance in a survey, thereby incentivizing facilities to take meaningful steps to permanently resolve their deficiencies. This proposed regulatory change would also provide more opportunities to impose CMPs in a manner that is consistent with the Congressional mandate to ensure that residents are protected from harm that often result in facilities with multiple occurrences of noncompliance. Because these changes focus more directly on the severity of noncompliance itself, we anticipate that, not only will they better protect nursing home residents and encourage lasting compliance, they will also create more consistency in the amount of imposed CMPs.

2. Imposing per Instance and per Day Civil Money Penalties on the Same Survey

As we noted earlier, the Act does not limit the imposition of both a PD and a PI on the same survey but only limits the total amount a penalty may be imposed for any individual day. Section 488.408(d)(2)(iii)–(iv) and § 488.408(e)(1)(iii)–(iv) outline the type of remedies that may be imposed based on the severity of the noncompliance, however these regulations do not state the manner in which the remedies may be imposed.

Because CMPs are designed to spur permanent resolution of deficiencies, We believe CMS and the States need flexibility to determine the range of CMPs that can be imposed on facilities that fail to meet the conditions of participation. For example, if a survey identifies isolated noncompliance that occurred prior to the start of the survey and also identifies separate noncompliance that began and continued to occur during the survey, we are currently unable to impose both a PI CMP and a PD CMP to address these two separate occurrences of noncompliance identified during the same survey. In other words, if a survey identified numerous instances of medication administration errors as well as systemic noncompliance with infection control policies, we believe imposing a PI CMP for the medication errors and a PD CMP for the infection control deficiencies, in this general example, could be a more effective enforcement response. Due to the additional instances of noncompliance identified, a PD CMP that covers the noncompliance with infection control requirements alone may not encourage the facility to sustain compliance. Without this type of flexibility, CMS cannot impose penalties that are sufficient to ensure that any systemic issues that caused the noncompliance are permanently corrected. Moreover, we have found that the failure of nursing homes to take the necessary steps to permanently resolve systemic problems increases the probability that deficiencies will continue, progressing to a higher scope and severity that ultimately results in harm or increased harm to residents.

For the previously stated reasons, we propose to revise §§ 488.408(e)(2)(ii) and 488.430(a) to expand our authority to impose both a PI CMP and a PD CMP, not to exceed the statutory and regulatory maximum amount on any given day even when combined, when surveyors identify noncompliance. Specifically, in § 488.408(e)(2)(ii), we propose that for each instance of noncompliance, CMS and the State may impose a PD CMP of $3,050 to $10,000 (as adjusted under 45 CFR part 102), a PI CMP of $1,000 to $10,000 (as adjusted under 45 CFR part 102), or both, in addition to the remedies specified in § 488.408(e)(2)(i). Additionally, we propose that when a survey contains multiple instances of noncompliance, CMS and the State may impose any combination of per instance or per day CMP for each instance of noncompliance within the same survey. Additionally, we propose to revise § 488.430(a) to allow for each instance of noncompliance, a PD CMP, PI CMP, ''or both'' may be imposed, regardless of whether or not the deficiencies constitute immediate jeopardy. We also propose to add that when a survey contains multiple instances of noncompliance, a combination of per instance and per day CMPs for each instance of noncompliance may be imposed within the same survey. These proposed revisions will enable PI CMPs to be imposed for noncompliance that was previously not able to be addressed once a PD CMP was selected. This would also allow CMS or a State survey agency to impose multiple PI CMPs for noncompliance that occurred prior to the start of a survey and use the survey start date to begin the PD CMP, thereby enabling more consistent CMP amounts to be imposed while still incentivizing a swift return to compliance.

Additionally, we propose to make conforming changes by revising § 488.434(a)(2)(iii) to clarify that both PD and PI CMPs can be imposed on the same survey and thus is included in the penalty notice to the facility. Furthermore, we propose to revise § 488.434(a)(2)(v) to indicate that the date and instance of noncompliance is not a singular event, but rather can be multiple ''date(s) of the instance(s) of noncompliance.'' Lastly, we propose to revise § 488.440(a)(2) to remove the phrase, ''for that particular deficiency,'' and replace with, ''per instance,'' which will allow for more than one PI CMP to be imposed on the same type of noncompliance or ''F tag'' citation. We seek public comment on these proposed revisions.

3. Timing of Enforcement

Sections 1819(h)(2)(A) and 1919(h)(1) and (3) of the Act state that when a facility is found to be in compliance with the requirements but ''. . . as of a previous period, did not meet such requirements,'' the Secretary and the State may impose a CMP for the days that the facility is found out of compliance with the requirements. The regulation at § 488.430(b) states that ''CMS or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.''

Due to an increase in the number of complaint surveys being conducted, the current regulation may result in an unanticipated limit on CMS's authority to impose remedies to the noncompliance deficiencies identified when the last standard survey was performed. For example, since 2015, the percent of complaint surveys increased from 80 to 87 percent of the total number of surveys conducted, resulting in more than 10,000 additional surveys. This increase in complaint survey activity has resulted in an increase in enforcement actions taken by the States and CMS. The increase in complaint surveys has resulted in more surveys being conducted within short timeframes of each other, which can create administrative difficulties. For example, one survey may be conducted shortly after another, not leaving enough time to impose a CMP for the first survey before the second survey is concluded. But, despite the fact that there are more surveys that identify additional deficiencies, the current regulations limit how far back CMS or the State may go when calculating a CMP amount: to the last standard survey.

We propose to revise § 488.430(b) by changing ''since the last standard survey'' to ''since the last three standard surveys.'' We believe this proposed revision aligns with the statutory mandate that the Secretary ensure that enforcement remedies adequately

protect the health and safety of nursing home residents in facilities where the Medicare and/or Medicaid programs pay for services. These proposed revisions are designed to enable CMS or State survey agencies to impose a variety of CMPs for noncompliance, particularly when surveyors have identified deficiencies that cannot be addressed because, for example, a subsequent survey has taken place. In these situations, it is important for CMS and the State to be able to impose a CMP (per day, per instance, or both), as warranted, to help ensure that the facility's compliance is permanent. Additionally, limiting review of past noncompliance to the last three standard surveys is more reflective of a facility's current compliance performance.

A proposed three-standard survey lookback period is also consistent with current agency practices. For example, CMS posts the survey results for each facility for the last three standard surveys and last 3 years of complaint surveys on the *Medicare.gov* Care Compare website to provide the public with information on the facility's compliance performance. This same timeframe is also used to calculate each facility's health inspection rating for the Five-Star Quality Rating System. We seek public comments on this proposal and also seek comments on an alternative look-back period that would also ensure CMPs are imposed in a manner that is not dependent on when the next standard survey is conducted.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Using the following format describe the information collection requirements that are in each section].

A. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Skilled Nursing Facility Value-Based Purchasing Program

We are not removing or adding any new or revised SNF VBP measure-related requirements or burden in this rule. Consequently, this final rule does not set out any new SNF VBP-related collections of information that would be subject to OMB approval under the authority of the PRA.

2. ICRs Regarding the Skilled Nursing Facility Quality Reporting Program (SNF QRP)

In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2-percentage points the otherwise applicable annual payment update to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year.

In section VI.C.3. of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category and modify one item collected as a standardized patient assessment data element under the SDOH category beginning with the FY 2027 SNF QRP. In section VI.E.3. of this proposed rule, we are also proposing that SNFs participating in the SNF QRP, be required to participate in a validation process. Specifically, we are proposing to adopt a similar validation process for the SNF QRP that we have adopted for the SNF VBP beginning with the FY 2027 SNF QRP.

As stated in section VII.C.3. of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category and modify one item collected as a standardized patient assessment data element under the SDOH category beginning with the FY 2027 SNF QRP. The proposed new and modified items would be collected using the MDS. The MDS, in its current form, has been approved under OMB control number 0938–1140. Four items would need to be added to the MDS at admission to allow for collection of these data, and one would be modified. Additionally, as stated in section VI.E.2. of this proposed rule, we are proposing SNFs would submit the four proposed new items and one modified item at admission only. The net result of collecting four new items at admission, modifying one item currently collected at admission, and removing the collection of one item at discharge is an increase of 0.9 minutes or 0.015 hour of clinical staff time at admission [(4 items × 0.005 hour) minus (1 item × 0.005 hour)]. We identified the staff type based on past SNF burden calculations, and our assumptions are based on the categories generally necessary to perform an assessment. We believe that the proposed new and modified items would be completed equally by a Registered Nurse (RN) and Licensed Practical and Licensed Vocational Nurse (LPN/LVN). However, individual SNFs determine the staffing resources necessary.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates.[71] To account for other indirect costs and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table 33. We established a composite cost estimate using our adjusted wage estimates. The composite estimate of $65.31/hr was calculated by weighting each hourly wage equally [($78.10/hr × 0.5) plus ($52.52/hr × 0.5) = $65.31].

[71] U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates. *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 33—U.S. BUREAU OF LABOR AND STATISTICS' MAY 2022 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Median hourly wage ($/hr)	Other indirect costs and fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Registered Nurse (RN)	29–1141	39.05	39.05	78.10
Licensed Practical and Licensed Vocational Nurse (LPN/LVN)	29–2061	26.26	26.26	52.52

We estimate that the burden and cost for SNFs for complying with requirements of the FY 2027 SNF QRP would increase under this proposal. Using FY 2023 data, we estimate a total of 1,966,662 admissions to and 754,287 planned discharges from 15,393 SNFs annually for an increase of 35,561.81 hours in burden for all SNFs [(1,966,662 admissions × 0.02 hour) minus (754,287 planned discharges × 0.005 hour)]. Given 0.02 hour at $65.31 per hour to complete an average of 128 5-day PPS assessments per provider per year minus 0.005 at $65.31 per hour to complete an average of 49 Planned Discharge assessments, we estimate the total cost would be increased by $150.88 per SNF annually, or $2,322,541.48 for all SNFs annually. The proposed increase in burden would be accounted for in a revised information collection request under OMB control number (0938–1140). The required 60-day and 30-day notices would publish in the **Federal Register** and the comment periods would be separate from those associated with this rulemaking.

In summary, under OMB control number (0938–1140), if the proposed policies in this proposed rule are finalized, we estimate the SNF QRP would result in an overall increase of 35,561.81 hours annually for 15,393 SNFs. The total cost increase related to this information collection is approximately $2,322,541.48 and is summarized in Table 34.

TABLE 34—PROPOSED ESTIMATED BURDEN ASSOCIATED WITH OMB CONTROL NUMBER 0938–1140 (CMS–10387) RELATED TO THE SNF QRP

Proposal	Per SNF		All SNFs	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Estimated Change in Burden associated with Proposal to Collect Four New Items as Standardized Patient Assessment Data Elements and Modify One Item Collected as a Standardized Patient Assessment Data Element beginning with the FY 2027 SNF QRP	+2.31	+$150.88	+35,561.81	+$2,322,541.48

3. ICRs Regarding the Minimum Data Set (MDS) Beginning October 1, 2025

The MDS is used for meeting the SNF Requirements of Participation, requirements under the SNF QRP, and for payment purposes under the SNF PPS. As outlined in the FY 2019 SNF PPS final rule (83 FR 39165 through 39265), several MDS items are not needed in case-mix adjusting the per diem payment for PDPM. However, they were not accounted for in the FY 2019 SNF PPS final rule. Therefore, we are removing these items from the 5-day Medicare-required assessment beginning October 1, 2025. We have provided an estimate of the reduction in burden here and in Table 35. The items to be removed are:

- O0400.A.1. Speech-Language Pathology and Audiology Services; Individual minutes.
- O0400.A.2. Speech-Language Pathology and Audiology Services; Concurrent minutes.
- O0400.A.3. Speech-Language Pathology and Audiology Services; Group minutes.
- O0400.A.3A. Speech-Language Pathology and Audiology Services; Co-treatment minutes.
- O0400.A.4. Speech-Language Pathology and Audiology Services; Days.
- O0400.A.5. Speech-Language Pathology and Audiology Services; Therapy start date.
- O0400.A.6. Speech-Language Pathology and Audiology Services; Therapy end date.
- O0400.B.1. Occupational Therapy; Individual minutes.
- O0400.B.2. Occupational Therapy; Concurrent minutes.
- O0400.B.3. Occupational Therapy; Group minutes.
- O0400.B.3A. Occupational Therapy; Co-treatment minutes.
- O0400.B.4. Occupational Therapy; Days.
- O0400.B.5. Occupational Therapy; Therapy start date.
- O0400.B.6. Occupational Therapy; Therapy end date.
- O0400.C.1. Physical Therapy; Individual minutes.
- O0400.C.2. Physical Therapy; Concurrent minutes.
- O0400.C.3. Physical Therapy; Group minutes.
- O0400.C.3A. Physical Therapy; Co-treatment minutes.
- O0400.C.4. Physical Therapy; Days.
- O0400.C.5. Physical Therapy; Therapy start date.
- O0400.C.6. Physical Therapy; Therapy end date.
- O0400.E.2. Psychological Therapy; Days.

The net result of removing the collection of these items is a decrease of 6.6 minutes of clinical staff time at admission. We believe that these items are completed equally by a RN and LPN/LVN. Individual SNFs determine the staffing resources necessary.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the BLS May 2022 National Occupational Employment and Wage Estimates.[72] To account for other

[72] U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates. *https://www.bls.gov/oes/current/oes_nat.htm.*

indirect costs and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 35. We established a composite cost estimate using our adjusted wage estimates. The composite estimate of $65.31/hr was calculated by weighting each hourly wage equally [($78.10/hr × 0.5) plus ($52.52/hr × 0.5) = $65.31].

Using FY 2023 data, we estimate a total of 1,966,662 admissions to 15,393 SNFs annually. This equates to a decrease of 216,332.82 hours in burden for all SNFs. Given 0.11 hour at $65.31 per hour to complete an average of 128 5-day PPS assessments per provider per year, we estimate the total cost would be decreased by $917.87 per SNF annually, or $14,128,696.47 for all SNFs annually.

TABLE 35—PROPOSED ESTIMATED SNF REDUCTION IN BURDEN ASSOCIATED WITH ASSOCIATED WITH OMB CONTROL NUMBER 0938–1140 (CMS–10387) RELATED TO THE MINIMUM DATA SET COLLECTION AND SUBMISSION

	Per SNF		All SNFs	
	Estimated change in annual burden hours	Estimated change in annual cost	Estimated change in annual burden hours	Estimated change in annual cost
Estimated Change in Burden associated with Removal of MDS items O0400.A, O0400.B, O0400.C, and O0400.E effective October 1, 2025	−14.05	−$917.87	−216,332.82	−$14,128,696.47

4. ICRs Regarding the Proposal for SNFs To Participate in a Validation Process

In section VI.E.3 of this proposed rule, we are proposing to require SNFs to participate in a validation process beginning with the FY 2027 SNF QRP. We have provided an estimate of burden here, and in Table 36, and note that the increase in burden would be accounted for in a new information collection request.

In section VI.E.3(a). of this proposed rule, we propose to require SNFs to participate in a validation process for assessment-based measures beginning with the FY 2027 SNF QRP. We identified the staff type based on past SNF burden calculations, and our assumptions are based on the categories generally necessary to perform an assessment. We believe that the medical records would be collected and submitted by a Medical Records and Health Information Technologist and Medical Registrar (HIT/MR). However, individual SNFs determine the staffing resources necessary. For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the BLS May 2022 National Occupational Employment and Wage Estimates.[73] To account for other indirect costs and fringe benefits, we have doubled the hourly wage to establish an adjusted wage estimate of $56.02/hr. These amounts are detailed in Table 36.

TABLE 36—U.S. BUREAU OF LABOR AND STATISTICS' MAY 2022 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Median hourly wage ($/hr)	Other indirect costs and fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Medical Records and Health Information Technologists and Medical Registrars (HIT/MR)	29–9021	28.01	28.01	56.02

We are proposing that our validation contractor would select, on an annual basis, up to 1,500 SNFs and up to 10 medical records from each of the selected SNFs. We are proposing that the selected SNFs would have the option to submit digital or paper copies of the requested medical records to the validation contractor.

For the purposes of burden estimation, we assume all of the activities associated with the validation process would be completed by a HIT/MR. For selected SNFs utilizing electronic health records (EHR), we anticipate an increase of 3 hours up to 7.5 hours of HIT/MR time per SNF to submit a sample of up to 10 records. For selected SNFs who do not utilize EHRs, we anticipate an increase of 5 hours up to 12.5 hours of HIT/MR time per SNF to submit a sample of up to 10 records. Additionally, SNFs who do not utilize EHRs may incur printing and shipping costs if they are unable to submit the records via an electronic portal, and for these SNFs, we estimate the cost to print and ship a sample of up to 10 records would range from $842.67 up to $4,114.35.

We also anticipate that a sample of up to 10 medical records would consist of SNF stays that vary in length of stay. We estimate the length of stay for each of the selected medical records could range from 20 days (or less) up to or exceeding 366 days. For purposes of our burden estimate, we anticipate the average sample of up to 10 medical records would be distributed among the possible lengths of stay (that is, approximately 40 percent of stays or 4 stays would be 1 to 30 days, 40 percent of stays or 4 stays would be 31 to 100 days, and 20 percent of stays or 2 stays would last 101 to 366 or more consecutive days). We also estimate that approximately 85 percent of nursing homes utilize some form of EHRs.[74] Therefore, we estimate the total cost to submit up to 10 medical records would range between $335,699.85 and $477,368.10 for all 1,500 SNFs selected, depending on the length of stay of the

[73] *https://www.bls.gov/oes/current/oes_nat.htm.*

[74] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6591108/#:~:text=In%20a%20nationwide%20sample%2C%20we,EHR%20adoption%20by%20nursing%20facilities.*

sample medical records and whether the SNFs use an EHR. We also estimate that total cost to submit up to 10 medical records would range between $263.29 [$335,699.85/(1,500 × 0.85 SNFs)] and $2,121.64 [$477,368.10/(1,500 × 0.15 SNFs)] per SNF selected depending on the length of stay of the sample of medical records and whether the SNF uses an EHR. On average we estimate the total cost would be increased by $813,067.95 for all 1,500 selected SNFs [[($263.29 × (1,500 × 0.85)] plus [$2,121.64 × (1,500 × 0.15)]] and $542.05 per selected SNF ($813,067.95/1,500 SNFs) annually.

In section VI.E.3(b). of this proposed rule, we propose to require SNFs to participate in a validation process for Medicare fee-for-service claims-based measures beginning with the FY 2027 SNF QRP. All Medicare fee-for-service claims-based measures are already reported to the Medicare program for payment purposes, and therefore there is no additional burden for providers.

TABLE 37—PROPOSED SNF BURDEN FOR A VALIDATION PROCESS

[OMB 0938–TBD, CMS–#####]

Proposal	Per selected SNF		All selected SNFs	
	Estimated change in annual burden hours	Estimated change in annual cost	Estimated change in annual burden hours	Estimated change in annual cost
Estimated Change in Burden associated with Proposed Participation in a Validation Process	+5.12	+$542.05	+7,680	+$813,067.95

Comments must be received on/by June 3, 2024.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by June 3, 2024.

X. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XI. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

a. Statutory Provisions

This rule updates the FY 2025 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted Federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. These are statutory provisions that prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, and we do not have the discretion to adopt an alternative approach on these issues.

With respect to the SNF QRP, this proposed rule proposes updates beginning with the FY 2027 SNF QRP. Specifically, we propose to collect four new items as standardized patient assessment data elements under the SDOH category and modify one item collected as a standardized patient assessment data element under the SDOH category in the MDS beginning with the FY 2027 SNF QRP. We believe these proposals would advance the CMS National Quality Strategy Goals of equity and engagement by encouraging meaningful collaboration between healthcare providers, caregivers, and community-based organizations to address SDOH prior to discharge from the SNF. We propose to adopt a validation process for the SNF QRP beginning with the FY 2027 SNF QRP to satisfy section 111(a)(4) of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) which requires that the measures and data submitted under the SNF QRP Program (section 1888(e)(6) of the Act) be subject to a validation process. To implement this proposed validation process for SNF QRP, we are also proposing conforming amendments to our regulation at § 413.360.

With respect to the SNF VBP Program, this rule proposes updates to the SNF VBP Program requirements for FY 2025 and subsequent years. Section 1888(h)(3) of the Act requires the Secretary to establish and announce performance standards for SNF VBP Program measures no later than 60 days before the performance period, and this proposed rule estimates numerical values of the performance standards for the FY 2027 program year for the SNFRM, SNF HAI, Total Nurse Staffing, Nursing Staff Turnover, Falls with Major Injury (Long-Stay), DC Function, and Long Stay Hospitalization measures; and numerical values of the performance standards for the FY 2028 program year for the DTC PAC SNF and SNF WS PPR measures. We are also required under section 1888(h)(1)(C) of the Act to establish a minimum number of measures that apply to a facility for the applicable performance period. Therefore, we are proposing to apply the same measure minimum we previously finalized for the FY 2027 program year (88 FR 53303) to the FY 2028 program year and subsequent program years.

b. Discretionary Provisions

In addition, this proposed rule includes the following discretionary provisions:

(1) SNF Market Basket Adjustment

We are proposing to rebase and revise the SNF market basket to reflect a 2022 base year. Since the inception of the SNF PPS, the market basket used to update SNF PPS payments has been periodically rebased and revised to reflect more recent data. We last rebased and revised the market basket applicable to the SNF PPS in the FY 2022 SNF PPS final rule (86 FR 42444 through 42463) where we adopted a 2018-based SNF market basket.

Given changes to the industry in recent years and public comments about the timeliness of the weights, we have been monitoring the Medicare cost report data to determine if a more frequent rebasing schedule than our standard schedule (which has generally been about every 4 years). In light of this analysis, we are proposing to

incorporate data that is more reflective of recent SNF expenses.

(2) SNF Forecast Error Adjustment

Each year, we evaluate the SNF market basket forecast error for the most recent year for which historical data is available. The forecast error is determined by comparing the projected SNF market basket increase each year with the actual SNF market basket increase in that year. In evaluating the data for FY 2023, we found that the forecast error for that year was 1.7 percentage points, exceeding the 0.5 percentage point threshold we established in regulation for proposing adjustments to correct for forecast error. Given that the forecast error exceeds the 0.5 percentage point threshold, current regulations require that the SNF market basket percentage increase for FY 2025 be adjusted upward by 1.7 percentage points to account for forecasting error in the FY 2023 SNF market basket update.

(3) Technical Updates to ICD–10 Mappings

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the PDPM, effective October 1, 2019. The PDPM utilizes ICD–10 codes in several ways, including using the patient's primary diagnosis to assign patients to clinical categories under several PDPM components, specifically the PT, OT, SLP and NTA components. In this rule, we finalize several substantive changes to the PDPM ICD–10 code mapping.

2. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

3. Overall Impacts

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2024 (88 FR 53200). We estimate that the aggregate impact will be an increase of approximately $1.3 billion (4.1 percent) in Part A payments to SNFs in FY 2025. This reflects a $1.3 billion (4.1 percent) increase from the update to the payment rates. We note in this proposed rule that these impact numbers do not incorporate the SNF VBP Program reductions that we estimate would total $187.69 million in FY 2025. We note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and (e)(5) of the Act and implementing regulations at § 413.337(d), we are updating the FY 2024 payment rates by a factor equal to the market basket percentage increase adjusted for the forecast error adjustment and reduced by the productivity adjustment to determine the payment rates for FY 2025. The impact to Medicare is included in the total column of Table 38. The annual update in this rule applies to SNF PPS payments in FY 2025. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2025 SNF PPS payment impacts appear in Table 38. Using the most recently available claims data, in this case FY 2022 we apply the current FY 2024 CMIs, wage index and labor-related share value to the number of payment days to simulate FY 2024 payments. Then, using the same FY 2022 claims data, we apply the FY 2025 CMIs, wage index and labor-related share value to simulate FY 2025 payments. We tabulate the resulting payments according to the classifications in Table 38 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2024 payments to the simulated FY 2025 payments to determine the overall impact. The breakdown of the various categories of data in Table 38 is as follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes contained in this proposed rule on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).

• The second column shows the number of facilities in the impact database.

• The third column shows the effect of the proposed update to the SNF PPS wage index due to adopting the updated census data and revised CBSAs in OMB Bulletin 23–01. This represents the effect of only the proposed adoption of the revised CBSAs, independent of the effect of the annual update to the wage index.

• The fourth column shows the effect of the annual update to the wage index, including the proposed updates to the labor related-share discussed in section V.A above. This represents the effect of using the most recent wage data available as well as accounts for the 5 percent cap on wage index transitions. The total impact of this change is 0.0 percent; however, there are distributional effects of the change.

• The fifth column shows the effect of all of the changes on the FY 2025 payments. The update of 4.1 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments would increase by 4.1 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 38, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this proposed rule, rural providers would experience a 4.9 percent increase in FY 2025 total payments.

TABLE 38—IMPACT TO THE SNF PPS FOR FY 2025

Impact categories	Number of facilities	Census data update (%)	Update wage data (%)	Total change (%)
Group				
Total	15,393	0.0	0.0	4.1
Urban	11,151	0.0	−0.1	4.0
Rural	4,242	−0.1	0.9	4.9
Hospital-based urban	360	0.1	−1.0	3.2
Freestanding urban	10,791	0.0	−0.1	4.0
Hospital-based rural	369	−0.1	0.8	4.8
Freestanding rural	3,873	−0.1	0.9	4.9
Urban by region				
New England	715	−0.3	−0.9	2.8
Middle Atlantic	1,467	−1.0	−0.8	2.3
South Atlantic	1,893	0.6	0.8	5.5
East North Central	2,166	1.0	−0.6	4.4
East South Central	566	0.4	2.1	6.7
West North Central	950	0.0	0.6	4.7
West South Central	1,454	0.2	1.0	5.3
Mountain	539	0.1	1.6	5.8
Pacific	1,396	−0.1	−1.4	2.6
Outlying	5	0.0	−2.3	1.7
Rural by region				
New England	119	0.6	−1.3	3.4
Middle Atlantic	226	−0.7	4.0	7.5
South Atlantic	527	−0.1	−0.3	3.7
East North Central	890	−0.1	0.2	4.2
East South Central	471	−0.1	1.5	5.6
West North Central	988	0.0	1.5	5.6
West South Central	740	−0.1	1.2	5.2
Mountain	193	0.0	2.1	6.2
Pacific	87	0.0	−0.6	3.4
Outlying	1	0.0	0.0	4.1
Ownership				
For profit	10,893	0.0	0.0	4.0
Non-profit	3,492	0.1	0.1	4.3
Government	1,008	−0.1	0.6	4.7

Note: The Total column includes the FY 2025 4.1 percent market basket update. The values presented in Table 38 may not sum due to rounding.

5. Impacts for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) for FY 2027

Estimated impacts for the SNF QRP are based on analysis discussed in section VI. of this proposed rule. In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2 percentage points the annual payment update applicable to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year.

As discussed in section VI.C.3. of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category and modify the Transportation item collected as a standardized patient assessment data element under the SDOH category beginning with admission assessments completed on October 1, 2025. Although the proposed increase in burden will be accounted for in a revised information collection request under OMB control number (0938–1140), we are providing impact information. With 1,966,662 admissions to and 754,287 planned discharges from 15,393 SNFs annually, we estimate an annual burden increase of 35,561.81 hours [(1,966,662 admissions × 0.02 hour) minus (754,287 planned discharges × 0.005 hour)] and an increase of $2,322,541.48 (35,561.81 hours × $65.31/hr). For each SNF, we estimate an annual burden increase of 2.31 hours (35,561.81 hours/15,393 SNFs) at an additional cost of $150.88 ($2,322,541.48 total burden/15,393 SNFs).

As discussed in in section VI.E.3. of this proposed rule, we are also proposing to require SNFs to participate in a validation process that would apply to data submitted using the MDS and SNF Medicare fee-for-service claims as a SNF QRP requirement. Specifically, we are proposing to adopt a similar validation process for the SNF QRP that we have adopted for the SNF VBP beginning with the FY 2027 SNF QRP. This proposal is in accordance with section 111(a)(4) of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) which requires that the measures and data submitted under the SNF QRP Program (section 1888(e)(6) of the Act) be subject to a validation process.

In section VI.E.3(a). of this proposed rule, we propose to require SNFs to participate in a validation process for assessment-based measures beginning with the FY 2027 SNF QRP. We are proposing that our validation contractor would select, on an annual basis, up to 1,500 SNFs and request that each SNF selected for the validation process submit up to 10 medical records. Although the proposed increase in burden will be accounted for in a new information collection request, we are providing impact information. We estimate the burden per selected SNF could range from 3 hours up to 7.5 hours for SNFs utilizing electronic health records and 5 hours up to 12.5 hours for SNFs who do not utilize electronic health records.

We also anticipate that a sample of 10 medical records would consist of SNF stays that vary in length of stay. We estimate the length of stay for each of the selected medical records could range from 1 day up to or exceeding 366 days. We also estimate that approximately 85 percent of nursing homes utilize some form of electronic health records (EHR),[75] and would not incur the costs of printing and shipping records. However, selected SNFs who do not utilize EHRs may incur printing and shipping costs if they are unable to submit the records via an electronic portal, and we estimate the cost to print and ship a sample of up to 10 records would range between $842.67 up to $4,114.35. Therefore, depending on the length of stay of the sample and whether the selected SNF uses an EHR, we estimate the total cost to submit medical records would range between $335,699.85 and $477,368.10 for all 1,500 selected SNFs and $263.29 [$335,699.85/(1,500 × 0.85 SNFs)] and $2,121.64 [$477,368.10/(1,500 × 0.15 SNFs)] per selected SNF. On average, we estimate the total cost would be increased by $813,067.95 for all 1,500 selected SNFs [[($263.29 × (1,500 × 0.85)] plus [$2,121.64 × (1,500 × 0.15)]] and $542.05 per selected SNF ($813,067.95/1,500 SNFs) annually.

In section VI.E.3(b). of this proposed rule, we propose to require SNFs to participate in a validation process for Medicare fee-for-service claims-based measures beginning with the FY 2027 SNF QRP. All Medicare fee-for-service claims-based measures are already reported to the Medicare program for payment purposes, and therefore there is no additional burden for providers.

We invite public comments on the overall impact of the SNF QRP proposals for FY 2027 displayed in Table 39.

TABLE 39—ESTIMATED IMPACTS FOR THE FY 2027 SNF QRP

Estimated burden for the FY2027 SNF QRP	Per SNF		All SNFs	
	Estimated change in annual burden hours	Estimated change in annual cost	Estimated change in annual burden hours	Estimated change in annual cost
Estimated Change in Burden associated with Proposal to Collect Four New SDOH Assessment Items and Modify One SDOH Assessment Item beginning with the FY 2027 SNF QRP	+2.31	+$150.88	+35,561.81	+$2,322,541.48
	Per Selected SNF		All Selected SNFs	
Estimated Change in Burden associated with Proposal to Adopt a Validation Process for SNFs Participating in the SNF QRP beginning with the FY 2027 SNF QRP	+5.12	+$542.05	+7,680	+$813,067.95

6. Impacts for the Minimum Data Set Beginning October 1, 2025

As discussed in section IX.A.3. of this proposed rule, we are removing MDS items that are not needed for case-mix adjusting the SNF per diem payment for PDPM but were not accounted for in the FY 2019 SNF PPS final rule (83 FR 39165 through 39265). We are providing impact information here and in Table 40. With 1,966,662 admissions to 15,393 SNFs annually, we estimate an annual burden decrease of 216,332.82 hours (1,966,662 admissions × 0.11 hour) and a decrease of $14,128,696.47 (216,332.82 hours × $65.31/hr). For each SNF, we estimate an annual burden decrease of 14.05 hours (216,332.82 hours/15,393 SNFs) for a reduction in cost of $917.87 ($14,128,696.47 total burden/15,393 SNFs).

[75] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6591108/#:~:text=In%20a%20nationwide%20sample%2C%20we,EHR%20adoption%20by%20nursing%20facilities.*

TABLE 40—ESTIMATED IMPACTS FOR THE PROPOSED CHANGES TO THE MDS DATA SET COLLECTION AND SUBMISSION BEGINNING OCTOBER 1, 2025

Estimated change in burden for the MDS removal of assessment items	Per SNF		All SNFs	
	Estimated change in annual burden hours	Estimated change in annual cost	Estimated change in annual burden hours	Estimated change in annual cost
Estimated Change in Burden associated with Removal of MDS items O0400A, O0400B, O0400C, and O0400E effective October 1, 2025	−14.05	−$917.87	−216,332.82	−$14,128,696.47

7. Impacts for the SNF VBP Program

The estimated impacts of the FY 2025 SNF VBP Program are based on historical data and appear in Table 41. We modeled SNF performance in the Program using SNFRM data from FY 2019 as the baseline period and FY 2023 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621).

For the FY 2025 program year, we will reduce each SNFs adjusted Federal per diem rate by 2 percent. We will then redistribute 60 percent of that 2 percent withhold to SNFs based on their measure performance. Additionally, in the FY 2023 SNF PPS final rule (87 FR 47585 through 47587), we finalized a case minimum requirement for the SNFRM, as required by section 1888(h)(1)(C)(ii) of the Act. As a result of these provisions, SNFs that do not meet the case minimum specified for the SNFRM for the FY 2025 program year will be excluded from the Program and will receive their full Federal per diem rate for that fiscal year. As previously finalized, this policy will maintain the overall payback percentage at 60 percent for the FY 2025 program year. Based on the 60 percent payback percentage, we estimated that we would redistribute approximately $281.53 million (of the estimated $469.22 million in withheld funds) in value-based incentive payments to SNFs in FY 2025, which means that the SNF VBP Program is estimated to result in approximately $187.69 million in savings to the Medicare Program in FY 2025.

Our detailed analysis of the impacts of the FY 2025 SNF VBP Program is shown in Table 41.

TABLE 41—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2025

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean performance score	Mean incentive payment multiplier	Percent of total payment
Group:					
Total*	10,858	20.21	31.8725	0.99154	100.00
Urban	8,509	20.32	30.4525	0.99093	86.41
Rural	2,349	19.81	37.0163	0.99375	13.59
Hospital-based urban**	181	19.64	41.4823	0.99545	1.51
Freestanding urban**	8,319	20.33	30.1971	0.99082	84.88
Hospital-based rural**	71	19.36	43.5091	0.99626	0.27
Freestanding rural**	2,223	19.81	36.9289	0.99374	13.19
Urban by region:					
New England	610	20.31	30.3760	0.99108	5.59
Middle Atlantic	1,259	20.03	34.4195	0.99264	19.04
South Atlantic	1,662	20.58	27.9590	0.99001	16.85
East North Central	1,543	20.63	25.7922	0.98890	11.47
East South Central	448	20.33	30.6263	0.99112	3.26
West North Central	573	19.86	36.0210	0.99327	3.82
West South Central	894	20.92	21.0260	0.98683	6.72
Mountain	385	19.62	40.0497	0.99492	3.70
Pacific	1,135	19.80	37.3699	0.99366	15.96
Outlying	0	.....	.....	.....	.....
Rural by region:					
New England	69	18.64	56.1674	1.00285	0.52
Middle Atlantic	159	19.23	46.9484	0.99845	1.06
South Atlantic	340	20.32	29.8026	0.99065	2.01
East North Central	566	19.66	38.5666	0.99422	3.29
East South Central	371	19.98	34.4449	0.99282	2.06
West North Central	345	19.67	37.5009	0.99383	1.52
West South Central	332	20.65	24.5102	0.98828	1.84
Mountain	97	18.88	51.9212	1.00002	0.57
Pacific	69	17.94	68.9668	1.00744	0.72
Outlying	1	22.54	0.0000	0.98025	0.00
Ownership:					
Government	432	19.95	33.9489	0.99235	2.86
Profit	8,065	20.31	30.2597	0.99085	78.39

TABLE 41—ESTIMATED SNF VBP PROGRAM IMPACTS FOR FY 2025—Continued

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean performance score	Mean incentive payment multiplier	Percent of total payment
Non-Profit	2,361	19.88	37.0019	0.99376	18.74

* The total group category excludes 3,842 SNFs that did not meet the finalized measure minimum policy. The total group category includes 19 SNFs that did not have historical payment data used for this analysis.

** The group category which includes hospital-based/freestanding by urban/rural excludes 64 swing bed SNFs that satisfied the current measure minimum policy.

In the FY 2024 SNF PPS final rule (88 FR 53324 through 53325), we adopted a validation process that applies to SNF VBP measures calculated using MDS data beginning with the FY 2027 program year. Specifically, we finalized that, on an annual basis, the validation contractor will randomly select up to 1,500 SNFs for validation and that for each SNF selected, the validation contractor will request up to 10 medical records. This new medical record submission requirement for the purposes of SNF VBP MDS validation would result in new burden on SNFs for the FY 2027 program year. We refer readers to the SNF QRP section at XI.A.5. of this proposed rule for details on the estimated annual burden increase that would result from this new chart submission requirement. We are not including additional details on burden in this section, to avoid double counting burden with the SNF QRP since the same charts will be utilized for both the SNF QRP and SNF VBP Program. We also note that this burden would be accounted for in the information collection request that is being developed and will be submitted to OMB for approval.

8. Impacts for Nursing Home Enforcement Revisions

A nursing home certified to participate in the Medicare and Medicaid programs as a SNF and NF is expected to be in compliance with Federal requirements as a condition of receiving payment for services provided to beneficiaries. If a facility is determined to be out of compliance and an enforcement decision is reached to impose a CMP, the proposed regulatory revisions would take effect.

We view the anticipated results of this rule as beneficial to nursing home residents. Specifically, we believe that additional flexibility to impose CMPs will allow us to better tailor the response to facility noncompliance in a way that assures that appropriate resident care occurs as well as lasting facility compliance is achieved. We also recognize that not all of the potential effects of this rule can be anticipated. It is difficult to quantify the full future effect of this rule on facilities' compliance activities or costs. If a facility is in substantial compliance, there is no basis to use any enforcement remedy. However, should a remedy be indicated, several alternative remedies may be considered in addition to a CMP. Since CMP amounts, once selected as an appropriate enforcement response, are based on when noncompliance occurred and the level of noncompliance, we are unable to predict the number or amount of CMPs that will be imposed. However, we do expect that the total amount of CMPs imposed would increase as a result of these proposals.

In 2022, the number of facilities that had CMPs imposed was 6,113 (41 percent). The average total amount of the CMPs imposed for each facility in 2022 was $17,775. The total dollar amount of PD CMPs imposed on facilities in 2022 was $186.4 million and the total dollar amount of PI CMPs was $40.6 million. Additionally, 45 percent of surveys in 2022 that had multiple findings of harm and were imposed a PI CMP as the remedy of choice only received one PI CMP. Under the proposed revisions, we anticipate an increased workload to CMS and States, and increased CMP amounts to providers when multiple instances of noncompliance resulting in harm or immediate jeopardy (IJ) are cited.

We calculated the additional costs for providers, CMS, and states by analyzing the number of surveys in CY2022 that would have had additional PI CMPs imposed by identifying surveys with multiple citations of noncompliance resulting in harm or immediate jeopardy (IJ), but only one PI CMP was imposed, or a PD CMP was imposed. We then multiplied the number of these surveys by the average number of citations resulting in harm or IJ, and by the average PI CMP amount. This calculation resulted in a total of approximately $25 million for all nursing homes for CY2022. We estimate this will result in a total increased cost to CMS and the States of $163,800 per year.

9. Alternatives Considered

As described in this section, we estimate that the aggregate impact of the provisions in this proposed rule will result in an increase of approximately $1.3 billion (4.1 percent) in Part A payments to SNFs in FY 2025. This reflects a $1.3 billion (4.1 percent) increase from the update to the payment rates.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket update, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

With regard to the proposal to adopt four new items as standardized patient assessment data elements under the SDOH category and modify the Transportation standardized patient assessment data element in the SDOH category beginning with the FY 2027 SNF QRP, we believe these proposals advance the CMS National Quality Strategy Goals of equity and engagement. We considered the alternative of delaying the proposal to collect these items but given the fact they would encourage meaningful

collaboration between healthcare providers, residents, caregivers, and community-based organizations to address SDOH prior to discharge from the SNF, we believe further delay is unwarranted.

With regard to the proposal to remove 22 items from the MDS beginning October 1, 2025, we routinely review the MDS for opportunities to simplify data submission requirements. We have identified that these items are no longer used in the calculation of the SNF per diem payment for PDPM but were not accounted for in the FY 2019 SNF PPS final rule (83 FR 39165 through 39265), and therefore no alternatives were considered.

With regard to the proposal to require SNFs participating in the SNF QRP to participate in a validation process beginning with the FY 2027 SNF QRP, we are required to implement a process to satisfy Section 1888(h)(12) of the Act (as added by Division CC, section 111(a)(4) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–120)). Because the validation process is statutorily required, no alternatives were considered.

With regard to the proposals for the SNF VBP Program, we discussed alternatives considered within those sections. In section VII.E.3. of the proposed rule, we discussed other approaches to incorporating health equity into the Program.

10. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 42 through 46, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule for FY 2025. Tables 38 and 42 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this proposed rule, based on the data for 15,503 SNFs in our database. Tables 39, 43, and 44 provide our best estimate of the additional cost to SNFs to submit the data for the SNF QRP as a result of the policies in this proposed rule. Table 45 provides our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies for this program. Table 46 provides our best estimate of the Nursing Home Enforcement provisions.

TABLE 42—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2024 SNF PPS FISCAL YEAR TO THE 2025 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$1.3 billion.
From Whom To Whom?	Federal Government to SNF Medicare Providers.

TABLE 43—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE PROPOSED CHANGES TO THE FY 2027 QRP PROGRAM

Category	Transfers/costs
Estimated Costs to SNFs for Proposed Changes to the FY 2027 QRP Program and to Selected SNFs for the Validation Process*	$3,135,609.43
Estimated Costs to SNFs for Proposed Changes to the FY 2027 QRP Program Who Are Not Selected for the Validation Process	2,322,541.48

* Up to 1,500 SNFs would be selected for the Validation Process.

TABLE 44—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED SAVINGS FOR THE REMOVAL OF MDS ITEMS NO LONGER NEEDED FOR CASE-MIX ADJUSTING THE PER DIEM SNF PAYMENT BEGINNING OCTOBER 1, 2025

Category	Transfers/costs
Savings to SNFs for Removing MDS Items	($14,128,696.47)

TABLE 45—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2025 SNF VBP PROGRAM

Annualized Monetized Transfers	$281.53 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

* This estimate does not include the 2 percent reduction to SNFs' Medicare payments (estimated to be $469.22 million) required by statute.

TABLE 46—ACCOUNTING STATEMENT: NURSING HOME ENFORCEMENT PROPOSALS

Category	Transfers/penalties
Estimated Increased Amount of Penalties	$25 million.*
From Whom To Whom?	SNF Medicare Providers to Federal Government.
Estimated additional cost to CMS and State Survey Agencies	$163,800.

* This estimate includes the estimated increase in the amount of PI CMPs that may be imposed under these proposed revisions.

11. Conclusion

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2024 (88 FR 53200). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2025 are projected to increase by approximately $1.3 billion, or 4.1 percent, compared with those in FY 2024. We estimate that in FY 2025, SNFs in urban and rural areas would experience, on average, a 4.0 percent increase and 4.9 percent increase, respectively, in estimated payments compared with FY 2024. Providers in the rural Middle Atlantic region would experience the largest estimated increase in payments of approximately 7.5 percent. Providers in the urban Outlying region would experience the smallest estimated increase in payments of 1.7 percent.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $30 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $34 million or less in any 1 year. (For details, see the Small Business Administration's website at *https://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2024 (88 FR 53200). Based on the above, we estimate that the aggregate impact for FY 2025 will be an increase of $1.3 billion in payments to SNFs, resulting from the SNF market basket update to the payment rates. While it is projected in Table 38 that all providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2025 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2023 Report to Congress (available at *https://www.medpac.gov/wp-content/uploads/2023/03/Ch7_Mar23_MedPAC_Report_To_Congress_SEC.pdf*), MedPAC states that Medicare covers approximately 10 percent of total patient days in freestanding facilities and 16 percent of facility revenue (March 2023 MedPAC Report to Congress, 207). As indicated in Table 38, the effect on facilities is projected to be an aggregate positive impact of 4.1 percent for FY 2025. As the overall impact on the industry as a whole, and thus on small entities specifically, meets the 3 to 5 percent threshold discussed previously, the Secretary has determined that this proposed rule will have a significant impact on a substantial number of small entities for FY 2025.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This proposed rule will affect small rural hospitals that: (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2024 (88 FR 53200)), the category of small rural hospitals is included within the analysis of the impact of this proposed rule on small entities in general. As indicated in Table 38, the effect on facilities for FY 2025 is projected to be an aggregate positive impact of 4.1 percent. As the overall impact on the industry as a whole meets the 3 to 5 percent threshold discussed above, the Secretary has determined that this proposed rule will have a significant impact on a substantial number of small rural hospitals for FY 2025.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This proposed rule will impose no mandates on State, local, or Tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule will have no substantial direct effect on State and local governments, preempt State law, or otherwise have federalism implications.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we believe that the number of commenters on this year's proposed rule is a fair estimate of the number of reviewers of last year's proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

The mean wage rate for medical and health service manages (SOC 11–9111) in BLS OEWS is $61.53, assuming benefits plus other overhead costs equal 100 percent of wage rate, we estimate that the cost of reviewing this rule is $123.06 per hour, including overhead

and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $492.24 (4 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $39,871.44 ($460.88 × 81 reviewers).

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 25, 2024.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.337 is amended by revising paragraph (f) to read as follows:

§ 413.337 Methodology for calculating the prospective payment rates.

* * * * *

(f) *Adjustments to payment rates under the SNF Value-Based Purchasing Program.*

Beginning with payment for services furnished on October 1, 2018, the adjusted Federal per diem rate (as defined in § 413.338(a)) otherwise applicable to a SNF for the fiscal year is reduced by the applicable percent (as defined in § 413.338(a)). The resulting amount is then adjusted by the value-based incentive payment amount (as defined in § 413.338(a)) based on the SNF performance score calculated for the SNF for that fiscal year under § 413.338 of this part.

■ 3. Section 413.338 is amended—

■ a. In paragraph (a) by—

■ i. Revising the definitions of ''Health equity adjustment (HEA) bonus points'' and ''Measure performance scaler'';

■ ii. Removing the definition of ''Performance score'';

■ iii. Adding the definition of ''SNF performance score'';

■ iv. Revising the definitions of ''SNF readmission measure'', ''Top tier performing SNF'', and ''Underserved multiplier'';

■ b. Removing paragraphs (d)(4) through (6);

■ c. Redesignating paragraphs (f)(1) through (4) as paragraphs (f)(2) through (5);

■ d. Adding a new paragraph (f)(1) and revising paragraphs newly redesignated paragraphs (f)(2) and (3);

■ e. Revising paragraph (j)(3);

■ f. By adding paragraphs (l), (m), and (n).

The revisions and additions read as follows:

§ 413.338 Skilled nursing facility value-based purchasing program.

(a) * * *

* * * * *

Health equity adjustment (HEA) bonus points means the points that a SNF can earn for a fiscal year based on its performance and proportion of SNF residents who are members of the underserved population.

* * * * *

Measure performance scaler means, for a fiscal year, the sum of the points assigned to a SNF for each measure on which the SNF is a top tier performing SNF.

* * * * *

SNF readmission measure means, prior to October 1, 2027, the SNF 30-Day All-Cause Readmission Measure (SNFRM) specified under section 1888(g)(1) of the Social Security Act. Beginning October 1, 2027, the term SNF readmission measure means the SNF Within-Stay Potentially Preventable Readmission (SNF WS PPR) Measure specified under section 1888(g)(2) of the Social Security Act.

* * * * *

Top tier performing SNF means a SNF whose performance on a measure during the applicable fiscal year meets or exceeds the 66.67th percentile of SNF performance on the measure during the same fiscal year.

Underserved multiplier means the mathematical result of applying a logistic function to the number of SNF residents who are members of the underserved population out of the SNF's total Medicare population, as identified from the SNF's Part A claims, during the performance period that applies to the 1-year measures for the applicable fiscal year.

* * * * *

(f) * * *

(1) CMS will provide quarterly confidential feedback reports to SNFs on their performance on each measure specified for the fiscal year. Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, CMS calculates the measure rates included in those reports using data that are current as of a specified date as follows:

(i) For the SNFRM, the specified date is 3 months after the last index SNF admission in the applicable baseline period or performance period.

(ii) For the Skilled Nursing Facility Healthcare Associated Infections Requiring Hospitalization (''SNF HAI''), Discharge to Community—Post-Acute Care Measure for Skilled Nursing Facilities (''DTC PAC SNF''), and Skilled Nursing Facility Within-Stay Potentially Preventable Readmissions (''SNF WS PPR'') measure, the specified date is 3 months after the last SNF discharge in the applicable baseline period or performance period.

(iii) For the Number of Hospitalizations per 1,000 Long Stay Residents (''Long Stay Hospitalization'') measure, the specified date is 3 months after the last day of the final quarter of the applicable baseline period or performance period.

(iv) For the Total Nursing Hours per Resident Day Staffing (''Total Nurse Staffing'') measure and the Total Nursing Staff Turnover (''Nursing Staff Turnover'') measure, the specified date is 45 days after the last day of each quarter of the applicable baseline period or performance period.

(v) For the Discharge Function Score for SNFs (''DC Function measure'') and Percent of Residents Experiencing One of More Falls with Major Injury (Long Stay) (''Falls with Major Injury (Long Stay)'') measure, the specified date is the February 15th that is approximately 4.5 months after the last day of the applicable baseline period or performance period.

(2) Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, which contain the

baseline period and performance period measure rates, respectively, SNFs will have 30 days following the date CMS provides each of these reports to review and submit corrections to the calculation of the measure rates contained in that report. The data used to calculate measure rates are not subject to review and correction under this paragraph. Any such correction requests must include:

(i) The SNF's CMS Certification Number (CCN),

(ii) The SNF's name,

(iii) The correction requested, and

(iv) The reason for requesting the correction, including any available evidence to support the request.

(3) Beginning not later than 60 days prior to each fiscal year, CMS will provide reports to SNFs on their performance under the SNF VBP Program for a fiscal year. SNFs will have the opportunity to review and submit corrections to their SNF performance scores and ranking contained in these reports for 30 days following the date that CMS provides the reports. Any such correction requests must include:

(i) The SNF's CMS Certification Number (CCN),

(ii) The SNF's name,

(iii) The correction requested, and

(iv) The reason for requesting the correction, including any available evidence to support the request.

* * * * *

(j) * * *

(3) Beginning with the FY 2027 program year, for all measures that are calculated using Minimum Data Set (MDS) information, CMS will validate the accuracy of this information. CMS will request medical records as follows:

(i) On an annual basis, a CMS contractor will randomly select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if the SNF submitted at least one MDS record in the calendar year that is 3 years prior to the applicable fiscal year or was included in the SNF VBP Program in the year prior to the applicable fiscal year.

(ii) For each SNF selected under paragraph (j)(3)(i) of this section, the CMS contractor will request in writing up to 10 medical records.

(iii) A SNF that receives a request for medical records under paragraph (j)(3)(ii) of this section must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request as documented on the request.

* * * * *

(l) *Measure Selection, Retention,* and *Removal Policy.* (1) The SNF VBP measure set for each fiscal year includes the SNF readmission measure CMS has specified under section 1888(g) of the Social Security Act for application in the SNF VBP Program.

(2) Beginning with FY 2026, the SNF VBP measure set for each fiscal year may include up to nine additional measures specified by CMS. Each of these measures remains in the measure set unless CMS removes or replaces it based on one or more of the following factors:

(i) SNF performance on the measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

(ii) Performance or improvement on a measure do not result in better resident outcomes.

(iii) A measure no longer aligns with current clinical guidelines or practices.

(iv) A more broadly applicable measure for the particular topic is available.

(v) A measure that is more proximal in time to the desired resident outcomes for the particular topic is available.

(vi) A measure that is more strongly associated with the desired resident outcomes for the particular topic is available.

(vii) The collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the Program.

(3) Upon a determination by CMS that the continued requirement for SNFs to submit data on a measure specified under paragraph (l)(2) of this section raises specific resident safety concerns, CMS may elect to immediately remove the measure from the SNF VBP Program. Upon removal of the measure, CMS will provide notice to SNFs and the public, along with a statement of the specific patient safety concern that would be raised if SNFs continued to submit data on the measure. CMS will also provide notice of the removal in the **Federal Register**.

(4) CMS uses rulemaking to make substantive updates to the specifications of measures used in the SNF VBP Program. CMS makes technical measure specification updates in a sub-regulatory manner and informs SNFs of measure specification updates through postings on the CMS website, listservs, and other educational outreach efforts to SNFs.

(m) *Extraordinary Circumstances Exception Policy* (1) A SNF may request and CMS may grant exceptions to the SNF Value-Based Purchasing Program's requirements under this section for one or more calendar months when there are certain extraordinary circumstances beyond the control of the SNF.

(2) A SNF may request an exception within 90 days of the date that the extraordinary circumstances occurred. Prior to FY 2025, the request must be submitted in the form and manner specified by CMS on the SNF VBP website at *https://www.cms.gov/Medicare/Quality/Nursing-Home-Improvement/Value-Based-Purchasing/Extraordinary-Circumstance-Exception* and include a completed Extraordinary Circumstances Request form (available on *https://qualitynet.cms.gov/*) and any available evidence of the impact of the extraordinary circumstances on the care that the SNF furnished to patients including, but not limited to, photographs and media articles. Beginning with FY 2025, a SNF may request an extraordinary circumstances exception by sending an email with the subject line ''SNF VBP Extraordinary Circumstances Exception Request'' to the SNF VBP Program Help Desk with the following information:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's business name and business address;

(iii) Contact information for the SNF's CEO or CEO-designated personnel, including all applicable names, email addresses, telephone numbers, and the SNF's physical mailing address (which cannot be a PO Box);

(iv) A description of the event, including the dates and duration of the extraordinary circumstance;

(v) Available evidence of the impact of the extraordinary circumstance on the care the

SNF provided to its residents or the SNF's ability to report SNF VBP data, including, but not limited to, photographs, media articles, and any other materials that would aid CMS in determining whether to grant the exception;

(vi) A date proposed by the SNF for when it will again be able to fully comply with the SNF VBP Program's requirements and a justification for the proposed date.

(3) Except as provided in paragraph (m)(4) of this section, CMS will not consider an exception request unless the SNF requesting such exception has complied fully with the requirements in paragraph (m)(2) of this section.

(4) CMS may grant exceptions to SNFs without a request if it determines that an extraordinary circumstance affected an entire region or locale.

(5) CMS will calculate a SNF performance score for a fiscal year for a SNF for which it has granted an exception request that does not include

its performance on a quality measure during the calendar months affected by the extraordinary circumstance.

(n) *SNF VBP Performance Standards.* (1) CMS announces the performance standards for each measure no later than 60 days prior to the start of the performance period that applies to the measure for the fiscal year.

(2) Beginning with FY 2021, if CMS discovers an error in the performance standard calculations subsequent to publishing their numerical values for a fiscal year, CMS will update the numerical values to correct the error. If CMS subsequently discovers one or more other errors with respect to the fiscal year, CMS will not further update the numerical values for that fiscal year.

(3) Beginning with FY 2025, CMS may update the numerical values of the performance standards for a measure if CMS incorporates non-substantive technical updates made to the measure between the time that CMS first announces the performance standards for the measure for a fiscal year and the time that CMS calculates SNF performance on the measure at the conclusion of the performance period for that measure for a fiscal year.

■ 4. Section 413.360 is amend by—

■ a. Revising paragraph (f)(1) introductory text;

■ b. Adding paragraph (f)(1)(iv);

■ c. Revising paragraph (f)(3); and

■ d. Adding paragraph (g).

The additions and revision read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

* * * * *

(f) * * *

(1) SNFs must meet or exceed the following data completeness thresholds with respect to a program year:

* * * * *

(iv) If selected for the data validation process under paragraph (g), the threshold set at 100 percent submission of medical charts.

* * * * *

(3) A SNF must meet or exceed each applicable threshold described in paragraph (f)(1) of this section to avoid receiving the applicable penalty for failure to report quality data set forth in § 413.337(d)(4) of this Part.

(g) *Data Validation Process.* (1) Beginning with the FY 2027 payment year: for all measures that are calculated using Minimum Data Set (MDS) information, CMS will validate the accuracy of this information. The process by which CMS will request medical records and by which SNFs must submit the requested medical records is as follows:

(i) On an annual basis, a CMS contractor will select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if it submitted at least one MDS record to CMS in the calendar year 3 years prior to the applicable program year, and if the SNF has been randomly selected for a periodic audit for the same year under § 413.338 of this part.

(ii) For each SNF selected under paragraph (g)(1) of this section, the CMS contractor will request up to 10 medical records. Each SNF selected will only be required to submit records once in a fiscal year, for a maximum of 10 records for each SNF selected. Each requested medical record must be the same medical record that has been requested for submission by the SNF for the same year under § 413.338 of this part. CMS will submit its request in writing to the selected SNF.

(iii) A SNF that receives a request for medical records under paragraph (g)(2) of this section must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request.

(2) Beginning with the FY 2027 payment year: the information reported through claims for all claims-based measures are validated for accuracy by Medicare Administrative Contractors (MACs).

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 5. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 6. Section 488.401 is amended by adding the definition of ''Instance or instances of noncompliance'' in alphabetical order to read as follows:

§ 488.401 Definitions.

* * * * *

Instance or instances of noncompliance means a factual and temporal occurrence(s) when a facility is not in substantial compliance with the requirements for participation. Each instance of noncompliance is sufficient to constitute a deficiency and a deficiency may comprise of multiple instances of noncompliance.

* * * * *

■ 7. Section 488.408 is amended by revising paragraph (e)(2)(ii) to read as follows:

§ 488.408 Selection of remedies.

* * * * *

(e) * * *

(2) * * *

(ii) For each instance of noncompliance, CMS and the State may impose a civil money penalty of $3,050-$10,000 (as adjusted annually under 45 CFR part 102) per day, $1,000-$10,000 (as adjusted annually under 45 CFR part 102) per instance of noncompliance, or both, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section. For multiple instances of noncompliance, CMS may impose any combination of per instance or per day civil money penalties for each instance within the same survey. The aggregate civil money penalty amount may not exceed $10,000 (as adjusted annually under 45 CFR part 102) for each day of noncompliance.

* * * * *

■ 8. Revise § 488.430 to read as follows:

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) CMS or the State may impose a civil money penalty for the number of days a facility is not in substantial compliance with one or more participation requirements or for each instance that a facility is not in substantial compliance, or both, regardless of whether or not the deficiencies constitute immediate jeopardy. When a survey contains multiple instances of noncompliance, CMS or the State may impose any combination of per instance or per day civil money penalties for each instance of noncompliance within the same survey.

(b) CMS or the State may impose a civil money penalty for the number of days of past noncompliance, including the number of days of immediate jeopardy, since the last three standard surveys.

■ 9. Section 488.434 is amended by revising paragraphs (a)(2)(iii) and (v) to read as follows:

§ 488.434 Civil money penalties: Notice of penalty.

(a) * * *

(2) * * *

(iii) Either the amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance or both;

* * * * *

(v) The date(s) of the instance(s) of noncompliance or the date on which the penalty begins to accrue;

* * * * *

■ 10. Section 488.440 is amended by revising paragraph (a)(2) to read as follows:

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a) * * *

(2) A civil money penalty for each instance of noncompliance is imposed in a specific amount per instance.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–06812 Filed 3–28–24; 4:15 pm]

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