and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device, MEDIBEACON. MEDIBEACON is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function. The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m2, GFR >120 ml/min/1.73m2, patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI). The MediBeacon® TGFR Sensor and exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR. The MediBeacon® TGFR Sensor is a single use device intended to attach to the patient's skin and excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor. Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment. Subsequent to this approval, the USPTO received patent term restoration applications for MEDIBEACON (U.S. Patent Nos. 8,115,000; RE47,413) from Medibeacon Inc., and the USPTO requested FDA's assistance in determining this patents' eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of MEDIBEACON represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that the FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MEDIBEACON is 4,175 days. Of this time, 3,598 days occurred during the testing phase of the regulatory review period, while 577 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective:* August 15, 2013. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective August 15, 2013.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* June 21, 2023. FDA has verified the applicant's claim that the premarket approval application (PMA) for MEDIBEACON (PMA P230019) was initially submitted June 21, 2023.

3. *The date the application was approved:* January 17, 2025. FDA has verified the applicant's claim that PMA P230019 was approved on January 17, 2025.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application(s) for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–24268 Filed 1–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) published a **Federal Register** Notice on October 1, 2025, with proposed updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines). The proposed updates specifically relate to recommendations for Screening for Cervical Cancer. Recommendations to update the Guidelines are developed under a

HRSA-funded cooperative agreement, the Women's Preventive Services Initiative (WPSI), for consideration by HRSA. Under this agreement, WPSI convenes expert health professionals to conduct rigorous reviews of the evidence following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, and external reviews, and it developed draft recommendations for HRSA's consideration. After consideration of public comment, HRSA has accepted the recommendations as revised and detailed in this notice. Under applicable law, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported Guidelines. The Departments of Labor, HHS, and the Treasury have previously issued regulations describing how group health plans and health insurance issuers apply the coverage requirements. Please see *https://www.hrsa.gov/womens-guidelines* for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–2170, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Under the Patient Protection and Affordable Care Act, Public Law 111–148, the preventive care and screenings set forth in the Guidelines are required to be covered without cost-sharing by certain group health plans and health insurance issuers. HRSA established the Guidelines in 2011 based on expert recommendations by the Institute of Medicine, now known as the National Academy of Medicine, developed under a contract with HHS. Since 2016, HRSA has funded cooperative agreements for WPSI to convene a coalition representing clinicians, academics, and consumer-focused health professional organizations to conduct a rigorous review of current scientific evidence, solicit and consider public input, and make recommendations to HRSA regarding updates to the Guidelines to improve adult women's health across the lifespan. HRSA then determines whether to support, in whole or in part, the recommended updates to the Guidelines.

For clarity, note that the Implementation Considerations address aspects of clinical and practical application of the Clinical Recommendations. Research Recommendations are provided to highlight areas where further research and clinical trials are needed to inform the development of Clinical Recommendations. The Implementation Considerations and Research Recommendations sections are not a part of the Clinical Recommendations accepted by the HRSA Administrator and therefore have no impact on health insurance coverage without cost-sharing. In the description of responses to the public comments below, the term ''recommendation'' is sometimes used in place of ''Clinical Recommendation.''

Recommended updates to the Guidelines are based on review and synthesis of existing clinical guidelines and new scientific evidence, following robust standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, and external reviews. Additionally, HRSA provides opportunity for public comment, including participation by patients and consumers, in the development of the Guidelines.

Discussion of Recommended Updated Guideline

As is standard practice, HRSA published a **Federal Register** Notice seeking public comment regarding the proposed updates to the Guidelines for Screening for Cervical Cancer (90 FR 47313 (Oct. 1, 2025)). All public comments were reviewed and considered as part of the deliberative process. A total of 42 responses were received, with each response containing one or more distinct comments.

Screening for Cervical Cancer

WPSI recommended retaining the existing Guideline on Screening for Cervical Cancer, with several updates to the language. Language of the final Clinical Recommendation is set out at the end of this Notice.

- The first change is the use of the full form of Women's Preventive Services Initiative, instead of the acronym WPSI, in the first sentence of the Guideline.
- The second change occurs in the second sentence of the Guideline and only restructures the sentence for clarity and does not provide any changes to the recommendation.
- Next, the abbreviation ''hrHPV'' was added after the term ''human papillomavirus'' for consistency and increased clarity that the recommendation is specific to high-risk HPV types. Corresponding revisions using the abbreviation are provided throughout the remaining text of the updated recommendation.
- The word ''co-testing'' was previously unhyphenated in the recommendation; a hyphen was added in the latest version of the recommendation.
- WPSI updated the Guideline regarding cervical cancer testing for women aged 30–65 and added ''primary hrHPV testing every 5 years (preferred) or cytology and hrHPV testing (co-testing) every 5 years. If hrHPV testing is not available, continue screening with cytology alone every 3 years.'' This update reflects current evidence-based practice on testing and interval screening.
- Next, a new sentence was added (''Patient-collected hrHPV testing is an appropriate method and should be offered as an option for cervical cancer screening in women aged 30 to 65 years at average risk.'') to reflect the new evidence and developments supporting the expansion of options for cervical cancer screening through patient-collected hrHPV testing.
- The last update to the Guideline adds language on additional testing to complete the cervical cancer screening process (''Additional testing may be required to complete the screening process and follow-up findings on the initial screening. If additional testing (*e.g.,* cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation are indicated, these services also are recommended to complete the screening process for malignancies.''). This update ensures the screening process for malignancies is complete should additional testing services (*e.g.,* cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation be clinically indicated. Additional testing to complete the screening process covers all cases of cervical cancer screening, regardless of whether the test was collected by the patient or clinician.

HRSA received 42 responses on these proposed updates, with each response containing one or more distinct comments. Public comments were largely positive about the updated Guideline, with an overwhelming majority of respondents expressing support for at least one component of the recommendation. The comments have been reviewed and organized into categories, with overview summaries of comments and responses provided below:

- *Adjusting Screening by Risk-Level/Defining Average Risk:*
  - *Comments:* Thirteen comments suggested adjustments to screening by risk, socioeconomic group, or age with

some requesting screening past 65, before age 20, and others requesting screening begin at age 25 in alignment with other guidelines. Four of these comments requested a definition for average risk.

○ *Response:* The evidence review did not determine a need to change the age for the start or stop of screening. Among the five major guidelines for average-risk women examined in the evidence review, four aligned on the same starting age, and all five recommended concluding screening at age 65. These guidelines are meant for average-risk women, a definition of which is available in the full evidence review (*https://www.hrsa.gov/sites/default/files/hrsa/about/cervical-cancer-screening-update.pdf*); the Implementation Considerations also provides notes around how WPSI defines average-risk. Screening approaches for those at high-risk are outside the scope of these recommendations. At present, the evidence does not support tailoring screening approaches based on socioeconomics. Accordingly, these comments were not accepted and no change was made in response to these comments.

• *Uniform Data System/Healthcare Effectiveness and Data Information Set Alignment:*

○ *Comments:* Ten comments noted that the addition of self-collection for cervical cancer screening provides the opportunity for HRSA to collect information through its Uniform Data System (UDS) for health centers for ''member-collected samples'' for cervical cancer screening that would align with an existing measure noted in the 2024 Healthcare Effectiveness and Data Information Set (HEDIS) General Guidelines used by health plans; one of these commentors requested UDS be revised to adopt the HEDIS measure language.

Another comment recommended that specific language be added to the recommendation to improve data collection in the UDS by socioeconomic subgroups as well as metrics regarding issues with screening (such as ''never-screened,'' ''delayed-initiation,'' etc.).

○ *Response:* While these comments go beyond the scope of this evidence review and recommendation, and thus no changes were made to the recommendation, HRSA has shared these observations and suggestions with HRSA staff that administer the Health Center Program, including UDS.

• *Supporting Implementation, Follow-up Care, and Public Education:*

○ *Comments:* Seven comments were provided that focused on supporting implementation, follow-up, and public education on the updated recommendation. Six of these comments requested more support/systems to address follow-up of positive results for home-based self-collection, particularly given concerns around loss to follow-up and access for underserved populations. One of these comments specifically requested expansion of community-based services and language on patient navigation for follow-up.

○ *Response:* While these comments go beyond the scope of this evidence review and recommendation, it should be noted that starting January 1, 2026, the evidence-based WPSI Patient Navigation Services for Breast and Cervical Cancer Screening Guideline, 89 FR 106522 (Dec. 30, 2024), takes effect, providing person-to-person navigation services without patient copay. A reminder of this recommendation has been added to the Implementation Considerations and additional research on the impact of patient navigation on follow-up care is already noted in the Research Recommendations.

○ *Comments:* Two comments requested more language delineating all necessary follow-up procedures/care or circumstances for additional testing; one of these requested specific language on an in-person follow-up visit for positive self-collected test results.

○ *Response:* While specific follow-up procedures and management of abnormal results are beyond the scope of the evidence review and recommendation, a note has been added to the Implementation Considerations stating follow-up for abnormal test results should follow established clinical guidelines.

○ *Comments:* Three of the seven comments suggested more robust outreach and education efforts, with one of the three asking for education to be tailored to highest need.

○ *Response:* While these comments go beyond the scope of this evidence review and recommendation, additional language has been added to the Implementation Considerations on the importance of patient-centered discussion and education, as well as the WPSI Patient Navigation Services for Breast and Cervical Cancer Screening Guideline, as noted above.

• *Equal Preference for hrHPV, Cytology, and Co-Testing/Adjusting Preferences:*

○ *Comments:* Seven comments requested equal weight be given to cytology, hrHPV, and co-testing, removing the preference for primary hrHPV testing; a number of these comments mentioned a desire to align with the draft 2024 U.S. Preventive Services Task Force (USPSTF) guideline. One comment requested cytology be used in conjunction with hrHPV testing.

○ *Response:* As per the 2025 WPSI evidence review, newer evidence released since the 2024 USPSTF evidence review informs primary hrHPV based screening for the 30 to 65 year age group as the preferred method, with increased detection of precancer compared with cytology-based screening and lower rates of precancer with subsequent screening seen with this modality. As such, these comments were not accepted and no change was made in response to these comments.

• *FDA Intended Use for Self-Collection and Other:*

○ *Comments:* Six comments mentioned concerns related to FDA approvals, and included concern that the FDA intended use for self-collected samples is only for situations when a clinician-collected sample cannot be obtained, a desire to note in the recommendation that FDA approvals are required for use, or other perceived FDA-related/regulatory limitations.

○ *Response:* In May 2025, the FDA approved the first at-home cervical cancer screening self-collection kit; this follows their earlier May 2024 approval of in-clinic self-collection kits for the same purpose. To provide additional clarity, a note was added to the Implementation Considerations on FDA approved methods.

• *Self-Collection Screening Frequency Changed to Shorter Interval:*

○ *Comments:* Five comments requested a shorter screening frequency for self-collected samples.

○ *Response:* No changes were made to the recommendation as self-collected samples had a similar test accuracy as clinician-collected samples and WPSI's evidence review did not support changing to an increased frequency of screening. A Research Recommendation has been added to address this.

• *Self-Collections as a Secondary Option:*

○ *Comments:* Five comments recommended self-collection as a secondary option or that it be considered only for select populations.

○ *Response:* The WPSI evidence review concluded that self-collected vaginal hrHPV has similar test accuracy for precancer when compared to clinician-collected samples, yielding similar proportions of positive screening results. Self-collection can also increase screening uptake, which facilitates earlier detection of cervical disease. Earlier detection is associated with improved treatment outcomes and, ultimately, the potential to prevent more

cervical cancer–related deaths. Accordingly, these comments were not accepted and no change was made in response to these comments.

- *Lack of U.S. Data:*
  - *Comments:* Three commentors mentioned a concern over the use of European studies or the lack of U.S. data around self-collection or preference for primary hrHPV testing.
  - *Response:* The studies used in the WPSI evidence review were comparable to the broader U.S. population for the research questions examined. Most comparative screening studies used in the WPSI Evidence Review's analysis were conducted in countries with organized screening programs similar to the U.S., along with one large population cohort study conducted in a U.S. health setting with an organized screening program representing a diverse group of patients. Accordingly, these comments were not accepted and no change was made to the recommendation in response to these comments.
- *Clarifications on Additional Screening to Complete the Screening Process:*
  - *Comments:* Two comments requested defining ''additional screening'' and what constitutes the end of screening, particularly for the purposes of billing and coding, with one of these comments requesting information on what to do about inconclusive results and two comments requesting guidance on coding and billing for the additional tests.
  - *Response:* This change to the recommendation was made in alignment with similar language in the breast cancer screening guideline, added in 2024, which also recommended additional testing to complete the screening process for malignancies. While billing and coding are not specifically addressed by the Clinical Recommendation, the Center for Consumer Information and Insurance Oversight and the tri-department committee, made up of the Department of Labor, the Department of the Treasury, and HHS, makes determinations regarding coverage and can be approached for assistance with billing and coding. As reflected in the recommendation, an inconclusive result would require additional testing to complete the screening process. As such, no change to the recommendation was made in response to these comments.
- *For and Against Extended Genotyping During Primary Screening:*
  - *Comments:* One commenter noted that they do not recommend routine extended genotyping with primary screening and appreciated the addition of ''hr'' in front of HPV to help indicate this, while another two comments requested including extended genotyping as part of primary screening.
  - *Response:* No changes were made to the recommendation as there was no evidence to support extended genotyping during primary screen for average risk populations.
- *Additional Technical Details Requested Comments and Responses:*
  - Three comments requested additional technical details.

One of these comments requested additional technical details including a need to test patients/partners for anal and oropharyngeal HPV, which was outside the scope of this recommendation and thus no change was made.

One comment requested exit screening protocols, which is already mentioned in the Implementation Considerations.

An additional comment supported hrHPV as the preferred method of testing but suggested including language indicating that other forms of screening, such as co-testing, are also effective. This language is reflected in the existing recommendation, thus no additional changes were made.

- *Single Comments and Responses:*
  - Single comments were received on the following topics:

One commenter requested the evidence review, which can be accessed by visiting HRSA's Women's Preventive Services Guidelines pages *https://www.hrsa.gov/womens-guidelines*). No change was made to the recommendation in response to this comment.

One comment was concerned the recommendation may lead to women having fewer gynecologic exams and potential increases in associated cancers. No changes were made as this recommendation does not change existing WPSI recommendations around the annual well-woman visit or any existing preventive cancer screenings connected to ongoing well-woman care.

One comment shared a concern that the recommendation will weaken reimbursement and institutional support. This comment was beyond the scope of the evidence review and recommendation, and no change was made.

One comment stressed the need to ensure scientific integrity for the development of the recommendation, which is a shared priority for HHS and HRSA. The evidence-based guideline development process is described elsewhere in this notice. No change was made to the recommendation in response to this comment.

One comment requested more inclusive language. No change was made based on this comment, as the guideline relates to all women at average risk of cervical cancer.

One comment requested a Research Recommendation to better assess age for first screening, which was added to the Research Recommendations.

Another comment requested more research on the best ways for providers to communicate to underserved groups. No change was made in response to this comment, as this goes beyond the scope of this evidence review and recommendation.

One commenter suggested adding a comma between ''biopsy'' and ''colposcopy'' in the final recommendation. The guideline was updated to include this grammatical edit, which does not change the substance or intent of the recommendation.

Acceptance of Recommendation

On December 29, 2025, the HRSA Administrator accepted WPSI's recommendation, which is revised as described above, and, as such, updated the HRSA-supported Women's Preventive Services Guidelines. The final Guideline for this topic reads as follows:

Screening for Cervical Cancer

''The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, cervical cancer screening using cervical cytology (Pap test) every 3 years is recommended. Co-testing with cytology and human papillomavirus (hrHPV) testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with primary hrHPV testing every 5 years (preferred) or cytology and hrHPV testing (co-testing) every 5 years. If hrHPV testing is not available, continue screening with cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years. Patient-collected hrHPV testing is an appropriate method and should be offered as an option for cervical cancer screening in women aged 30 to 65 years at average risk. Additional testing may be required to complete the screening process and follow-up findings on the initial screening. If additional testing (*e.g.,* cytology, biopsy, colposcopy, extended genotyping, dual stain) and pathologic evaluation are indicated, these services

also are recommended to complete the screening process for malignancies.''

Non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must cover without cost-sharing the services and screenings listed on the updated Women's Preventive Services Guidelines for plan years (in the individual market, policy years) that begin 1 year after this date. Thus, for most plans, this update will take effect for purposes of the Section 2713 coverage requirement in 2027. Additional information regarding the Women's Preventive Services Guidelines can be accessed at the following link: *https://www.hrsa.gov/womens-guidelines.*

Authority: Section 2713(a)(4) of the Public Health Service Act, 42 U.S.C. 300gg–13(a)(4).

Thomas J. Engels,

Administrator.

[FR Doc. 2025–24235 Filed 1–2–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1568E]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2026

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2026 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective January 5, 2026.

FOR FURTHER INFORMATION CONTACT: Heather Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish production quotas for each basic class of controlled substance listed in schedule I and II and ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

II. Background

The 2026 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2026 in order to provide for the estimated medical, scientific, research, and industrial needs of the U.S., lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

On November 28, 2025, a notice titled ''Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2026'' was published in the **Federal Register**.[1] This notice proposed the 2026 APQs for each basic class of controlled substance listed in schedules I and II and the 2026 AANs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed APQs and the proposed AANs on or before December 15, 2025.

III. Comments Received

Within the public comment period, DEA received 5,044 comments from DEA registrants, chronic pain patients, patients with attention deficit/hyperactivity disorder (ADHD), pain advocacy associations, U.S. professional associations, U.S. doctors and nurses, and others. The comments included concerns about perceived domestic opioid drug shortages due to further quota reductions; patient difficulty filling authorized opioid and stimulant prescriptions; increases in drug overdose deaths despite a continued decrease in production quotas; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; concerns of ADHD medication efficacy and shortages based on quotas associated with isomer ratios; ordering thresholds for pharmacies, data collection and methodology; tools used to determine diversion estimates; adequate quotas for research purposes, stake holder collaboration; requests for a public hearing; requests for an extension to the comment period; and comments not pertaining to DEA-regulated activities. While all comments were posted to *regulations.gov*, DEA restricted the attachments to 22 comments from public view due to confidential business information and/or confidential personal identifying information.

Pain Medication (Schedule II Opioids)

Issue (Medication Out of Stock at Pharmacy Level): Many commenters expressed that due to the decreases in the aggregate production quotas for oxycodone and hydrocodone, they have had difficulty filling legitimate prescriptions. They stated they often experienced delays or have to visit multiple pharmacies to get their prescriptions filled. These issues have negatively impacted their quality of life and caused mental health-related issues, possibly leading to suicide. Additionally, commenters expressed concerns over the cardiovascular effects they experienced when pain is left untreated for an extended period of time due to the delay in getting medications.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific, and export needs of the United States. DEA utilizes the available, reliable data and information received by the agency at the time APQs are proposed and proactively monitors drug production, distribution and supply during the year. However, drug shortages may occur due to factors outside of DEA's control such as manufacturing and quality problems, processing delays, supply chain disruptions, or discontinuations. In such circumstances, if the drug manufacturer notifies the Food and Drug Administration (FDA) Drug Shortage Staff, FDA will coordinate with DEA to address and minimize the impact of drug shortages if both agencies believe action is warranted. Currently, FDA has not listed on its Drug Shortage website any nationwide shortages of oxycodone and hydrocodone products. Additionally, if a patient is faced with a delay in

[1] Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2026, 90 FR 54745 (November 28, 2025).