identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–2107 for ''Cross Labeling Oncology Drugs in Combination Regimens.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Marc Theoret, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2218, Silver Spring, MD 20993, 301–796–4099; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Cross Labeling Oncology Drugs in Combination Regimens.'' This guidance describes FDA's current recommendations on including relevant information in labeling for oncology drugs approved for use in combination regimens.

This guidance finalizes the draft guidance of the same title issued on November 20, 2020 (85 FR 74352). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarity on our recommendations for the content of each section of the prescribing information, including how doses or dosage modifications for any other drug in the combination regimen should be described in labeling.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cross Labeling Oncology Drugs in Combination Regimens.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314, including the submission of labeling in 21 CFR 314.50(e)(2)(ii) and (l)(1)(i) and the submission of new drug applications (NDAs) and supplemental NDAs, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 regarding the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information for the content and format of prescription drug labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information in FDA's guidance entitled ''Formal Meetings Between FDA and Sponsors and Applicants for PDUFA Products'' have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23866 Filed 11–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Request for Public Comment on Two Draft Recommendations To Update the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Diabetes in Pregnancy and Screening for Type 2 Diabetes After Pregnancy

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

ACTION: Notice.

SUMMARY: This notice seeks comments on two draft recommendations to update the HRSA-Supported Women's Preventive Services Guidelines (''Guidelines'') relating to Screening for Diabetes in Pregnancy and Screening for Type 2 Diabetes after Pregnancy. The existing Guidelines address Screening for Gestational Diabetes Mellitus (GDM) and Screening for Diabetes Mellitus after Pregnancy. These draft recommendations have been developed through a cooperative agreement, known as the Women's Preventive Services Initiative (WPSI), with the American College of Obstetricians and Gynecologists (ACOG), through which they convene health professionals to develop draft recommendations. 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, which describe how group health plans and health insurance issuers apply the coverage requirements.

DATES: Members of the public are invited to provide written comments no later than December 5, 2022. All comments received on or before this date will be reviewed and considered by WPSI and provided for further consideration by HRSA in determining the recommended updates that it will support.

ADDRESSES: Members of the public who wish to provide comments can do so by accessing the public comment web page at *https://www.hrsa.gov/womens-guidelines.*

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Under section 1001(5) of the Patient Protection and Affordable Care Act, Public Law 111–148, which added section 2713 to the Public Health Service Act, 42 U.S.C. 300gg–13, 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 the Department of Health and Human Services. Since 2011, there have been advancements in science and gaps identified in these guidelines, including a greater emphasis on practice-based clinical considerations. Accordingly, since March 2016, HRSA has funded cooperative agreements with ACOG, known as the 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. Under the cooperative agreement, ACOG formed WPSI, consisting of 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 organizational representatives who are 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 then takes the HRSA-approved recommendations and disseminates them through the development of implementation tools and resources for both patients and practitioners.

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.

The existing Guidelines relating to diabetes state:

''**Screening for Gestational Diabetes Mellitus**

WPSI recommends screening pregnant women for GDM after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

WPSI suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.''

''**Screening for Diabetes Mellitus After Pregnancy**

WPSI recommends women with a history of GDM who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum (see Table 1).

Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (*e.g.,* oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first 6 months postpartum regardless of the result.''

Draft Updated Clinical Recommendations for Public Comment

Screening for Diabetes in Pregnancy

WPSI proposes to update the Screening for GDM Guideline to revise the title to read ''Screening for Diabetes in Pregnancy'' and to revise the clinical recommendation to read: ''The Women's Preventive Services Initiative recommends screening pregnant women for GDM after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) to prevent adverse birth outcomes. WPSI recommends screening pregnant women with risk factors for type 2 diabetes or GDM before 24 weeks of gestation—ideally at the first prenatal visit.''

Screening for Type 2 Diabetes After Pregnancy

WPSI also proposes to update the Screening for Diabetes Mellitus after Pregnancy Guideline to revise the title to read ''Screening for Type 2 Diabetes after Pregnancy'' and to revise the

clinical recommendation to read: ''The WPSI recommends screening for type 2 diabetes in women with a history of GDM who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum. Women who were not screened in the first year postpartum or women with a negative initial postpartum screening test result should be screened at least every 3 years for a minimum of 10 years after pregnancy. For those with a positive screening test result in the early postpartum period (*i.e.,* 4–6 weeks postpartum), testing should be repeated at least 6 months postpartum to confirm the diagnosis of diabetes regardless of the type of initial test (*e.g.,* fasting plasma glucose, hemoglobin A1c, oral glucose tolerance test). Repeat testing is also indicated for women screened with hemoglobin A1c in the first 6 months postpartum regardless of whether the test results are positive or negative because the hemoglobin A1c test is less accurate during the first 6 months postpartum.''

Discussion of Updated Clinical Recommendations

Screening for Diabetes in Pregnancy

WPSI recommended three updates to the Guideline on Screening for GDM. The first change is a revision to the title of the Guideline from ''Screening for GDM'' to ''Screening for Diabetes in Pregnancy.'' This change to the title was made for consistency with the clinical recommendation, which includes screening for gestational diabetes and screening for preexisting diabetes, as the previous title described a more limited scope in screening. The second update recommended by WPSI is to change language in the second sentence of the recommendation from ''diabetes mellitus'' to ''type 2 diabetes or GDM.'' This change reflects that ''diabetes mellitus'' is commonly described as type 2 diabetes. Third, WPSI modified the recommendation by relocating the information on specific types of screening to the Implementation Considerations section of the Guideline. The existing Guideline recommends the 2-step approach, because of its high sensitivity and specificity. In its recommended update, WPSI continues to recommend the 2-step approach, but has relocated it to the Implementation Considerations section, and also added the 1-step approach to the list of screening modalities in the Implementation Considerations section, because both approaches are acceptable screening tests based on studies described in the updated 2021 United States Preventive Services Task Force evidence review. Both the 1-step and 2-step screening modalities are within the scope of this Guideline.

Screening for Type 2 Diabetes After Pregnancy

WPSI also recommended five updates to the Guideline on Screening for Diabetes Mellitus After Pregnancy. First, WPSI recommended updating the title of the Guideline by changing it from ''Screening for Diabetes Mellitus After Pregnancy'' to ''Screening for Type 2 Diabetes After Pregnancy.'' This change was made because ''diabetes mellitus'' is now more commonly described as type 2 diabetes. Second, WPSI recommended removing the reference to Table 1 based upon feedback from the clinical community, noting that the table might be confusing and could be simplified in written format, and recommended including this information in narrative form. Third, WPSI recommends screening for ''women who are not screened in the first year postpartum'' and ''women with a positive screening test result in early postpartum.'' This recommendation was added to ensure screening for women who were not screened postpartum for various reasons (*e.g.,* scheduling, lack of transportation, availability of testing, etc.), and to reflect that universal screening for women with a history of GDM is more appropriate than risk-based screening because the risk of developing type 2 diabetes is high among all such individuals. Fourth, WPSI also recommended adding new language to recommend repeat testing after 6 months postpartum to confirm a positive test result from the early postpartum period (4–6 weeks postpartum). Fifth, WPSI also recommended adding new language to the Guideline explaining that hemoglobin A1c tests conducted within the first 6 months postpartum should be repeated because the test is less accurate when conducted during the first 6 months postpartum. Screening for type 2 diabetes after pregnancy as described in this Guideline, including follow-up diabetes screening testing, is within the scope of this Guideline.

Members of the public can view each complete updated draft recommendation by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

Carole Johnson,

Administrator.

[FR Doc. 2022–23860 Filed 11–2–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting and Solicitation for Written Comment

AGENCY: Department of Health and Human Services, Office of the Secretary, Office for Civil Rights, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders.

ACTION: Notice of meeting and solicitation for written comment.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders will hold a virtual, two-day meeting on December 5 and December 6, 2022.

DATES: The Commission will meet on December 5, 2022, and December 6, 2022, from 4:00 p.m. Eastern Time (ET) to approximately 7:00 p.m. ET on both days. The confirmed time and agenda will be posted on the website for the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders: *https://www.hhs.gov/about/whiaanhpi/commission/index.html* when this information becomes available.

Written comments, in response to the questions listed below, will be accepted via email at *AANHPICommission@hhs.gov* with the subject line ''PACAANHPI: Response to <insert the issue and question>.'' To be assured consideration in the development of future recommendations, written comments must be submitted and received at the email address provided above, no later than 11:59 p.m. ET on Thursday, December 1, 2022. Submissions received after the deadline will not be reviewed.

ADDRESSES: The meeting will be live streamed. Registration is required through the following link: *https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpis-registration-449829250397.*

FOR FURTHER INFORMATION CONTACT: Caroline Goon, Designated Federal