received (including those under review or on hold) until the publication date of this **Federal Register** document for transferred products and, if applicable, until a final decision on the submission is reached. For questions on any submissions with CDRH, please contact CDRH Product Jurisdiction at *CDRHProductJurisdiction@fda.hhs.gov.* For questions on submissions to CBER, please contact *CBERProductJurisdiction@fda.hhs.gov.*

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31266 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3248]

Fosun Pharma USA Inc., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on July 29, 2024. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 28, 2024. The document indicated that FDA was withdrawing approval of the ANDAs 073462 for tolmetin sodium capsules, equivalent to (EQ) 400 milligrams (mg) base; 073588 for tolmetin sodium tablets, EQ 200 mg base; 074002 for tolmetin sodium tablets, EQ 600 mg base; 077040 for citalopram hydrobromide tablets, EQ 10 mg base, EQ 20 mg base; EQ 40 mg base; 085787 for trifluoperazine hydrochloride (HCl) concentrate, EQ 10 mg base/milliliters (mL); 086808 for cyproheptadine HCl tablets, 4 mg; 087774 for phenylbutazone capsules, 100 mg; and 088602 for pseudoephedrine HCl; triprolidine HCl tablets, 60 mg/2.5.mg, held by Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540. Additionally, ANDAS 075631 for ketorolac tromethamine injectable, 15 mg/mL and 30 mg/mL; 076427 for milrinone lactate injectable, EQ 1 mg base/mL; 076791 for haloperidol lactate injectable, EQ 5 mg base/mL; 076828 haloperidol lactate injectable, EQ 5 mg base/mL; 077947 for fluconazole injectable, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL); 078197 for granisetron HCl injectable, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL); 091436 for levofloxacin injectable, EQ 500 mg/20 mL (EQ 25 mg/mL); 207101 for sumatriptan succinate injectable, EQ 6 mg base/0.5 mL (EQ12 mg base/mL); and 215065 for methocarbamol solution, 1gram/10 mL (100 mg/mL), held by Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015; and the ANDAs 090367 for levofloxacin tablets, 250 mg, 500 mg, 750 mg; and 211959 for clobazam tablets, 10 mg and 20 mg, held by Celltrion USA, Inc., U.S. Agent for Celltrion, Inc., One Evertrust Plaza, Suite 1207, Jersey City, NJ 07302; and the ANDA 212053 for chlorzoxazone tablet, 375 mg and 750 mg, held by i3 Pharmaceuticals LLC, 200 Park Ave., Warminster, PA 18974. Before FDA withdrew the approval of these ANDAs, Fosun Pharma USA Inc.; Baxter Healthcare Corp.; Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.; and i3 Pharmaceuticals LLC, 200 Park Ave., Warminster, PA 18974, informed FDA that they did not want the approval of the ANDAs withdrawn. Because Fosun Pharma USA Inc.; Baxter Healthcare Corp.; Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.; and i3 Pharmaceuticals, LLC, timely requested that approval of their respective ANDAs not be withdrawn, the approvals are still in effect. This notice corrects these errors.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, July 29, 2024 (89 FR 60902), appearing on page 60902 in FR Doc. 2024–16627, the following correction is made:

On page 60902, in the table, the entries for ANDA 073462, ANDA 073588, ANDA 074002, ANDA 075631, ANDA 076427, ANDA 076791, ANDA 076828, ANDA 077040, ANDA 077947, ANDA 078197, ANDA 085787, ANDA 086808, ANDA 087774, ANDA 088602, ANDA 090367, ANDA 091436 ANDA 207101, ANDA 211959, ANDA 212053, and ANDA 215065 are removed.

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31307 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Health Resources and Services Administration-Supported Women's Preventive Services Guidelines

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

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) published a **Federal Register** Notice on October 22, 2024, with proposed updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines). The proposed updates specifically relate to recommendations for Screening and Counseling for Intimate Partner and Domestic Violence, Breast Cancer Screening for Women at Average Risk, and Patient Navigation Services for Breast and Cervical Cancer Screening. Recommendations to update the Guidelines are developed by the Women's Preventive Services Initiative (WPSI) for consideration by HRSA. 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 develops 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, Health and Human Services, 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 HRSA-supported Women's Preventive Services Guidelines (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 the Department of Health and Human Services. Since 2016, HRSA has funded cooperative agreements with the American College of Obstetricians and Gynecologists for the Women's Preventive Services Initiative (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.

WPSI includes an Advisory Panel and two expert committees, the Multidisciplinary Steering Committee and the Dissemination and Implementation Steering Committee, which are comprised of a broad coalition of experts in disease prevention and women's health issues. With oversight by the Advisory Panel, and with input from the Multidisciplinary Steering Committee, WPSI examines the evidence to develop new (and update existing) recommendations for women's preventive services. WPSI's Dissemination and Implementation Steering Committee takes HRSA-approved recommendations and disseminates them through the development of implementation tools and resources for both patients and practitioners.

For clarity, note that the Implementation Considerations of the WPSI documents 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.

WPSI bases its recommended updates to the Guidelines on review and synthesis of existing clinical guidelines and new scientific evidence, following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, and external reviews. Additionally, HRSA requires that WPSI incorporate processes to assure opportunity for public comment, including participation by patients and consumers, in the development of the updated Guidelines.

Discussion of Recommended Updated Guidelines

As is standard practice, HRSA published a **Federal Register** Notice seeking public comment regarding the proposed updates to the Guidelines (89 FR 84354).[1] WPSI considered all public comments as part of its deliberative process, provided the comments to HRSA for its consideration, and submitted final recommended updates for Screening and Counseling for Intimate Partner and Domestic Violence, Breast Cancer Screening for Women at Average Risk, and Patient Navigation Services for Breast and Cervical Cancer Screening. A total of 28 comments were received and considered.

Screening and Counseling for Intimate Partner and Domestic Violence

WPSI largely recommended retaining the existing Guideline on Screening and Counseling for Intimate Partner and Domestic Violence with several minor updates. The first proposed change was a revision to the title of the Guideline, with corresponding revisions throughout, to better reflect current clinical terminology by replacing ''Interpersonal and Domestic Violence'' with ''Intimate Partner and Domestic Violence.'' WPSI also recommended adding the word ''adult'' prior to ''women'' in the recommendation, to clarify that both adolescent and adult women are included in the screening and counseling guidance. The words ''referral to'' were removed from the last sentence to improve clarity.

WPSI received eight comments on these proposed updates. One commenter suggested adding universal education as a mechanism to address intimate partner violence in health care settings. Based on this comment, WPSI added universal education to the Implementation Considerations section for the recommendation. Another comment recommended an expansion of research into intimate partner violence, which WPSI added to the Research Recommendations. Another commenter suggested adding referral and consult to a forensic medical examiner to the recommendation, which was not accepted as it was not represented in the evidence review for this topic. Several commenters supported WPSI's recommendations and one suggested the development of continuous care frameworks for follow-up services and the use of telehealth in support of those services. These comments were not accepted as they are already included in the implementation considerations of the recommendation or are beyond the scope of the review, which did not include the development of a continuous care frameworks. One comment suggested alignment with the U.S. Preventive Services Task Force (USPSTF), which describes specific populations, including vulnerable patients, and another suggested specifying the inclusion of ''older adult women.'' These comments were not accepted, as WPSI's evidence review and recommendation supports screening of all women, not just certain vulnerable populations or age groups.

Breast Cancer Screening for Women at Average Risk

WPSI recommended several updates to the existing Guideline on Breast Cancer Screening for Women at Average Risk. WPSI recommended updates to the first sentence of this Guideline, replacing the phrase ''average-risk women'' with ''women at average risk for breast cancer'' to clarify the target population for this recommendation and to use person-first language that puts the individual before the diagnosis or screening modality. The title was also changed from ''Breast Cancer Screening for Average-Risk Women'' to ''Breast Cancer Screening for Women at Average Risk'' for similar reasons. Two new sentences were added following the first sentence: ''Women may require additional imaging to complete the screening process or to address findings on the initial screening mammography. If additional imaging (*e.g.,* MRI, ultrasound, mammography) and pathology exams are indicated, those services are also recommended to complete the screening process for malignancies.'' These two sentences were added to ensure women who need additional screening to complete their initial screening receive it. Imaging in addition to initial screening

[1] *See https://www.federalregister.gov/documents/2024/10/22/2024-24445/notice-of-request-for-public-comments-on-draft-recommendations-for-the-hrsa-supported-womens.*

mammography, such as special mammography views, ultrasound, or MRI, may be needed in individual clinical situations when clinicians require an enhanced view of breast tissue to differentiate normal from abnormal findings. A tissue biopsy may also need to be performed to determine whether abnormal findings are cancer, normal tissue, or other type of lesion. WPSI also recommended removing the following sentence from the existing Guideline, ''These screening recommendations are for women at average risk of breast cancer'' as this information is now included in the revised first sentence of the updated Guideline.

WPSI received thirteen comments on this proposed update. One comment requested a definition for ''women at average risk,'' which is provided in the full evidence review and will be restated on WPSI's website, as the 2016 evidence review defined ''women at average risk'' as those without risk factors indicating high risk (includes deleterious BRCA mutations and their untested first-degree relatives; other hereditary genetic syndromes; previously diagnosed high-risk breast lesions; and history of high dose radiation therapy to the chest between the ages of 10 to 30 years). Two commenters requested screening for women under age 40. No change was made as WSPI did not document new evidence changes in its review. Others requested screening for women of increased risk. No change was made in response to these comments as this specific guideline relates to women at average risk of breast cancer. Another comment requested edits to the recommendation related to racial disparities and gender inclusivity WSPI made no changes given that the proposed recommendation is intended to address all women at average risk. Three commenters requested that the recommendation address ''annual screening'' and one commenter opposed ending screening at age 74. No changes were made based on these comments as they were not supported by evidence that met WPSI's inclusion criteria. One commenter suggested that the recommendation would be clearer if the phrase ''pathology exams'' was changed to ''pathology tests.'' In response to this comment, WPSI updated the recommendation to ''pathology evaluation'' to improve clarity. Multiple commenters requested language to address dense breast tissue, and one recommended using digital mammography for women with dense breast tissue. While there are currently no randomized controlled trials to support separate recommendations for women with dense breasts, the updated clinical recommendation supports additional testing to complete initial screening, if needed, which may be more common for women with dense breasts. No changes were made in response to these comments. One comment recommended WPSI align with the U.S. Preventive Services Task Force (USPSTF) recommendations on breast cancer screening. No changes were made in response to this comment as WPSI's charge differs from that of the USPSTF, with WPSI's statutory authority including coverage of additional preventive care and screenings not described in evidence-based items or services that have a rating of ''A'' or ''B'' in the current recommendations of the USPSTF.

Patient Navigation Services for Breast and Cervical Cancer Screening

Based on clinical research, patient navigation services for breast and cervical cancer screening have been found to be effective in reducing barriers to screening and follow-up care, resulting in higher screening rates. WPSI recommended a new Guideline on Patient Navigation Services for Breast and Cervical Cancer Screening. Breast cancer screening rates were 14.1% higher for 35,752 patients randomized to patient navigation services versus usual care or active controls in a WPSI meta-analysis of 33 randomized control trials based in U.S. health care settings. The same meta-analysis showed rates for cervical cancer screening and follow-up were higher with patient navigation by 15.7%, based on 22 randomized control trials with 12,221 participants. In one study included in WPSI's meta-analysis, prevention care managers working in federally qualified health centers (FQHCs) who employed patient navigation services increased breast cancer screening among patients without a mammogram in the past 18 months to 68% compared to 57% for patients in usual care.

Research also shows that reducing barriers to screening and follow-up care can result in earlier identification of breast and cervical cancer, enabling patients to enter into treatment earlier, preventing progression of these conditions, improving health outcomes and survival rates, and ultimately can reduce disparities in cancer morbidity and mortality. In the meta-analysis, patient navigation services increased screening and follow-up for breast cancer by 10.2% in populations described as low-income.

WPSI received seven comments on this proposed recommendation. Comments were generally supportive and WPSI appreciated the positive feedback. Two commenters recommended adding culturally appropriate components to patient navigation services and addressing relevant social determinants of health. No changes were made based on these comments as these considerations are outlined in the Implementation Considerations section. Three commenters requested including billing and coding guidance to support the implementation of the recommendation. One comment suggested it may be premature to release the guideline without such information. Under its cooperative agreement with HRSA, WPSI develops tools and resources for patients and providers that include information on billing and coding, which will be updated to address these patient navigation services. Another comment requested WPSI expand the Research Recommendations to include comparative effectiveness trials of patient navigation services. WPSI updated the Research Recommendations to include this suggestion. Two commenters questioned the level of evidence available to support the guideline and one of them requested the evidence review. The October 22, 2024, **Federal Register** notice provided data from the WPSI evidence review to detail the clinical effect of the proposed recommendation and the final evidence review includes a comprehensive listing of the clinical evidence considered by WSPI. A final comment requested cervical cancer screening guidelines be updated. WPSI will begin reviewing the evidence for cervical cancer screening in 2025, if funds are available to support the review.

Acceptance of Recommendation

On December 20, 2024, the HRSA Administrator accepted WPSI's recommendations, which are revised as described above, and, as such, updated the HRSA-supported Women's Preventive Services Guidelines. The final Guidelines for these topics read as follows:

(1) Screening and Counseling for Intimate Partner and Domestic Violence

The final Guideline for Screening and Counseling for Intimate Partner and Domestic Violence reads: ''The Women's Preventive Services Initiative recommends screening adolescent and adult women for intimate partner and domestic violence, at least annually, and, when needed, providing or referring to intervention services.

Intimate partner and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and appropriate supportive services.''

(2) Breast Cancer Screening for Women at Average Risk

The final Guideline for Breast Cancer Screening for Women at Average Risk reads: ''The Women's Preventive Services Initiative recommends that women at average risk of breast cancer initiate mammography screening no earlier than age 40 years and no later than age 50 years. Screening mammography should occur at least biennially and as frequently as annually. Women may require additional imaging to complete the screening process or to address findings on the initial screening mammography. If additional imaging (*e.g.,* magnetic resonance imaging (MRI), ultrasound, mammography) and pathology evaluation are indicated, these services also are recommended to complete the screening process for malignancies. Screening should continue through at least age 74 years, and age alone should not be the basis for discontinuing screening.

Women at increased risk also should undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.''

(3) Patient Navigation Services for Breast and Cervical Cancer Screening

The final Guideline for Patient Navigation Services for Breast and Cervical Cancer Screening reads: ''The Women's Preventive Services Initiative recommends patient navigation services for breast and cervical cancer screening and follow-up, as relevant, to increase utilization of screening recommendations based on an assessment of the patient's needs for navigation services. Patient navigation services involve person-to-person (*e.g.,* in-person, virtual, hybrid models) contact with the patient. Components of patient navigation services should be individualized. Services include, but are not limited to, person-centered assessment and planning, health care access and health system navigation, referrals to appropriate support services (*e.g.,* language translation, transportation, and social services), and patient education.''

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 2026. 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).

Carole Johnson,

Administrator.

[FR Doc. 2024–31228 Filed 12–27–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education Payment Program: Updated Methodology To Determine Full-Time Equivalent Resident Count

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

ACTION: Request for public comment.

SUMMARY: This notice seeks public comment on updating the Children's Hospitals Graduate Medical Education (CHGME) Payment Program's method of determining an eligible children's hospital (as defined within the Public Health Service Act) weighted allopathic and osteopathic full-time equivalent (FTE) resident count when a children's hospital's weighted allopathic and osteopathic FTE resident count exceeds its direct graduate medical education (GME) FTE resident cap in order to be consistent with the methodology used by the Centers for Medicare & Medicaid Services (CMS) beginning in the fiscal year (FY) 2026 application cycle.

DATES: Comments on this notice should be received no later than January 29, 2025.

ADDRESSES: Written comments should be submitted to Robyn Duarte, Public Health Analyst, by email *RDuarte1@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: Robyn Duarte, Public Health Analyst, Bureau of Health Workforce, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3254.

SUPPLEMENTARY INFORMATION: The CHGME Payment Program is authorized by section 340E of the Public Health Service Act. For direct GME payments, section 340E(c)(1)(B) requires that the average number of FTE residents in the hospital's approved residency programs be determined according to section 1886(h)(4) of the Social Security Act. As noticed in the March 1, 2001, **Federal Register** (66 FR 12940), section 1886(h)(4) has been implemented by regulations at 42 CFR 413.78 through 413.83 (formerly 42 CFR 413.86(f)–(i)), which HRSA has used to determine the total and weighted numbers of FTE residents. In the CMS FY 2023 inpatient prospective payment systems (IPPS) and long-term care hospital prospective payment system (LTCH PPS) final rule published in the **Federal Register** on August 10, 2022 (87 FR 48780, 49065–49072) (referred to as the ''FY 2023 IPPS/LTCH PPS final rule''), CMS modified the Medicare direct GME payment methodology and amended section 413.79 by revising paragraphs (c)(2)(iii) and (d)(3). Through this notice, HRSA is seeking comment on its intent to adopt the same direct GME payment methodology as CMS when HRSA calculates FTE residents for the CHGME Payment Program beginning in the FY 2026 application cycle.

Background

To the extent feasible, HRSA has historically sought consistency with CMS regulations to minimize burden for children's teaching hospitals participating in the CHGME Payment Program that must also comply with CMS regulations. Consistency reduces the potential challenges in reporting FTE resident counts to Medicare and CHGME.

Currently, the CHGME Payment Program methodology for determining the weighted allopathic and osteopathic FTE resident count applies the direct GME FTE resident cap when a hospital's weighted allopathic and osteopathic FTE resident count is greater than its direct GME FTE resident cap. The current CHGME direct GME methodology reduces a hospital's weighted direct GME resident count by a proportion equal to the ratio of its GME FTE resident cap to its unweighted direct GME resident count. The direct GME FTE resident cap is applied to reduce the weighting factor of residents who are beyond their initial residency