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 (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Grillo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0591; or James Myers, 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FDA is announcing the availability of a draft guidance for industry entitled ''Drug Interactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance is intended to assist applicants in developing the DRUG INTERACTIONS section of the Prescribing Information labeling as described in FDA regulations for the content and format of labeling for human prescription drug and biological products.[1]

Prescription drug labeling must contain a summary of the essential information necessary for safe and effective use of the drug and is a primary tool for FDA to communicate drug interaction information to healthcare practitioners. Effective communication of drug interaction information informs the optimal use of the drug and the healthcare practitioner's clinical decision-making (*e.g.,* prescribing decisions or management instructions).

The purpose of this guidance is to provide recommendations on what information to include in, and how to present and organize the information within, the DRUG INTERACTIONS section of prescription drug labeling to enhance communication of clinically significant drug interactions and facilitate the safe and effective use of prescription drugs by healthcare practitioners. This guidance also provides illustrative examples of the content and format of drug interaction information in prescription drug labeling.

In addition, the guidance includes an FDA website (*https://www.fda.gov/CYPandTransporterInteractingDrugs*) as one resource that health care practitioners can use to view examples of clinical substrates, inhibitors, and inducers of Cytochrome P–450 (CYP) enzymes and substrates and inhibitors of transporters. FDA is seeking input regarding the utility of this website as a resource that health care practitioners can reference to find examples of clinical substrates, inhibitors, and inducers of CYP enzymes and substrates and inhibitors of transporters. FDA is also seeking input on ways to describe drug interactions in labeling, specifically when drugs have numerous, clinically relevant drug interactions (*e.g.,* azole antimycotics) that require listing many interactions. In addition, FDA is seeking input on ways to describe complex drug-interaction scenarios, including but not limited to:

- Concurrent inhibition of an enzyme and a transporter by a drug;
- Concurrent inhibition and induction of a drug's metabolic pathway by one or more enzymes;
- Increased inhibition of drug elimination by use of inhibitors of more than one enzyme that metabolizes the drug;
- Inhibition of an enzyme other than the genetic polymorphic enzyme in poor metabolizers taking a substrate metabolized by both enzymes;
- Effect of enzyme/transporter inhibitors in subjects with organ impairment; and
- Two drugs acting as both precipitant and object of a drug interaction.

The draft guidance, when finalized, will represent the current thinking of FDA on ''Drug Interaction Information in Human Prescription Drug and Biological Product Labeling.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 314 and 601 are approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information in 21 CFR parts 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

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

Dated: October 16, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24442 Filed 10–21–24; 8:45 am]

BILLING CODE 4164–01–P

[1] 21 CFR 201.56(a) and (d) and 201.57(c)(8). This guidance applies to drugs, including biological products that are regulated as drugs. For the purpose of this guidance, ''drug product'' or ''drug'' will be used to refer to human prescription drug and biological products that are regulated as drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Request for Public Comments on Draft Recommendations for the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening and Counseling for Intimate Partner and Domestic Violence, Breast Cancer Screening for Women at Average Risk, and Patient Navigation for Breast and Cervical Cancer Screening

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

ACTION: Notice.

SUMMARY: This notice seeks comment on draft recommendations for the HRSA-supported Women's Preventive Services Guidelines (''Guidelines'') relating to Screening and Counseling for Intimate Partner and Domestic Violence, Breast Cancer Screening for Women at Average Risk, and Patient Navigation for Breast and Cervical Cancer Screening. These draft recommendations have been developed by the Women's Preventive Services Initiative (WPSI), through which clinicians, academics, and expert health professionals develop draft recommendations for HRSA's consideration. Under applicable law, non-grandfathered group health plans and health insurance issuers 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 Treasury have issued regulations and policy guidance 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 November 21, 2024. 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.womenspreventivehealth.org/.*

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 HRSA-Supported Women's Preventive Services 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.

Since 2016, HRSA has funded cooperative agreements to support WPSI to convene 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 women's health across the lifespan. HRSA determines whether to support, in whole or in part, the recommended updates to the Guidelines. WPSI consists 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 takes 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 its recommendations to update the Guidelines. This notice seeks comment on three Guidelines:

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

WPSI recommends updating the existing Guideline for Screening and Counseling for Interpersonal and Domestic Violence. The current Guideline for Screening and Counseling for Interpersonal and Domestic Violence is: ''WPSI recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing, or referring for initial intervention services. Interpersonal 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 referral to appropriate supportive services.''

The proposed updated Guideline for Screening and Counseling for Intimate Partner and Domestic Violence is: ''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 referral to appropriate supportive services.''

Background

WPSI recommends several updates to the language of this Guideline. The first change is a revision to the title of the Guideline from ''Interpersonal and Domestic Violence'' to ''Intimate Partner and Domestic Violence.'' This change to the title was made to be consistent with language generally used in the clinical setting and the more commonly used term of ''intimate partner violence'' in the medical field. Corresponding revisions to change references from ''interpersonal'' to ''intimate partner'' have been made throughout the text of the recommendation. WPSI also recommends 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 assist with clarity on the meaning of ''intervention services.'' Comments are sought on these proposed updates.

(2) Breast Cancer Screening for Women at Average Risk

WPSI is recommending updating the existing Guideline for Breast Cancer Screening for Average-Risk Women. The current guideline for Breast Cancer Screening for Average-Risk Women is: ''WPSI recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

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

The proposed updated Guideline for Breast Cancer Screening for Women at Average Risk is: ''The Women's Preventive Services Initiative recommends that women at average-risk of breast cancer initiate mammography screening no earlier than age 40 and no later than age 50. 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.,* MRI, ultrasound, mammography) and pathology exams are indicated, those services are also recommended to complete the screening process for malignancies. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

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

Background

WPSI recommends several updates to the language of this Guideline. The first change is a revision to the title from ''Breast Cancer Screening for Average-Risk Women'' to ''Breast Cancer Screening for Women at Average Risk.'' This change to the title was made to be consistent with changes recommended for the first sentence of this Guideline and to use person-first language that puts the individual before the diagnosis or screening modality. WPSI recommends updates to the first sentence of this Guideline, replacing the phrase ''average-risk women'' with ''women at average-risk for breast cancer'' to clarify that the target population for this recommendation is specific to breast cancer.

Two new sentences were added to follow 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 modifications address the circumstances where initial mammography screening for women at average risk for breast cancer is incomplete or additional action is necessary to fully complete breast cancer screening for the individual. Specifically, these two sentences were added to ensure completed screening for women who were initially screened for breast cancer and need additional screening tests. Imaging in addition to initial screening 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. In an analysis of 405,191 women in the Breast Cancer Surveillance Consortium breast imaging registry who underwent digital mammography, 40,557 (10 percent) were recommended for additional imaging, and 6,628 (1.6 percent) were recommended for biopsy.[1]

WPSI also has 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. Comments are sought on these proposed updates.

(3) Patient Navigation for Breast and Cervical Cancer Screening

WPSI is proposing a new Guideline for Patient Navigation for Breast and Cervical Cancer Screening, as follows: ''The Women's Preventive Services Initiative (WPSI) 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 need 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.''

Background

WPSI has submitted a new draft clinical recommendation on Patient Navigation for Breast and Cervical Cancer Screening for review, comment, and consideration. Recent clinical research has found consistent effectiveness of patient navigation services for breast and cervical cancer screening in reducing barriers to screening and follow-up care, resulting in higher screening rates. 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.

Research suggests that patient navigation is effective across a wide range of health care settings and provider types. 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.[2] Another study included in the meta-analysis analyzed rural Latinas who had not previously undergone recommended screening. The study found that enhanced education efforts increased cervical cancer screening to 53.4% as compared to 34% in usual care without these navigation services.[3]

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. Based on this

[1] Nelson HD, O'Meara ES, Kerlikowske K, Balch S, Miglioretti D. Factors Associated With Rates of False-Positive and False-Negative Results From Digital Mammography Screening: An Analysis of Registry Data. Ann Intern Med. 2016 Feb 16;164(4):226–35. doi: 10.7326/M15–0971. Epub 2016 Jan 12. PMID: 26756902; PMCID: PMC5091936.

[2] Beach ML, Flood AB, Robinson CM, et al. Can language-concordant prevention care managers improve cancer screening rates? Cancer Epidemiol Biomarkers Prev. 2007;16(10):2058–64. doi: 10.1158/1055–9965.EPI–07–0373. PMID: 17932353.

[3] Thompson B, Carosso EA, Jhingan E, et al. Results of a randomized controlled trial to increase cervical cancer screening among rural Latinas. Cancer. 2017;123(4):666–74. doi: 10.1002/cncr.30399. PMID: 27787893.

clinical evidence that supports the preventive benefits of patient navigation services for breast and cervical cancer screening, WPSI recommends adding these patient navigation services to the Guidelines. Comments are sought on this proposed Guideline.

Members of the public can view the complete updated and new draft clinical recommendations, as well as the implementation considerations and research recommendations (which are not part of the Guidelines), by accessing WPSI's web page at *https://www.womenspreventivehealth.org/.*

Carole Johnson,

Administrator.

[FR Doc. 2024–24445 Filed 10–21–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD or Committee) will hold one additional public meeting in the 2024 calendar year. Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings.* This notice is consistent with the information about ACTPCMD's calendar year 2024 meetings found in the **Federal Register** notice dated May 15, 2024, Meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry.

DATES: The ACTPCMD meeting will be held on:

- November 15, 2024, 10:00 a.m.–5:00 p.m. Eastern Time.

ADDRESSES: This meeting will be held by teleconference and/or a video conference platform. For updates on how the meeting will be held, visit the ACTPCMD website 20 days before the date of the meeting, where instructions for joining the meeting will be posted. For meeting information updates, go to the ACTPCMD website meeting page at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Officer, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N102, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary of Health and Human Services as well as the Chair and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. ACTPCMD also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C of the PHS Act, and recommends appropriation levels for programs under this Part.

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For the November 15th meeting, agenda items may include, but are not limited to, discussion of recommendations for the committee's 23rd report, as well as exploratory topic discussions for the committee's 24th report. Refer to the ACTPCMD website listed above for all current and updated information concerning the November 15th ACTPCMD meeting, including the agenda and meeting materials that will be posted 20 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACTPCMD should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date.

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the meeting they wish to attend.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–24328 Filed 10–21–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Black Lung Clinics Program Performance Measures

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 21, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION: