

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the hospital or health system pharmacy and the prescriber to document the statement of significant difference (revised draft guidance).	1,538	30	46,140	.08 (5 minutes) .....	3,691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Records of the statement of significant difference (revised draft guidance) .....	1,538	30	46,140	.03 (2 minutes) .....	1,384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Persons with access to the internet may obtain an electronic version of the revised draft guidance at either 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.*

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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: [HHSPlan@hhs.gov](mailto:HHSPlan@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.*

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**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