of the FD&C Act (21 U.S.C. 353(e)) to require, under section 503(e)(2)(A) of the FD&C Act (as amended), annual reporting by wholesale distributors, beginning on January 1, 2015. Section 503(e)(2)(B) of the FD&C Act (as amended) requires FDA to make certain information about wholesale distributors' licensure available to the public on FDA's Web site. Section 205 of the DSCSA added section 584 to the FD&C Act (21 U.S.C. 360eee–3); under section 584 of the FD&C Act (as amended), 3PL facilities are required to report annually, beginning on November 27, 2014.

FDA previously published the draft guidance ''DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers'' (Annual Reporting draft guidance), which described who must report, what should be reported, when to report, and how to report (December 9, 2014, 79 FR 73083). The Annual Reporting draft guidance is available on the Wholesale Distributor and Third-Party logistics Providers Reporting Web page at *http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm*. This draft guidance supplements the information in the Annual Reporting draft guidance by addressing questions and comments that FDA received about annual reporting since publication of the Annual Reporting draft guidance. Topics covered in this guidance include clarifications about who must report, what should be reported, when to report, and how to report. This guidance also addresses questions related to the public availability of reported information.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA intends to finalize this draft guidance and the Annual Reporting draft guidance in one unified final guidance on annual reporting requirements under the DSCSA. Once issued that unified final guidance will represent the current thinking of FDA regarding annual reporting by prescription drug wholesale distributors and third-party logistics providers. It will not establish any rights for any person and will not be binding on FDA or the public. You will be able to use an alternative approach to that described in the final guidance if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

This draft guidance addresses proposed information collections that are subject to review by OMB under the PRA. These information collections were also addressed in the draft guidance entitled ''Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers,'' the availability of which was announced in a notice published in the **Federal Register** of December 9, 2014. In that **Federal Register** notice, FDA published a 60-day notice requesting public comment on the proposed collections of information (79 FR 73083). This draft guidance provides further clarification regarding those information collections.

In compliance with the PRA, FDA intends to submit these proposed collections of information to OMB for review and approval, including providing notice of that submission and opportunity for the public to comment to OMB on the proposed information collections. In accordance with the PRA, the agency will inform the public of OMB approval, including the associated currently valid OMB control number, before conducting or sponsoring a collection of information.

Dated: January 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00233 Filed 1–9–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Function and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Chapter AC, ''Office of the Assistant Secretary for Health (OASH), as last amended at 75 FR 53304–53305, dated August 31, 2010. This amendment reflects the realignment of personnel oversight, administration and management functions for the Office of Adolescent Health in the OASH. Specifically, this notice establishes the Division of Research and Evaluation, the Division of Strategic Communications, and the Division of Program Operations within the Office of Adolescent Health. The changes are as follows:

I. Under Part A, Chapter AC, under Office of the Assistant Secretary for Health, make the following changes:

A. Under Section ACR.20, Organization, ''M. Office of Adolescent Health (ACR)'' replace the entire section with:

The Office of Adolescent Health is headed by a Director who reports to the Assistant Secretary for Health.

B. Under Section ACR. 20, Functions, ''M. Office of Adolescent Health (ACR)'' replace the entire section with:

1. Office of Adolescent Health (ACR). The Office of Adolescent Health (OAH), headed by the Director of the Office of Adolescent Health, is responsible for implementing the provisions assigned to it under Section 1708 of the Public Health Service Act (42 U.S.C. 300u–7). The Office, by providing Department-wide leadership working with PHS agencies and other HHS Operating Divisions and Staff Divisions and the private sector, establishes, coordinates and advocates policies, programs and activities for the improvement of adolescent health. OAH supports grant programs, evaluation and research studies, services, prevention and health promotion activities, training, education, partnership engagement, and information dissemination activities. The Office: (1) Oversees operations and administrative management, personnel management, and budget formulation and execution for programs managed within OAH; (2) coordinates legislative and policy activities related to adolescent health and OAH programs; (3) coordinates correspondence control and executive secretariat functions; (4) serves as a focal point within HHS to coordinate the continuing

implementation of health objectives for adolescents, assures liaison occurs with relevant HHS agencies and offices, and facilitates access to services for adolescents; (5) negotiates and awards grants and enters into cooperative agreements and contracts with public and nonprofit entities; (6) enters into interagency agreements with other PHS/Federal organizations in support of adolescent health; (7) ensures the appropriate exercise of delegated authorities and responsibilities; (8) develops a broad range of health information and health promotion materials; (9) supports the planning and conduct of research and evaluation studies; (10) designs, manages and monitors evaluation studies, and information collection review and approval processes; (11) assesses the focus and impact of ongoing programs and activities, and prepares evaluation studies and reports; (12) disseminates information about program activities and research evaluation studies, including in peer reviewed publications; (13) oversees the implementation and administration of competitive grants and cooperative agreements, monitors grantee activities, and prepares analytical reports on program trends; (14) provides training and technical assistance for grant programs and professionals working with adolescents, manages capacity building needs for grant programs, and assesses performance of grantee operations; (15) supports the replication and use of evidence-based approaches and fosters innovative strategies in programs serving adolescents; (16) manages the development of grant funding announcements and contract scopes of work and the review and award of program grants; (17) manages information, education and awareness activities, and media and press relations; (18) develops and coordinates strategic plans and special initiatives; (19) oversees public health information and promotes OAH programs and partnerships; (20) manages exhibits and develops visual and other graphic and social media materials regarding adolescent health, and ensures compliance with 508 requirements; (21) manages adolescent health information, including the OAH Web site and social media, consistent with the policies of the HHS Assistant Secretary for Public Affairs; (22) coordinates, develops, researches, and prepares briefing materials on issues of adolescent health.

II. Delegations of Authority. Directives or orders made by the Secretary, Assistant Secretary for Health, or Director, Office of Adolescent Health, all delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegation, provided they are consistent with this reorganization.

III. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Dated: January 5, 2017.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2017–00312 Filed 1–9–17; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information From Organizations Utilizing Business Models Supporting Private Sector Vaccine Management

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This is a Request for Information (RFI) about business models, existing, under development or planned, that support health care providers for any of the components related to private-sector immunization services (*e.g.,* excluding vaccines provided through federal and state programs, such as the Vaccines for Children Program, Children's Health Insurance Program, Medicaid, and Medicare): Vaccine purchase, distribution, storage and handling, inventory management, reporting to Immunization Information Systems (IIS), including models for populating IIS directly/automatically from electronic health records (EHRs), immunization coverage assessment, forecasting vaccine demand, and billing. The RFI is being issued by the National Vaccine Program Office (NVPO) of the U.S. Department of Health and Human Services.

The NVPO is located in the Office of the Assistant Secretary for Health (ASH), Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS). The NVPO is responsible for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities.

The National Vaccine Program was established in compliance with Title XXI of the Public Health Service Act (Pub. L. 99–660) (§ 2101) (42 U.S. Code 300aa–et seq (PDF—78 KB)) to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. Development of a National Vaccine Plan (NVP) has been mandated to the NVPO as a mechanism for the Director of the National Vaccine Program (the Assistant Secretary for Health) to communicate priorities for both federal and non-federal stakeholders regarding vaccine research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines in order to carry out the program's responsibilities. Goal 4 of the plan, Ensure a Stable Supply of, Access to, and Better Use of Recommended Vaccines in the United States, focuses in part on increasing and improving access to vaccines in health care provider settings. This RFI seeks information on innovative business models to support health care providers to increase and improve their ability to provide immunization services, as described below.

In its efforts to promote vaccination coverage across the lifespan, the NVPO is seeking information about business models, existing, under development or planned, that enable health care providers to offer vaccines to their privately-insured/private-pay patients. The NVPO is most interested in innovative business models aimed at reducing any of the barriers to implementing vaccination services such as vaccine purchase, billing, storage and handling, IIS reporting, including models for populating IIS directly/automatically from EHRs, forecasting vaccine demand, and managing private vaccine inventories. In addition, the NVPO is interested in models that can demonstrate improvements in the immunization coverage rates of the patients seen in the health care settings utilizing such models as well as improvements in reporting to IIS.

DATES: Information from Organizations Utilizing Business Models Supporting Private Sector Vaccine Management responsive to this RFI should be submitted as described in the **ADDRESSES** section below no later than midnight, 12:00 a.m. EDT on January 25, 2017.

ADDRESSES: Information from Organizations Utilizing Business Models Supporting Private Sector Vaccine Management responsive to this RFI should be submitted in Portable