

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

| Activity   | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours   |
|--|-----------------------|--------------------------------------|--------------------------|-------------------------------|---------------|
| Consultation between the hospital or health system pharmacy and the prescriber to document the statement of significant difference (revised draft guidance).   | 1,538                 | 30                                   | 46,140                   | .08 (5 minutes) .....         | 3,691         |
| Consultation between the hospital or health system pharmacy and prescriber and the notation on the prescription documenting the prescriber's determination of significant difference (503A copies guidance). | 1,537                 | 50                                   | 76,850                   | .05 (3 minutes) .....         | 3,843         |
| Hospital or health system pharmacy checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage (503A copies guidance).  | 4,613                 | 200                                  | 922,600                  | .03 (2 minutes) .....         | 27,678        |
| <b>Total</b> .....   |                       |                                      |                          |                               | <b>35,212</b> |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| Activity   | Number of record-keepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours  |
|--|--------------------------|------------------------------------|----------------------|----------------------------------|--------------|
| Records of the statement of significant difference (revised draft guidance) .....  | 1,538                    | 30                                 | 46,140               | .03 (2 minutes) .....            | 1,384        |
| Records of documentation of significant difference (503A copies guidance) .....  | 1,537                    | 50                                 | 76,850               | .03 (2 minutes) .....            | 2,306        |
| Records of frequency and number of prescriptions filled for compounded drug products that are essentially a copy (503A copies guidance). | 3,075                    | 20                                 | 61,500               | .03 (2 minutes) .....            | 1,845        |
| <b>Total</b> .....   |                          |                                    |                      |                                  | <b>5,535</b> |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**IV. Electronic Access**

Persons with access to the internet may obtain an electronic version of the revised draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 4, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–21970 Filed 10–6–21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Request for comments on the draft Department Strategic Plan for FY 2022–2026**

**AGENCY:** Office of the Secretary, Office of the Assistant Secretary for Planning and Evaluation, Health and Human Services.

**ACTION:** Request for comments on the draft HHS Strategic Plan FY 2022–2026.

**SUMMARY:** The Department of Health and Human Services (HHS) is seeking public comment on its draft Strategic Plan for Fiscal Years 2022–2026 through the Department of Health and Human Services website at [www.hhs.gov/about/draft-strategic-plan/index.html](http://www.hhs.gov/about/draft-strategic-plan/index.html).

**DATES:** Submit comments on or before November 7, 2021.

**ADDRESSES:** Written comments can be provided by email, Fax, or U.S. mail.

*Email: [HHSPPlan@hhs.gov](mailto:HHSPPlan@hhs.gov).*

*Fax: (202) 690–5882.*

*Mail:* U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Division of Strategic Planning, Attn: Strategic Plan Comments, 200 Independence Avenue SW, Room 434E, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:**

Margo Bailey, (202) 730–8504.

**SUPPLEMENTARY INFORMATION:** The draft Department of Health and Human Services Strategic Plan FY 2022–2026 is provided as part of the strategic planning process under the Government Performance and Results Modernization Act of 2010 (GPRA–MA)(Pub. L. 111–352) to ensure that Agency stakeholders are given an opportunity to comment on this plan.

This document articulates how the Department will achieve its mission through five strategic goals. These five strategic goals are (1) Protect and Strengthen Equitable Access to High Quality and Affordable Health Care, (2) Safeguard and Improve National and Global Health Conditions and Outcomes, (3) Strengthen Social Well-being, Equity, and Economic Resilience, (4) Restore Trust and Accelerate Advancements in Science and Research for All, and (5) Advance Strategic Management to Build Trust, Transparency, and Accountability. Each goal is supported by objectives and strategies.

The strategic planning consultation process is an opportunity for the Department to refine and strengthen the HHS Strategic Plan FY 2022–2026. We look forward to receiving your comments by November 7, 2021. The text of the draft HHS Strategic Plan FY 2022–2026 is available through the Department of Health and Human Services website at [www.hhs.gov/about/draft-strategic-plan/index.html](http://www.hhs.gov/about/draft-strategic-plan/index.html). For comparison purposes, the current HHS Strategic Plan FY 2018–2022 can be viewed at <https://www.hhs.gov/about/strategic-plan/index.html>.

For those who may not have internet access, a hard copy can be requested from the contact point, Margo Bailey, (202) 730–8504.

Dated: September 29, 2021.

**Rebecca Haffajee,**

*Acting Assistant Secretary for Planning and Evaluation (ASPE), Principal Deputy, ASPE.*

[FR Doc. 2021–21939 Filed 10–5–21; 8:45 am]

**BILLING CODE 4150–05–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Request for Public Comments on the Development of the 2021–2022 IACC Strategic Plan for Autism Spectrum Disorder (ASD)**

**SUMMARY:** On behalf of the Interagency Autism Coordinating Committee (IACC), the National Institute of Mental Health (NIMH) Office of Autism Research

Coordination (OARC) is seeking public comments to assist the IACC in identifying priorities for the 2021–2022 update of the IACC Strategic Plan for Autism Spectrum Disorder (ASD) as required by the Autism Collaboration, Accountability, Research, Education and Support (CARES) Act of 2019. The IACC is requesting public comments on research, services, and policy issues related to the seven topics addressed by the IACC Strategic Plan: Screening and Diagnosis, Biology, Risk Factors, Treatments and Interventions, Services, Lifespan Issues, and Infrastructure and Surveillance. The IACC is also requesting information on two additional issues related to autism described in two supplemental questions that are included in this Request for Public Comment.

**DATES:** Responses to this notice are voluntary and the public comment period will be open from October 1, 2021–November 30, 2021.

**ADDRESSES:** All comments must be submitted electronically via the web-based form at: <https://iacc.hhs.gov/meetings/public-comments/requests-for-information/2021/strategic-plan.shtml>.

**FOR FURTHER INFORMATION CONTACT:** Specific questions about this Request for Public Comment should be directed to: Rebecca Martin by phone at (301) 435–0886 or email at [iaccpublicinquiries@mail.nih.gov](mailto:iaccpublicinquiries@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The IACC <http://www.iacc.hhs.gov/> is a federal advisory committee composed of federal and public members that provides advice to the Secretary of Health and Human Services on autism spectrum disorder. The Committee is authorized under the Autism CARES Act of 2019, Public Law 116–60. The law requires that the IACC develop a Strategic Plan for autism research and update the Plan annually. The current IACC Strategic Plan can be viewed at: <https://iacc.hhs.gov/publications/strategic-plan/2019/>. The IACC last provided an update on the progress of the Strategic Plan in 2019, after which the committee went out of session as a new committee was being appointed. The IACC reconvened in July 2021 and is now developing a new update of the IACC Strategic Plan.

The IACC Strategic Plan chapters are organized around seven topic areas that are related to community-focused questions:

- Question 1. How Can I Recognize the Signs of ASD, and Why is Early Detection So Important? (Topic: Screening and Diagnosis)
- Question 2. What Is the Biology Underlying ASD? (Topic: Biology)

- Question 3. What Causes ASD, and Can Disabling Aspects of ASD be Prevented or Preempted? (Topic: Risk Factors)
- Question 4. Which Treatments and Interventions Will Help? (Topic: Treatments and Interventions)
- Question 5. What Kinds of Services and Supports Are Needed to Maximize Quality of Life for People on the Autism Spectrum? (Topic: Services)
- Question 6. How Can We Meet the Needs of People with ASD as They Progress into and through Adulthood? (Topic: Lifespan Issues)
- Question 7. How Do We Continue to Build, Expand, and Enhance the Infrastructure System to Meet the Needs of the ASD Community? (Topic: Infrastructure and Surveillance)

The Committee also seeks public comment related to the two following questions:

- Supplemental Question 1. What are important issues for the IACC to consider with regard to the impact of the COVID–19 pandemic on the autism community?
- Supplemental Question 2. What are important issues for the IACC to consider with regard to the needs of underserved populations within the autism community, including racial and ethnic minorities, economically disadvantaged communities, and rural populations?

**Submission Information.** For each topic/question in the Request for Public Comment, commenters may provide input on what they consider to be the most important research, services, and policy issues and remaining gaps in the subject area covered by that Question.

Please note that the web form will accept a maximum of 1,500 characters (including letters, numbers, punctuation, etc.) per topic area. A valid email address is required for submission, and only one submission per email address will be accepted. If duplicate submissions are received (*i.e.*, form letters), only one example of such a submission will be included in the final set of comments.

The information that commenters provide will become part of the public record; as such, please do not include any personally identifiable or confidential information in the comments. The web form will provide the option of submitting responses anonymously, or the choice to include a name and/or organization associated with the comment. Comments are subject to redaction in accordance with federal policies and the IACC's public

comment guidelines and privacy policy. To view the IACC's public comment guidelines and privacy policy, visit: <https://iacc.hhs.gov/meetings/public-comments/guidelines/>. All comments or summaries of comments received will be made publicly available on the IACC website [www.iacc.hhs.gov](http://www.iacc.hhs.gov) within 90 days of the closing deadline for this notice. Email addresses associated with comments will not be included as part of the public disclosure. After the closing deadline, responses cannot be edited or withdrawn. No basis for claims against the U.S. Government shall arise as a result of a response to this request for information or from the Government's use of such information.

**Instructions.** All comments must be submitted through the web form at <https://iacc.hhs.gov/meetings/public-comments/requests-for-information/2021/strategic-plan.shtml>. Individuals submitting comments will receive an onscreen confirmation acknowledging receipt of the comment, but commenters will not receive individualized feedback or responses from the IACC. Only one comment per email address will be accepted, and if duplicate comments are received, only one example will be provided to the IACC.

Dated: September 30, 2021.

**Susan A. Daniels,**

*Director, Office of Autism Research Coordination, National Institute of Mental Health.*

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**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.