TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Recommended disclosure activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
The publication date of any referenced or included publication(s) (if not specified in the publication or citation); Q2.	1,008	3	3,024	0.1 (6 minutes)	302.4
When firms share an SIUU communication in the form of an unabridged CPG or reference text in its entirety that discusses a wide range of medical products and that discussion is not primarily focused on one or more of a firm's medical products, the firm should include, in lieu of some of the specific disclosures listed above, a more general statement in the SIUU communication, such as ''This [CPG/reference text] describes some uses of medical products that are not approved by the FDA and the safety and effectiveness of any unapproved use(s) have not been established.''; Q4.	1,008	3	3,024	0.1 (6 minutes)	302.4
When firms share an SIUU communication in the form of a firm-generated presentation of scientific information from an accompanying reprint that SIUU communication should clearly disclose what portions of the communication are firm-generated; Q4.	1,008	10	10,080	0.1 (6 minutes)	1,008
Total	.....	.....	174,384	.....	75,902.4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a current listing of firms promoting approved/cleared human and animal drug products (747), combined with an estimated number of device firms marketing products (261), we assume 1,008 firms (''number of respondents'' in table (1) may each choose to publicly share 30 *SIUU communications* annually. Our estimate of the burden per disclosure (2.5 hours) reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

III. Request for Comment on Other Issues for Consideration

FDA is interested in additional matters related to communications by *firms* about scientific information on *unapproved use(s)* of *approved/cleared medical products.* This revised draft guidance pertains to these communications by *firms* to *HCPs* engaged in making clinical practice decisions for the care of an individual patient. FDA is specifically seeking input on the following:

1. What considerations, if any, exist that are unique to communications of scientific information about *unapproved use(s)* of *approved/cleared medical products* by *firms* to researchers (including *HCPs* working in their capacity as researchers)?

2. What other factors should *firms* consider when sharing firm-generated presentations (as described in the draft guidance) to ensure that presentations are truthful, non-misleading, factual and unbiased and provide all information necessary for *HCPs* to interpret the strengths and weaknesses and validity and utility of the presented information?

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*, *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: October 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23372 Filed 10–23–23; 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 Proposed Update to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents

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

ACTION: Notice.

SUMMARY: This notice seeks public comment on a proposed update to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care (''Bright Futures Periodicity Schedule''), as part of the HRSA-supported preventive services guidelines for infants, children, and adolescents.

DATES: Members of the public are invited to provide written comments on the proposed update no later than November 24, 2023. All comments received on or before this date will be reviewed and considered by the Bright Futures Periodicity Schedule Working Group and provided for further consideration by HRSA in determining the recommended updates that it will support.

ADDRESSES: Members of the public interested in providing comments can do so by accessing the public comment web page at: *www.aap.org/en/forms/bright-futures-american-academy-of-pediatrics-recommendations-preventive-health-care/.*

FOR FURTHER INFORMATION CONTACT: Savannah Kidd, M.S., M.F.T.; Senior Public Health Analyst; Division of Child, Adolescent, and Family Health; Maternal and Child Health Bureau; HRSA; email: *SKidd@hrsa.gov,* telephone: 301–287–2601.

SUPPLEMENTARY INFORMATION: The Bright Futures Periodicity Schedule is maintained through a cooperative agreement, the Infant, Child, and Adolescent Preventive Services Program, for which the American Academy of Pediatrics (AAP) is the current recipient. When its preventive care and screening recommendations have been accepted by HRSA, the Bright Futures Periodicity Schedule is part of the HRSA-supported preventive services guidelines for infants, children, and adolescents. Under section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13) and pertinent regulations, non-grandfathered group health plans and health insurance issuers must provide coverage, without cost sharing, for certain preventive services for plan years (in the individual market, policy years) that begin on or after the date that is 1 year after the date the recommendation or guideline is issued. These include HRSA-supported preventive health services provided for in the Bright Futures Periodicity Schedule as part of the HRSA-supported preventive services guidelines for infants, children, and adolescents under 42 U.S.C. 300gg–13(a)(3).

Through the Infant, Child, and Adolescent Preventive Services cooperative agreement, the AAP is required to administer a process for developing and regularly recommending, as needed, updates to the Bright Futures Periodicity Schedule through a comprehensive, objective, and transparent review of available evidence that incorporates opportunity for public comment. Accordingly, AAP reviews the evidence to determine whether updates are needed, develops recommended updates, seeks and considers public comments, and makes recommendations to HRSA. The proposed update to the Bright Futures Periodicity Schedule includes additions to existing footnotes, which provide up-to-date information and recommendations to providers but will not change the clinical recommendations and associated requirement for coverage without cost-sharing under section 2713 of the Public Health Service Act. The footnotes that AAP proposes to be revised are as follows:

1. Footnote 4, relating to the first week well-child visit, also called the 3–5 Day Visit, will be revised with an updated reference that aligns with the Bright Futures recommendation regarding providers helping families that choose to breastfeed.

2. Footnote 5, relating to Body Mass Index, is the *Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity* (*https://doi.org/10.1542/peds.2022-060640*) published in the January 2023 issue of Pediatrics. This updated reference aligns with the Bright Futures recommendation regarding measuring body mass index starting at the 24-month visit through the 21-year visit and provides non-stigmatizing recommendations for evaluating and treating children who are experiencing weight gains.

3. Footnote 14, relating to Behavioral/Social/Emotional Screening, is the U.S. Preventive Services Task Force Recommendation Statement, *Screening for Anxiety in Children and Adolescents* (*https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-anxiety-children-adolescents*) published in the October 2022 issue of the Journal of the American Medical Association. This additional reference aligns with the Bright Futures recommendation to use screening instruments to better identify children experiencing anxiety, followed by a confirmatory diagnostic assessment and follow-up.

4. Footnote 15, relating to Tobacco, Alcohol, or Drug Use Assessment, is the Centers for Disease Control and Prevention's *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States* (*https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf*) and the National Institute on Drug Abuse's policy brief, *Naloxone for Opioid Overdose: Life-Saving Science* (*https://nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science*). The proposed footnote aligns with the Bright Futures recommendation to assess patients for substance use with a validated screening tool. These additional references also describe the utility of prescribing Naloxone if there is concern for substance or opioid use.

5. Footnote 21, relating to Newborn Bilirubin Screening, is *Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation* (*https://doi.org/10.1542/peds.2022-058859*), published in the August 2022 issue of Pediatrics. This reference aligns with the Bright Futures recommendation for universal bilirubin screening for all newborn infants between 24 and 28 hours after birth.

6. Footnote 35, relating to Oral Health, is *Maintaining and Improving the Oral Health of Young Children* (*https://doi.org/10.1542/peds.2022-060417*), published in the December 2022 issue of Pediatrics. This reference aligns with the Bright Futures recommendation that every child has a dental home by 1 year of age. Additionally, the updated reference encourages providers to screen for social determinants of health, as well as access to medical and dental care, as they influence oral health status and oral health inequities.

With respect to Footnote 15, HRSA welcomes comment on the evidence regarding the effect of prescribing Naloxone in the setting of a primary care preventive visit on preventing or reducing opioid overdoses and opioid overdose deaths.

Authority: Section 2713(a)(3) of the Public Health Service Act, 42 U.S.C. 300gg–13(a)(3).

Carole Johnson,

Administrator.

[FR Doc. 2023–23396 Filed 10–23–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Lara S. Hwa, Ph.D. (Respondent), who is an Assistant Professor, Department of Psychology and Neuroscience, Baylor University (BU), and formerly was a Postdoctoral Fellow, School of Medicine, University of North Carolina at Chapel Hill (UNC–CH). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH), grants K99/R00 AA027576, T32 AA007573, F31 AA027129, F32 AA026485, R01 AA019454, U01 AA020911, R01 AA025582, and P60 AA011605 and included in two grant applications submitted for PHS funds, specifically K99 AA027576 submitted to NIAAA, NIH, and R01 DK136486 submitted to