Estimated Annual Respondent Burden

Hospitals administer the AHRQ Hospital Survey on Patient Safety Culture every 20 months on average. Therefore, the number of hospital submissions to the database varies because hospitals do not submit data every year. Data submission is typically handled by one point-of-contact (POC) who is either a hospital patient safety manager or a survey vendor. The POC completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form. The POCs typically submit data on behalf of 3 hospitals, on average, because many hospitals are part of a multi-hospital system that is submitting data, or the POC is a vendor that is submitting data for multiple hospitals. Exhibits 1 and 2 are based on an estimated 304 individual POCs who will complete the database submission steps and forms in the coming years, not based on the number of ''hospitals.'' The Hospital Information Form is completed by all POCs for each of their hospitals. The total annual burden hours are estimated to be 1,793.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $91,297 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form and Data Submission*	304	1	5.6	1,702
Data Use Agreement	304	1	3/60	15
Hospital Information Form	304	3	5/60	76
Total	912	NA	NA	1,793

*The Eligibility and Registration Form requires 3 minutes to complete; however about 5.5 hours is required to prepare/plan for the data submission. This includes the amount of time POCs and other hospital staff (CEO, lawyer, database administrator) typically spend deciding whether to participate in the database and preparing their materials and data set for submission to the database, and performing the submission.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Form and Data Submission	304	1,702	50.95	86,717
Data Use Agreement	304	15	50.33	755
Hospital Information Form	304	76	50.33	3,825
Total	912	1,793	NA	91,297

*Wage rates were calculated using the mean hourly wage based on occupational employment and wage estimates from the Dept of Labor, Bureau of Labor Statistics' May 2012 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at *http://www.bls.gov/oes/current/naics3_622000.htm.* Wage rate of $50.33 is based on the mean hourly wages for Medical and Health Services Managers (11–9111). Wage rate of $50.95 is the weighted mean hourly wage for: Medical and Health Services Managers (11–9111;$50.33 × 2.6 hours = $130.86), Lawyers (23–1011; $72.71 × 0.5 hours = $36.36), Chief Executives (11–1011($95.36 × 0.5 hours = $47.68), and Database Administrators (15–1141; $35.20 × 2 hours = $70.40) [Weighted mean = ($130.86 + 36.36 + 47.68 + 70.40)/5.6 hours = $285.30/5.6 hours = $50.95/hour].

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 23, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–18366 Filed 7–30–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6048–N]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Temporary Moratoria on Enrollment of Ambulances Suppliers and Providers and Home Health Agencies in Designated Geographic Areas

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the imposition of a temporary moratorium on the enrollment of home health agencies in Miami-Dade and Cook counties as well as selected surrounding

areas, and on the enrollment of new ambulance suppliers and providers in Harris County and surrounding counties to prevent and combat fraud, waste, and abuse.

DATES: *Effective Date:* July 30, 2013.

FOR FURTHER INFORMATION CONTACT: August Nemec, (410) 786–0612.

News media representatives must contact our Public Affairs Office at (202) 690–6145 or email them at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Authority To Impose Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act), the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new fee-for-service (FFS) Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the state later determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all of the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In the February 2, 2011 **Federal Register** (76 FR 5862), CMS published a final rule with comment period titled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,'' which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services Office of Inspector General (HHS–OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type or particular geographic areas or both. At § 424.570(a)(1)(ii), CMS stated that it would announce a temporary moratorium in a **Federal Register** notice that includes the rationale for the imposition of the temporary enrollment moratorium. The rationale will include the factors for imposing a moratorium on a case by case basis. This notice fulfills that requirement.

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. However, a provider or supplier may use the existing appeal procedures at 42 CFR Part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium, though the scope of any such appeal would be limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied as a result of the imposition of a temporary moratorium (§ 424.514(d)(2)(v)(C)).

B. Determination of the Need for a Moratorium

In imposing these enrollment moratoria, CMS considered both qualitative and quantitative factors suggesting a high risk of fraud, waste, or abuse. CMS relied on its and law enforcement's longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and administrative investigations and prosecutions. Our determination of high risk areas of fraud in these provider and supplier types and geographic areas was then confirmed by our data analysis, which relied on factors CMS identified as strong indicators of fraud risk.

Because fraud schemes are highly migratory and transitory in nature, many of our program integrity authorities and anti-fraud activities are designed to allow the agency to adapt to emerging fraud in different areas. The laws and regulations governing our moratoria authority give us flexibility to use any and all relevant criteria for future moratoria and CMS retains the authority to impose any future moratorium on a case-by-case basis.

1. Application to Medicaid and the Children's Health Insurance Program (CHIP)

The February 2, 2011 final rule also implemented section 1902(kk)(4) of the Act, establishing new Medicaid regulations at § 455.470. Under § 455.470(a)(1) through (3), the Secretary [1] may impose a temporary moratorium, in accordance with § 424.570, on the enrollment of new providers or provider types after consulting with any affected State Medicaid agencies. The State Medicaid agency will impose a temporary moratorium on the enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program unless the state later determines that the imposition of a moratorium would adversely affect Medicaid beneficiaries' access to medical assistance and so notifies the Secretary. The final rule also implemented section 2107(e)(1)(D) of the Act by providing, at § 457.990 of the regulations, that all of the provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act, as well as the implementing regulations, also apply to CHIP.

Section 1866(j)(7) of the Act authorizes imposition of a temporary enrollment moratorium for Medicare, Medicaid and/or CHIP, ''if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.'' While there may be exceptions, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. Many of the new anti-fraud provisions in the Affordable Care Act reflect this concept of ''reciprocal risk'' in which a provider that poses a risk to one program poses a risk to the other programs. For example, section 6501 of the Affordable Care Act titled, ''Termination of Provider Participation under Medicaid if Terminated Under Medicare or Other State Plan,'' which amends section 1902(a)(39) of the Act, requires State Medicaid agencies to terminate the participation of any individual or entity if such individual

[1] The Secretary has delegated to CMS authority to administer Titles XVIII, XIX, and XXI of the Act. For more information see the September 6, 1984 **Federal Register** (49 FR 35247) and the December 16, 1997 **Federal Register** (62 FR 65813).

or entity is terminated under Medicare or any other State Medicaid plan.[2] Additional provisions in title VI, Subtitles E and F of the Affordable Care Act also support the determination that categories of providers and suppliers pose the same risk to Medicaid as to Medicare. Section 6401(a) of the Affordable Care Act required us to establish levels of screening for categories of providers and suppliers based on the risk of fraud, waste and abuse determined by the Secretary. Section 6401(b) of the Affordable Care Act required State Medicaid agencies to screen providers and suppliers based on the same levels established for the Medicare program. This reciprocal concept is also reflected in the Medicare moratorium regulations at § 424.570(a)(2)(ii) and (iii), which permit CMS to impose a Medicare moratorium based solely on a state imposing a Medicaid moratorium. Therefore, CMS has determined that there is a reasonable basis for concluding that a category of providers or suppliers that poses a risk to Medicare also poses a similar risk to Medicaid and CHIP, and that a moratorium in all of these programs is necessary to effectively combat this risk.

2. Consultation With Law Enforcement

In consultation with the HHS–OIG and the Department of Justice (DOJ), CMS identified two provider and supplier types in three geographic areas that warrant temporary enrollment moratoria. CMS reached this determination based in part on the federal government's experience with the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a joint effort between DOJ and HHS to prevent fraud, waste and abuse in the Medicare and Medicaid programs. The Medicare Fraud Strike Force teams are a key component of HEAT and operate in nine cities nationwide.[3] Each Medicare Fraud Strike Force team combines the programmatic and administrative action capabilities of CMS, the analytic and investigative resources of the FBI and HHS–OIG, and the prosecutorial resources of DOJ's Criminal Division's Fraud Section and the United States Attorneys Offices. The Strike Force teams use advanced data analysis techniques to identify high billing levels in health care fraud hotspots so that interagency teams can target emerging or migrating schemes along with chronic fraud by criminals masquerading as health care providers or suppliers. The locations of the Strike Force teams are identified by analyzing where Medicare claims data reveal aberrant billing patterns and intelligence data analysis suggests that fraud may be occurring.

It is important to note that all of the moratoria target areas identified in this notice—Miami, Houston, and Chicago—are Strike Force cities, and each of these areas has experienced intense, sustained criminal prosecution activity with respect to the provider and supplier types subject to these moratoria. In addition, CMS's own administrative investigations and oversight have been equally intense in these areas. Through CMS's own anti-fraud activities, in addition to the federal government's coordinated HEAT efforts, CMS has determined that home health agencies in Miami and Chicago and the surrounding areas, and ambulance companies in Houston and the surrounding area pose a significant risk of fraudulent activity.

As a part of ongoing antifraud efforts, the HHS–OIG and CMS have learned that some fraud schemes are viral, meaning they replicate rapidly within communities, and that health care fraud also migrates—as law enforcement cracks down on a particular scheme, the criminals may redesign the scheme or relocate to a new geographic area.[4] As a result, CMS has determined that it is necessary to extend these moratoria beyond the target counties to bordering counties, unless otherwise noted, to prevent potentially fraudulent providers and suppliers from enrolling their practices in a neighboring county with the intent of providing services in a moratorium-targeted area. CMS will monitor the surrounding counties, as well as the entirety of each affected state, by reviewing claims utilization and activity, for indicia of activity designed to evade these moratoria. Throughout the duration of these moratoria, CMS will continue to consult with law enforcement, to assess and address the spread of any significant risk of fraud beyond the moratorium areas.

3. Data Analysis

The scope of the data analysis included reviewing Medicare and Medicaid enrollment and claims data. CMS identified all counties across the nation with 200,000 or more Medicare beneficiaries (''comparison counties''), and analyzed certain key metrics which we believe to be strong indications of potential fraud risk. These metrics included factors such as: the number of providers or suppliers per 10,000 Medicare FFS beneficiaries; the compounded annual growth rate in provider or supplier enrollments; and the ''churn rate''—the rate of providers entering and exiting the program—as measured by the percent of the target provider or supplier community continuously receiving Medicare payments since 2008. We know that when some providers and suppliers incur a substantial debt to Medicare, they then exit the Medicare program or shut down operations altogether, and attempt to re-enroll through another vehicle or under a new business identity. The moratoria are intended to curtail this churning of providers to new enrollments. CMS also reviewed the 2012 FFS Medicare payments to providers and suppliers in the target areas based on the average amount spent per beneficiary who used services furnished by the targeted provider and supplier types.

The three areas subject to the temporary enrollment moratoria are the only counties that contain Strike Force cities that also consistently ranked near the top for the aforementioned metrics among counties with at least 200,000 Medicare beneficiaries in 2012. This analysis helps confirm the federal government's previously described experience in its HEAT and Strike Force activities, and provides further support for CMS' determination that the moratoria are appropriate in these areas. See Tables 1 and 2 of this notice for a summary of the moratoria areas and some of the metrics examined.

4. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid and CHIP is of critical importance to CMS and our state partners, and CMS carefully evaluated access for the three target moratoria areas. To determine if the moratoria would create an access to care issue for Medicaid and CHIP beneficiaries in the targeted areas and surrounding counties, CMS consulted with the appropriate State Medicaid Agencies and State Departments of Emergency Medical Services. All of our state partners were supportive of our analysis and

[2] Although section 6501 of Affordable Care Act does not specifically state that individuals or entities that have been terminated under Medicare or Medicaid must also be terminated from CHIP, we have required CHIP, through federal regulation, to take similar action regarding termination of a provider that is also terminated or had its billing privileges revoked under Medicare or any State Medicaid plan.

[3] The Medicare Strike Force operates in Miami, FL; Los Angeles, CA: Detroit, MI; Houston, TX; Brooklyn, NY; Baton Rouge, LA; Tampa, FL; Chicago, IL; and Dallas, TX.

[4] Testimony of the Inspector General, ''Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges.'' See *http://www.hhs.gov/asl/testify/2011/03/t20110302i.html.*

proposals, and together with CMS, have determined that these moratoria will not create access of care issues for Medicaid or CHIP beneficiaries.

In order to determine if the moratoria would create an access to care issue for Medicare beneficiaries, CMS reviewed its own data regarding the number of providers and suppliers in the target and surrounding counties, and confirmed that there are no reports to CMS of access to care issues for these provider and supplier types. CMS also reviewed recent reports by the Medicare Payment Advisory Commission (MedPAC), an independent Congressional agency established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program. MedPAC has a Congressional mandate to monitor beneficiaries' access to care and publishes its review of Medicare expenditures annually. Based on our analysis of each target market and review of MedPAC's March 2013 report (finding no access issues to Medicare home health services [5]), and its June 2013 report (finding no access issues to Medicare ambulance services [6]), CMS does not believe these moratoria will cause an access to care issue for Medicare beneficiaries.

In the March report, MedPAC also recommended that CMS use its authorities under current law to examine providers with aberrant patterns of utilization for possible fraud and abuse. With regard to home health services, MedPAC stated that a moratorium on the enrollment of new HHAs would prevent new agencies from entering markets that may already be saturated.[7] CMS will continuously monitor for reductions in the number of HHA providers and Part B ambulance suppliers, as well as beneficiary complaints, and will continue consultation with the states, for any indication of a potential access to care issue.

5. When a Temporary Moratorium Does Not Apply

Under § 424.570(a)(1)(iii), a temporary moratorium does not apply to changes in practice locations, changes to provider or supplier information such as phone number, address, or changes in ownership (except changes in ownership of HHAs that require initial enrollments under § 424.550). Also, in accordance with § 424.570(a)(1)(iv), the moratorium does not apply to an enrollment application that a CMS contractor has already approved, but has not yet entered into the Provider Enrollment Chain and Ownership System (PECOS) at the time the moratorium is imposed.

6. Lifting a Temporary Moratorium

In accordance with § 424.570(b), these temporary enrollment moratoria will remain in effect for 6 months. If CMS deems it necessary, the moratoria may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratoria before the end of the initial 6-month period and, if applicable, any subsequent moratorium periods. If one or more of the moratoria are extended, CMS will publish notice of such extensions in the **Federal Register**.

As provided in § 424.570(d), CMS may lift a moratorium at any time if the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, circumstances warranting the imposition of a moratorium have abated, the Secretary has declared a public health emergency, or in the judgment of the Secretary, the moratorium is no longer needed.

Once a moratorium is lifted, provider or supplier types that were unable to enroll because of the moratorium will be designated to CMS' high screening level under § 424.518(c)(3)(iii) and § 455.450(e)(2) for 6 months from the date the moratorium was lifted.

II. Home Health Moratoria—Geographic Areas

Under its authority at § 424.570(a)(2)(i) and (a)(2)(iv), CMS is implementing a temporary moratorium on the Medicare enrollment of HHAs in the geographic areas discussed in this section. Under regulations at § 455.470 and § 457.990, this moratorium will also apply to the enrollment of HHAs in Medicaid and CHIP.

A. Moratorium on Enrollment of Home Health Agencies in the Florida Counties of Miami-Dade and Monroe

CMS has determined that there are factors in place that warrant the imposition of a temporary Medicare enrollment moratorium for HHAs in Miami-Dade County (which contains the City of Miami), as well as extending the moratorium to one bordering county—Monroe. Florida has divided the state into 11 home health ''licensing districts,'' that prevent a home health agency from providing services outside its own licensing district. Monroe is the only bordering county within the same licensing district as Miami-Dade. CMS has determined that it is necessary to extend this moratorium to Monroe to prevent potentially fraudulent HHAs from enrolling their practices in a neighboring county to avoid the moratorium. In this instance, it is not necessary to extend the moratorium to the other counties that border Miami-Dade because of the state's home health licensing rules that prevent providers enrolling in these counties from serving beneficiaries in Miami-Dade. CMS has also consulted with the State Medicaid Agency and reviewed available data, and determined that the moratorium will also apply to Medicaid and CHIP.

Beginning on the effective date of this notice, no new HHAs will be enrolled into Medicare, Medicaid or CHIP with a practice location in the Florida counties of Miami-Dade or Monroe, unless their enrollment application has already been approved, but not yet entered into PECOS or the State Enrollment System at the time the moratorium is imposed.

1. Consultation With Law Enforcement

Consistent with § 424.570(a)(2)(iv), CMS has consulted with both the HHS–OIG and DOJ regarding the imposition of a moratorium on new HHAs in Miami-Dade and Monroe counties. Both HHS–OIG and DOJ agree that a significant potential for fraud, waste, or abuse exists with respect to HHAs in the affected geographic areas. The HHS–OIG has previously identified Miami-Dade as an HHA fraud-prone area because it is a Strike Force location where individuals have been charged with billing potentially fraudulent home health services, and is located in a state that had a high percentage of HHAs with questionable billing identified by the HHS–OIG.[8] There has also been considerable Strike Force and law enforcement activity in this area of the country. Since 2011, the U.S. Attorney's Office for the Southern District of Florida has filed 41 home health fraud cases and charged 98 individuals that have resulted in 85 guilty pleas and 8 trial convictions. For example, in May 2013, a patient recruiter for a Miami

[5] MedPAC, March 2013, ''Report to Congress: Medicare Payment Policy, Chapter 9 home health services.'' *http://www.medpac.gov/documents/Mar13_entirereport.pdf.*

[6] MedPAC, June 2013, ''Chapter 7, Mandated Report: Medicare payment for ambulance services.'' *http://www.medpac.gov/chapters/Jun13_Ch07.pdf*

[7] MedPAC, March 2013, ''Report to Congress: Medicare Payment Policy, Chapter 9 home health services.'' *http://www.medpac.gov/documents/Mar13_entirereport.pdf.*

[8] Office of Inspector General Report, ''CMS and Contractor Oversight of Home Health Agencies.'' (OEI–04–11–00220). See *https://oig.hhs.gov/oei/reports/oei-04-11-00220.pdf.* The HHS–OIG defines an ''HHA fraud-prone area'' as those that are—(1) Strike Force Cities; (2) Strike Force cities where individuals have been charged with billing potentially fraudulent home health services; and (3) located in a state that had a high percentage of HHAs with questionable billing identified by the HHS–OIG.

health care company was sentenced to serve 37 months in prison for his participation in a $20 million Medicare fraud scheme.[9] In February 2013, the owners and operators of two Miami health care agencies were sentenced to 9 years and more than 4 years in prison, respectively, and ordered to pay millions in restitution for their participation in a $48 million Medicare fraud scheme that billed for unnecessary home health care and therapy services.[10] Also, in August 2012, the owner and operator of a Miami health care agency pleaded guilty for his participation in a $42 million Medicare home health fraud scheme.[11] In April 2012, the U.S. District Court in Miami sentenced the three owners of a Miami home health care agency to 120 months, 87 months, and 87 months, respectively for their participation in a $60 million Medicare home health care fraud scheme. CMS program integrity contractors are also actively investigating home health agencies in this area.

2. Data Analysis

a. Medicare Data Analysis

CMS' data show that in 2012, there were 26 U.S. counties nationally, including Miami-Dade, with at least 200,000 Medicare beneficiaries. CMS excluded Miami-Dade County, and used the remaining 25 counties as ''comparison counties.'' In the comparison counties, there was an average of 1.8 HHAs per 10,000 Medicare FFS beneficiaries.[12] In Miami-Dade County, there were 37.6 HHAs per 10,000 Medicare FFS beneficiaries. This means that the ratio of HHAs to Medicare FFS beneficiaries was 1,960 percent greater in Miami-Dade County than in the comparison counties.

[9] Department of Justice, ''Patient Recruiter of Miami Home Health Company Sentenced to 37 Months in Prison for Role in $20 Million Health Care Fraud Scheme.'' See *http://www.justice.gov/opa/pr/2013/May/13-crm-510.html.*

[10] Department of Justice, ''Owners of Miami Home Health Companies Sentenced to Prison in $48 million Health Care Fraud Scheme.'' See *http://www.justice.gov/opa/pr/2013/February/13-crm-243.html.*

[11] Department of Health and Human Services and Department of Justice, ''Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2012.'' See *http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf.*

[12] Throughout this notice, the ''comparison counties'' data also excludes New York County, New York because of the unique local conditions, such as that county's high density, compact geography, and high real estate costs, very few HHAs that serve the large number of beneficiaries in the county are located within the county. We believe this outlier would have biased the average to be artificially low, and could potentially over-represent the difference in ratios between the target county and the comparison counties.

Miami-Dade County had the highest ratio of HHAs to Medicare FFS beneficiaries compared to the comparison counties.

CMS' data show that from 2008 through 2012, the total number of operational HHAs in Miami-Dade County increased from 385 to 662. The compounded annual growth rate of HHAs in Miami-Dade County is 15 percent, more than double the national average of 7 percent. In addition, of the 662 HHAs active in Miami-Dade County in 2012, 56 percent of these HHAs have not been billing continuously—a strong indicator of churn—since 2008, while only 32 percent of HHAs in 2012 had not been continuously billing since 2008 in the average comparison county.

CMS' data show that in 2012, HHAs in Miami-Dade County were receiving payments of $10,287 per average Medicare home health user per year, compared to HHAs in the comparison counties, which received payments of $5,783. Payments to HHAs in Miami-Dade were 77 percent greater than the average for the comparison counties. Miami-Dade had the highest payments to HHAs compared to the comparison counties. High outlier payments to Miami-Dade home health agencies have persisted for several years despite CMS' efforts to limit outlier payments through policy changes. In 2010, CMS implemented a home health agency-level cap on outlier payments so that, in any given year, an individual HHA would receive no more than 10 percent of its total home health prospective payment system (HH PPS) payments in outlier payments. Before the policy change, HHAs in Miami-Dade County were receiving average annual Medicare payments per home health beneficiary that were nearly 400 percent greater than the comparison counties in 2008 ($20,801 compared to $5,935). While this policy has been successful in reducing costs in Miami-Dade, CMS believes more needs to be done.

b. Medicaid Data Analysis

As discussed previously in section I.B.1. of this notice, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. In addition, the data also show a significantly higher concentration of home health providers per Medicaid beneficiaries in Miami-Dade County than elsewhere in the state. CMS compared Miami-Dade against the entire state because Medicaid policies are not uniform across different states. Specifically, in 2010,[13] Miami-Dade County, which is home to just 16 percent of all Florida Medicaid home health beneficiaries, is nevertheless home to 45 percent of all the home health providers in the state. This disproportionate supply in Miami-Dade County, compared to the rest of the state, is reflected in the number of providers per Medicaid beneficiary: Miami-Dade County has 96 home health providers per 1,000 Medicaid beneficiaries—a provider density rate close to 3 times the Florida-wide provider density of 35 home health providers per 1,000 Medicaid beneficiaries.

2. Beneficiary Access to Care

Based upon CMS' consultation with the State Medicaid agency, CMS has concluded that imposing this temporary moratorium will not create an access to care issue for Medicaid or CHIP beneficiaries in Miami-Dade or the surrounding counties at this time. Accordingly, under § 455.470 and § 457.990, this moratorium will apply to the enrollment of HHAs in Medicaid and CHIP, unless the State later determines that imposition of the moratorium would adversely impact beneficiary access to care and so notifies CMS under § 455.470(a)(3).

CMS reviewed Medicare data for the target and surrounding counties, and found that there are no problems with access to home health agencies in Miami-Dade or surrounding counties. In addition, as described in section I.B.4. of this notice, MedPAC has not reported any problems with Medicare beneficiary access to home health care. While CMS has determined there are no access to care issues for Medicare beneficiaries, nevertheless, the agency will continuously monitor these areas under a moratorium for changes such as an uptick in beneficiary complaints to ensure there is no access to care issue.

As a result of law enforcement consultation and consideration of the factors described previously, CMS has determined that a temporary enrollment moratorium is needed to combat fraud in this area.

B. Moratorium on Enrollment of Home Health Agencies in the Illinois Counties of Cook, DuPage, Kane, Lake, McHenry, and Will

CMS has determined that there are factors in place to warrant the imposition of a temporary enrollment moratorium for HHAs in Cook County (which contains the City of Chicago).

[13] CMS used 2010 data from the Medicaid Statistical Information System (MSIS) because it was the most recent data available for all three states in this notice.

CMS has determined that it is necessary to extend this moratorium to the surrounding counties to prevent potentially fraudulent HHAs from enrolling their practices in a neighboring county to avoid the moratorium. To this end, CMS is extending the moratorium to five surrounding counties—DuPage, Kane, Lake, McHenry, and Will.

Beginning on the effective date of this notice, no new HHAs will be enrolled into Medicare, Medicaid or CHIP with a practice location in Illinois counties of Cook, DuPage, Kane, Lake, McHenry, and Will, unless their enrollment application has already been approved, but not yet entered into PECOS or the State Enrollment System at the time the moratorium is imposed.

1. Consultation With Law Enforcement

Consistent with § 424.570(a)(2)(iv), CMS has consulted with both the HHS–OIG and DOJ regarding the imposition of a moratorium on new HHAs in Cook County and the surrounding counties. Both HHS–OIG and DOJ agree that a significant potential for fraud, waste, or abuse exists with respect to HHAs in the affected geographic areas. HHS–OIG has identified Chicago as a Strike Force location where individuals have been charged with billing potentially fraudulent home health services.[14] Since July 2011, the U.S. Attorney's Office for the Northern District of Illinois has filed approximately 11 home health fraud cases and charged 45 individuals that have resulted in 15 trial convictions. For example, in May 2013, two individuals were charged in separate home health fraud schemes in Chicago as part of a Medicare Fraud Strike Force operation.[15] In December 2012, the co-owner of a former home health care business was sentenced to 10 years in federal prison for defrauding Medicare of more than $2.9 million by submitting tens of thousands of false claims annually that misrepresented medical services provided to beneficiaries.[16] In August 2012, a home health care agency in suburban Chicago, two nurses who are part owners of the company and a third nurse affiliated with them, along with two marketers, were indicted on Federal charges for allegedly participating in a conspiracy to pay and receive kickbacks in exchange for the referral of Medicare patients for home health care services.[17] Additionally, CMS program integrity contractors are also actively investigating home health agencies in this area.

2. Data Analysis

a. Medicare Data Analysis

CMS' data show that in 2012, there were 26 U.S. counties nationally, including Cook, with at least 200,000 Medicare beneficiaries. CMS excluded Cook County, and used the remaining 25 counties as ''comparison counties.'' In 2012, there was an average of 1.8 HHAs per 10,000 Medicare FFS beneficiaries. In Cook County, there were 7.7 HHAs per 10,000 Medicare FFS beneficiaries. This means that the ratio of HHAs to Medicare FFS beneficiaries was 327 percent greater in Cook County than in the comparison counties.

CMS' data show that from 2008 through 2012, the total number of operational HHAs in Cook County increased from 301 to 509. Cook County's compounded annual growth rate of HHAs is 14 percent, double the national average of 7 percent. The number of HHAs in Cook County was 280 percent greater than the comparison counties in 2012.

CMS' data show that in 2012, HHAs in Cook County were receiving payments of $6,884 per average Medicare home health user per year, compared to HHAs in the comparison counties, which received payments of $5,900. In 2012, payments to HHAs in Cook County were 17 percent higher than HHAs in the comparison counties. Payments remain some of the highest nationally as compared to the 25 comparison counties, and CMS is taking action through this moratoria to address the potential fraud risk here.

b. Medicaid Data Analysis

As discussed previously in section I.B.1. of this notice, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. In addition, the data also show a markedly higher annual utilization of Medicaid home health services in Cook County compared to the entire state. CMS compared Cook County against the entire state because Medicaid policies are not necessarily uniform across different states. In 2010[18] in Cook County, Medicaid spent $2,721 per home health user annually, or 57 percent more than the $1,728 per home health user that Medicaid spent in the state as a whole. On the provider side, the average Medicaid home health provider in Cook County received total annual payments of $92,356, or 51 percent more than the $60,991 the average Illinois provider received.

3. Beneficiary Access to Care

After consulting with the State Medicaid agency and reviewing available data, CMS has concluded that imposing this temporary moratorium will not create an access to care issue for Medicaid or CHIP beneficiaries in Cook County or the surrounding counties at this time. Accordingly, under § 455.470 and § 457.990, this moratorium will apply to the enrollment of HHAs in Medicaid and CHIP, unless the state later determines that imposition of the moratorium would adversely impact beneficiary access to care and so notifies us under § 455.470(a)(3).

CMS reviewed Medicare data for the target and surrounding counties, and found that there are no problems with access to home health agencies in Cook County or surrounding counties. In addition, as described in section I.B.4. of this notice, MedPAC has not reported any problems with Medicare beneficiary access to home health care. While CMS has also determined there are no access to care issues for Medicare beneficiaries, nevertheless, the agency will continuously monitor these areas under a moratorium for changes, such as any uptick in beneficiary complaints, to ensure there is no access to care issue.

As a result of the factors and consultation previously described, CMS has determined that a temporary enrollment moratorium is needed to combat fraud in this area.

III. Ambulance Moratorium—Geographic Area

Under its authority at § 424.570(a)(2)(i) and (a)(2)(iv), CMS is implementing a temporary moratorium on the Medicare Part B enrollment of ambulance suppliers in the geographic area discussed in this section. The moratorium does not apply to provider-based Medicare ambulances, which are owned and/or operated by a Medicare provider (or furnished under arrangement with a provider) such as a

[14] Office of Inspector General Report, ''CMS and Contractor Oversight of Home Health Agencies.'' (OEI–04–11–00220). See *https://oig.hhs.gov/oei/reports/oei-04-11-00220.pdf.*

[15] Federal Bureau of Investigation, ''Federal Medicare Fraud Strike Force Charges Chicago-Area Defendants with Defrauding Medicare and Other Health Insurers.'' See *http://www.fbi.gov/chicago/press-releases/2013/federal-medicare-fraud-strike-force-charges-chicago-area-defendants-with-defrauding-medicare-and-other-health-insurers.*

[16] Department of Justice, ''Owner of Former South Suburban Home Health Care Business Sentenced to 10 Years in Prison for $2.9 million Medicare Fraud.'' See *http://www.justice.gov/usao/iln/pr/chicago/2012/pr1220_01.pdf.*

[17] HHS and DOJ, ''Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2012.'' See *http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf.*

[18] The most recent data available.

hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program,[19] and are not required to enroll separately as a supplier in Medicare Part B.[20]

Under regulations at § 455.470 and § 457.990, this moratorium will also apply to Medicaid and CHIP. In contrast to Medicare enrollment rules, the Texas Health and Human Service Commission requires provider-based ambulance companies to enroll as ambulance providers,[21] therefore this moratorium applies to both independent and provider-based ambulances attempting to newly enroll in Medicaid and CHIP. The moratorium does not apply to air ambulances attempting to enroll in Medicare, Medicaid or CHIP.

A. Moratorium on Enrollment of Ambulance Suppliers in the Texas Counties of Harris, Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery, and Waller

CMS has determined that the imposition of a temporary enrollment moratorium for ambulance suppliers that in enroll in Medicare Part B, and Medicaid or CHIP ambulance providers in Harris County (which contains the City of Houston) is warranted, and is extending the moratorium to seven surrounding counties—Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery, and Waller. CMS has determined that it is necessary to extend this moratorium to the surrounding counties to prevent potentially fraudulent ambulance suppliers and providers from enrolling their practices in a neighboring county to avoid the moratorium. CMS has also consulted with the State Medicaid Agency and reviewed available data and has determined that the moratorium will also apply to Medicaid and CHIP.

Beginning on the effective date of this notice, no new ambulance suppliers will be enrolled into Medicare Part B, and no new ambulance providers will be enrolled in Medicaid or CHIP with a practice location in the Texas Counties of Harris, Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery, or Waller unless their enrollment application has already been approved, but not yet entered into PECOS or the State Enrollment System at the time the moratorium is imposed. The moratorium does not apply to air ambulance service suppliers and providers attempting to enroll in Medicare, Medicaid and CHIP.

1. Consultation With Law Enforcement

Consistent with § 424.570(a)(2)(iv), CMS has consulted with both the HHS–OIG and DOJ regarding the imposition of a moratorium on new Medicare ambulance suppliers and new Medicaid or CHIP providers in Harris County and surrounding counties. Both the HHS–OIG and DOJ agree that a significant potential for fraud, waste or abuse exists with respect to ambulance companies in the affected geographic areas. Houston is also a Strike Force location. The HHS–OIG previously found that the Medicare ambulance transport benefit may be highly vulnerable to abuse in areas with high utilization, such as Harris County and surrounding areas.[22] There has also been considerable Strike Force and law enforcement activity in this area of the country. Since April 2012, the US Attorney's Office for the Southern District of Texas has filed 6 cases in Houston alleging that the companies submitted fraudulent claims totaling over $9.5 million to Medicare for ambulance transports, and 7 individuals have been charged in connection with these cases resulting in 3 guilty pleas and 1 trial conviction. For example, in March 2013, the owner and operator of a Houston-area ambulance company was convicted by a federal jury in Houston of multiple counts of health care fraud for submitting false and fraudulent claims to Medicare.[23] In October 2012, as part of the Medicare Fraud Strike Force activity in Houston, the administrator of a Houston-based ambulance company, pleaded guilty to charges that he submitted approximately $1,734,550 in fraudulent claims to Medicare.[24] In May 2012, the owners and operators of four different ambulance companies were charged in Houston for billing Medicare for ambulance rides that were medically unnecessary as part of a nationwide Medicare Fraud Strike Force takedown.[25] Additionally, CMS program integrity contractors are also actively investigating ambulance suppliers in this area.

2. Data Analysis

a. Medicare Data Analysis

CMS' data show that in 2012, there were 26 U.S. counties nationally, including Harris, with at least 200,000 Medicare beneficiaries. CMS excluded Harris County, and used the remaining 25 counties as ''comparison counties.'' In the comparison counties in 2012, there was an average of 0.8 ambulance suppliers per 10,000 Medicare FFS beneficiaries. In Harris County, there were 9.5 ambulance suppliers per 10,000 Medicare FFS beneficiaries. This means that the ratio of ambulance suppliers to Medicare FFS beneficiaries was 1,065 percent greater in Harris County than in the 25 comparison counties. Harris County had the highest ratio of ambulance suppliers to Medicare FFS beneficiaries compared to the comparison counties.

The number of ambulance suppliers in Harris County was also 848 percent greater than the comparison counties in 2012. In addition, of the 275 ambulance suppliers active in Harris County, 66 percent have not been continuously billing—a strong indicator of churn—since 2008, compared to the average comparison county where only 19 percent of ambulance suppliers in 2012 had not been continuously billing since 2008. Harris County had the highest number of providers not continuously billing since 2008 compared to all of the comparison counties.

b. Medicaid Data Analysis

As discussed previously in section I.B.1. of this notice, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. In addition, the number of Medicaid ambulance providers per Medicaid ambulance patient in Harris County is extraordinarily high, compared to other areas in the state of Texas. Specifically, Harris County has more than twice the number of ambulance providers per Medicaid ambulance patient as the rest of Texas. (Harris County: 19.1 suppliers per 1,000 Medicaid ambulance recipients versus 7.8 suppliers per 1,000 Medicaid ambulance recipients in the rest of Texas).

[19] Medicare Claims Processing Manual, CMS Pub. No. 100–04, Chapter 15, ''Ambulance.'' See *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c15.pdf.*

[20] Medicare Program Integrity Manual, Chapter 15, Medicare Enrollment. See *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf.*

[21] Texas Medicaid Provider Procedures Manual, Ambulance Services Handbook. See *http://www.tmhp.com/tmppm/2011/Vol2_Ambulance_Services_Handbook.pdf.*

[22] Office of Inspector General Report, ''Medicare Payments for Ambulance Transports.'' (OEI–05–02–0590). See *http://oig.hhs.gov/oei/reports/oei-05-02-00590.pdf.*

[23] Department of Justice, ''Owner and Operator of Houston-Area Ambulance Service Convicted in Medicare Fraud Scheme.'' See *http://www.justice.gov/opa/pr/2013/March/13-crm-273.html.*

[24] Department of Justice press release, ''Houston Ambulance Company Pleads Guilty to Fraud,'' See *http://www.justice.gov/opa/pr/2012/October/12-crm-1242.html.*

[25] Department of Justice, ''Medicare Fraud Strike Force Charges 107 individuals for approximately $452 million in False Billing.'' See *http://www.justice.gov/opa/pr/2012/May/12-ag-568.html.*

3. Beneficiary Access to Care

After consulting with the Texas State Medicaid agency and the State Department of Health Emergency Medical Services and reviewing available data, CMS has concluded that imposing this temporary moratorium will not create an access to care issue for Medicaid or CHIP beneficiaries in Harris County or the surrounding counties at this time. Accordingly, under § 455.470 and § 457.990, this moratorium will apply to the enrollment of ambulance providers in Medicaid and CHIP, unless the state later determines that imposition of the moratorium would adversely impact beneficiary access to care and so notifies CMS under § 455.470(a)(3).

CMS reviewed Medicare data for the target and surrounding counties, and found that there are no problems with access to ambulance suppliers in Harris County or surrounding counties. In addition, as described in section I.B.4. of this notice, MedPAC has not reported any problems with Medicare beneficiary access to ambulance services. While CMS has determined that this temporary moratorium will not create an access to care issue for Medicare beneficiaries in Harris County or the surrounding counties at this time, nevertheless, the agency will continuously monitor these areas under a moratorium for changes, such as any uptick in beneficiary complaints, to ensure there is no access to care issue. As a result of the factors and consultation described previously, CMS has determined that a temporary enrollment moratorium is needed to combat fraud in this area.

IV. Summary of the Moratoria Areas

CMS is executing its authority under sections 1866(j)(7), 1902(kk)(4), and 2107(e)(1)(D) of the Act to implement a moratorium in the following counties for these providers and suppliers (see Tables 1 and 2):

TABLE 1—HOME HEALTH AGENCY MORATORIA

Target city and state	Counties	HEAT Strike Force city	Ratio of HHAs to Medicare FFS beneficiaries as compared to comparison counties [1] (2012)	Medicaid data (2010)
Miami, FL	Miami-Dade, Monroe	Yes	1,960 percent higher.	Ratio of HHAs to Medicaid beneficiaries was 3 times higher than rest of state.
Chicago, IL	Cook, Dupage, Kane, Lake, McHenry, Will.	Yes	327 percent higher	Spending per home health users was 57 percent more than the state as a whole.

[1] CMS data shows that in 2012, there were 26 U.S. counties nationally, including Miami-Dade County, Florida, Cook County, Illinois and Harris County, Texas, but excluding New York County, New York, with at least 200,000 Medicare beneficiaries. In the ''comparison counties'' (when either Miami-Dade County or Cook County were excluded) there was an average of 1.8 HHAs per 10,000 Medicare FFS beneficiaries.

TABLE 2—AMBULANCE MORATORIUM

Target City and State	Counties	HEAT Strike Force city	Ratio of ambulance suppliers to Medicare FFS beneficiaries as compared to comparison [1] counties (2012)	Medicaid data (2010)
Houston, TX	Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, Waller.	Yes	1,065 percent higher.	Ratio of ambulance providers to Medicaid beneficiaries was 2 times higher than rest of state.

[1] CMS data shows that in 2012, there were 26 U.S. counties nationally, including Miami-Dade County, Florida; Cook County, Illinois; and Harris County, Texas, but excluding New York County, New York, with at least 200,000 Medicare beneficiaries. In the ''comparison counties,'' which also excluded Harris County, there was an average of 0.8 ambulance suppliers per 10,000 Medicare FFS beneficiaries.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

We have examined the impact of this notice 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), 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) and the Congressional Review Act (5 U.S.C. 804(2).

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). A regulatory impact analysis (RIA) must be prepared for major regulatory actions with economically significant effects ($100 million or more in any 1 year). This notice will prevent the enrollment of new home health providers and ambulance suppliers in Medicare, and ambulance providers in Medicaid and CHIP. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. Additionally, CMS is unable to estimate

how many providers and suppliers will submit applications for enrollment during the moratoria, although it anticipates that most providers and suppliers will not submit applications during the moratoria period. Therefore, this notice does not reach the economic threshold and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $35.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this notice will not have a significant economic 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 an action 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 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This notice will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35; Sec. 1103 of the Social Security Act (42 U.S.C. 1302).

Dated: July 25, 2013

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–18394 Filed 7–26–13; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Environmental Impact Considerations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 25, 2013, the Agency submitted a proposed collection of information entitled ''Environmental Impact Considerations'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0322. The approval expires on May 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18410 Filed 7–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0853]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices Current Good Manufacturing Practice Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Submit either electronic or written comments on the collection of information by September 30, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of