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If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Wednesday, July 10, 2019. The agenda, roster, and minutes will be available from Ms. Heather Phelps, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Phelps' phone number is (301) 427-1128.

SUPPLEMENTARY INFORMATION:

I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App., this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). The Council is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Wednesday, July 24, 2019, the Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at www.webconferences.com/ahrq. The meeting will begin with an update on AHRQ's budget, programs and initiatives. The agenda will also include a discussion of AHRQ's strategic goals related to improving care for people living with multiple chronic conditions, diagnostic error, and data and analytics.

The agenda will also allow for further discussion about advancing patient-centered care for people living with multiple chronic conditions. The final agenda will be available on the AHRQ website at www.AHRQ.gov no later than Wednesday, July 17, 2019.

Dated: July 11, 2019.

Virginia L. Mackay-Smith,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 84 FR 10518-10519, dated March 21, 2019) is amended to reflect the reorganization of the National Center for Injury Prevention and Control, Deputy Director for Non-Infectious Diseases, Centers for Disease Control and Prevention. This reorganization will streamline the current organizational structure, improve the overall employee/supervisor ratio, eliminate workflow inefficiencies, and improve customer service.

I. Under Part C, Section C-B, Organization and Functions, the following organizational unit is deleted in its entirety:

- Division of Unintentional Injury Prevention (CUHD)
- Home, Recreation, and Transportation Branch (CUHDB)
- Health Systems and Trauma Systems Branch (CUHDC)

II. Under Part C, Section C-B, Organization and Functions, make the following change:

- Update the functional statements for the Office of the Director (CUH1)
- Update the functional statements for the Office of Policy and Partnerships (CUH12)
- Update the functional statements for the Office of Program Management and Operations (CUH13)
- Update the functional statements for the Office of Communication (CUH14)

- Retitle the Office of the Associate Director for Science (CUH17) to the Office of Science (CUH17)
- Establish the Office of Strategy and Innovation (CUH18)
- Establish the Office of Informatics (CUH19)
- Update the functional statements for the Division of Violence Prevention (CUHC)
- Update the functional statements for the Office of the Director (CUHC1)
- Update the functional statements for the Surveillance Branch (CUHCB)
- Update the functional statements for the Research and Evaluation Branch (CUHCC)
- Update the functional statements for the Prevention Practice and Translation Branch (CUHCD)
- Establish the Field Epidemiology and Prevention Branch (CUHCE)
- Retitle the Division of Analysis, Research, and Practice Integration (CUHF) to the Division of Injury Prevention (CUHF)
- Update the functional statements for the Office of the Director (CUHF1)
- Retitle the Statistics, Programming, and Economics Branch (CUHFB) to the Applied Science Branch (CUHFB)
- Retitle the Practice Integration and Evaluation Branch (CUHFC) to the Program Implementation and Evaluation Branch (CUHFC)
- Establish the Data Analytics Branch (CUHFD)
- Establish the Division of Overdose Prevention (CUHG)
- Establish the Office of the Director (CUHG1)
- Establish the Epidemiology and Surveillance Branch (CUHGB)
- Establish the Health Systems and Research Branch (CUHGC)
- Establish the Prevention Programs and Evaluation Branch (CUHGD)

III. Under Part C, Section C-B, Organization and Functions, insert the following:

- *Office of the Director (CUH1).* (1) Manages, directs, coordinates, and evaluates National Center for Injury Prevention and Control (NCIPC) activities; (2) provides administrative support, program management, and fiscal services to the center; (3) provides overall guidance and support for center-wide grant activities; (4) consults and coordinates activities with medical, engineering, and other scientific and professional organizations interested in injury prevention and control; (5) coordinates NCIPC program activities with other CDC components, other Public Health Service (PHS) agencies, PHS regional offices, other Federal agencies, State and local health

departments, community-based organizations, business and industry; (6) coordinates technical assistance to other nations and international organizations in establishing and implementing injury prevention and control programs; (7) develops goals and objectives and provides leadership, policy formation, scientific oversight, and guidance in program planning and development; (8) directs and coordinates information resources management activities, the production and distribution of technical and nontechnical injury prevention and control publications and information, and the conduct of health education and health promotion activities, and; (9) supports the activities of the Secretary's Advisory Committee for Injury Prevention and Control.

- *Office of Policy and Partnerships (CUH12)*. (1) Advises NCIPC and CDC leadership and staff on policy and partnership issues relevant to NCIPC; (2) conducts monitoring and analysis of policy issues potentially affecting NCIPC and its constituents; (3) coordinates partnership activities across NCIPC; (4) engages in partnerships with external organizations to meet mutual goals; (5) identifies and defines emerging or cross-cutting long-term policy issues and develops action plans that support and advance action; (6) manages issues proactively in order to minimize their negative effects, maximize their potential opportunities, and avoid the need for crisis management; (7) oversees and coordinates performance-related activities for NCIPC; (8) provides information for the development of NCIPC's annual budget submission and supporting documents; (9) provides liaison with staff offices and other officials of CDC; (10) reviews, prepares, and coordinates policy and briefing documents, and; (11) leads and coordinates the congressional strategy and outreach as informed by NCIPC and agency priorities.

- *Office of Program Management and Operations (CUH13)*. (1) Coordinates NCIPC-wide program, administrative, and management support services in the areas of fiscal management, personnel, travel, performance, FOIA, workforce planning, space, and other administrative services; (2) coordinates NCIPC requirements relating to contracts, grants, cooperative agreements, and reimbursable agreements; (3) manages annual budget formulation, budget justifications, and budget oversight; (4) develops and implements financial and administrative policies, procedures, and operations, as appropriate, for NCIPC, and prepares special reports and

studies, as required; (5) maintains liaison with related center staff and other officials of CDC, and; (6) plans, coordinates, and provides overall management support, advice, and guidance to NCIPC.

- *Office of Communication (CUH14)*. (1) Coordinates and leads the implementation of CDC-wide communication initiatives and policies, including health literacy, plain language, and CDC branding; (2) executes web development for the NCIPC intranet and provides technical assistance and training to OD offices in accessing and using NCIPC wiki for internal communication and information sharing; (3) facilitates cross-division and cross-CIO coordination of health communication activities, sharing of lessons learned, and development of best practices; (4) develops and manages relationships with a wide range of partners and customers, including other PHS agencies, Federal and State departments and agencies, and private organizations; (5) leads and oversees news media strategy and evaluation, including news response, media monitoring, proactive media engagement, media training, and long lead pitching; (6) leads digital communication and marketing strategies and manages digital channels; (7) leads strategic planning for communications and branding programs and projects for NCIPC and injury and violence issues; (8) manages and coordinates clearance of NCIPC print and non-print materials, ensuring adherence to and consistency with CDC and Department of Health and Human Services (HHS) information and publication policies and guidelines; (9) oversees, manages, and executes CDC web and digital governance through matrix management and work group structures; (10) provides communication support to OD offices and technical assistance and training in accessing centralized communication systems available through CDC's Office of the Associate Director for Communications (OADC) and other offices; (11) provides ongoing communication leadership and support to NCIPC's Office of the Director and divisions in furthering the center's mission to prevent violence and unintentional injury and to reduce their consequences; (12) provides oversight and approval for CDC logo licensing requests from external partner organizations and involving NCIPC divisions and programs; (13) represents NCIPC on cross-CIO and external committees, workgroups, and at conferences relating to health communication activities; (14) serves as primary liaison between NCIPC and

OADC, and; (15) through matrix management, provides strategic communication direction and technical assistance across NCIPC to ensure all health communication activities are evidence-based and demonstrate impact.

- *Office of Science (CHU17)*. (1) Provides scientific leadership for the center, and informs and guides staff on scientific matters; (2) ensures NCIPC produces the highest quality, most useful, and most relevant science possible; (3) leads the development of research priorities for the center in collaboration with divisions and offices; (4) provides staff training on scientific topics, science policy, and regulations; (5) mentors scientists and fellows; (6) manages scientific clearance for NCIPC; (7) oversees and directs Institutional Review Board, Office of Management Budget-Paperwork Reduction Act, and Confidentiality activities for the center; (8) conducts peer review of intramural research and scientific programs; (9) directs the center's Open Data Access policy and assures scientists follow CDC's policies on data release and sharing; (10) facilitates scientific collaborations between external and internal investigators; (11) leads, manages, and oversees NCIPC's external advisory board; (12) leads Healthy People Activities in partnership with divisions and offices and coordinates, tracks, and assesses progress toward Healthy People objectives; (13) manages and coordinates Epidemic Intelligence Service Officer program and activities; (14) provides scientific leadership in the areas of extramural research supported by NCIPC, National Center for Environmental Health (NCEH), and the Agency for Toxic Substances and Disease Registry (ATSDR); (15) promotes and prepares initiatives to stimulate extramural research in relevant priority areas; (16) directs all activities of the extramural research program to address priorities for NCIPC, NCEH, and ATSDR in partnership with the division programs; (17) coordinates and conducts pre-award activities for grant management, in-depth external primary and secondary peer review of extramural research applications, recommends award selections to divisions and center directors, and manages post-award activities; (18) ensures compliance with all regulations and policies governing extramural research programs, and; (19) disseminates and evaluates extramural research progress, findings, and impact.

- *Office of Strategy and Innovation (CUH18)*. (1) Provides strategic leadership and coordination across a range of injury and violence topics with

a focus on the NCIPC strategic priorities; (2) leads the advancement of innovative approaches to using data to inform injury and violence prevention; (3) develops, in collaboration with divisions and offices, the overall strategic goals and objectives for NCIPC and provides leadership to develop a plan of action to achieve these goals and objectives; (4) identifies strategic opportunities to collaborate with other divisions/offices in NCIPC, CDC Centers, Institute, and Offices (CIOs), PHS Agencies, and other federal departments and Agencies, and governmental and private organizations to advance injury and violence prevention; (5) identifies emerging or cross-cutting injury and violence topics and works with other divisions/offices to support and advance action on them; (6) participates with divisions and offices in NCIPC to establish research priorities for the center, and; (7) ensures NCIPC produces the highest quality, most useful, and most relevant science possible.

- *Office of Informatics (CUH19)*. (1) Reports all IT project costs, schedules, performances, and risks; (2) provides expert consultation in application development, information science, and technology to affect the best use of resources; (3) performs technical evaluation and/or integrated baseline reviews of all information systems' products and services prior to procurement to ensure software purchases align with center strategy; (4) coordinates all enterprise-wide IT security policies and procedures with the Office of the Chief Information Security Officer; (5) ensures operations are in accordance with CDC Capital Planning and Investment Control guidelines; (6) ensures adherence to CDC enterprise architecture policies, guidelines, and standards; (7) consults with divisions and offices to determine IT needs and to develop strategic and action plans; (8) participates in the evolution, identification, development, and/or adoption of appropriate informatics standards in conjunction with the Injury programs; (9) ensures coordination of data harmonization and systems interoperability within the center and facilitates linkage to related CDC-wide strategies; (10) provides leadership in the center's IRGB and coordination with CDC's IRGC; (11) collaborates with other divisions/offices in NCIPC, CIOs, PHS agencies, other federal departments and agencies, universities, NGOs, and private organizations as appropriate.

- *Division of Violence Prevention (CUHC)*. (1) Provides leadership in developing and executing a national

program for the prevention and control of violence and its consequences; (2) plans, establishes, and evaluates surveillance systems to monitor national trends in morbidity, mortality, disabilities, and cost of violence-related injuries and deaths, and facilitates the development of surveillance systems by state and local agencies; (3) plans, directs, conducts, and supports research focused on the causes of violence and the development and evaluation of strategies to prevent and control violence-related injuries and deaths; (4) produces new, evidence-based scientific knowledge that informs policies, practice, and programs in the violence field; (5) plans, conducts, supports, and evaluates demonstration projects and programs to prevent and control violence; (6) develops and disseminates policies, recommendations, and guidelines for the prevention of violence and its consequences; (7) proposes goals and objectives for linking health system and violence control activities with public health activities, including surveillance, prevention, health care, and rehabilitation of injury; (8) proposes goals and objectives for national violence prevention and control programs, monitors progress toward these goals and objectives, and recommends and develops guidelines for priority prevention and control activities; (9) provides expertise in public health practice, surveillance, evaluation, and research for violence prevention; (10) provides technical assistance, consultation, training, and epidemiological, statistical, educational, and other technical services to assist state and local health departments and community-based organizations in the planning, development, implementation, evaluation, and overall improvement of violence prevention programs; (11) facilitates the development and supports the dissemination of research findings and transfer of violence prevention and control technologies to federal, state, and local agencies, private organizations, and other national and international groups; (12) sustains a public health infrastructure for violence prevention at federal, state, local, and tribal levels; (13) facilitates similar strategic planning activities by other federal, state, and local agencies, academic institutions, and private and other public organizations, and; (14) collaborates with other divisions of NCIPC, CDC Centers/Institutes/Offices, HHS agencies, other federal, state, and local departments and agencies, academic institutions, and voluntary,

private sector, and international organizations, as appropriate.

- *Office of the Director (CUHC1)*. (1) Plans, directs, coordinates, and evaluates the activities of the division; (2) establishes and interprets policies and determines program priorities; (3) provides administrative, fiscal, and technical support for division programs and units; (4) provides national leadership and guidance in violence prevention and control program planning, development, and evaluation; (5) provides leadership for developing research in etiologic, epidemiologic, and behavioral aspects of violence prevention and control to inform policies, practice, and programs; (6) prepares and tracks responses and coordinates provision of materials requested by Congress and the HHS; (7) prepares, tracks, and coordinates controlled and general correspondence; (8) assures multi-disciplinary collaboration in violence prevention and control activities; (9) collaborates with subject matter experts, program and policy staff, develops and implements communication strategies, campaigns, and plans to meet the needs of division programs and mission; (10) coordinates with the NCIPC Office of Communication to execute and support NCIPC- and CDC-wide communication initiatives and policies; (11) develops tailored messages and materials to promote dissemination of scientific findings, evidence-based prevention strategies, priority recommendations, and guidelines through traditional media outlets, social media, and other channels; (12) provides consultation on international violence prevention and control activities of the division; (13) prepares, edits, and monitors clearance of manuscripts for publication in scientific and technical journals and publications, including articles and guidelines published in the Morbidity and Mortality Weekly Report (MMWR), and other violence-related publications for the public, and; (14) in carrying out the above functions, establishes linkages and collaborates, as appropriate, with other divisions and Offices in NCIPC, with other CIOs throughout CDC, non-governmental organizations; and with national level prevention partners that impact on violence prevention programs.

- *Surveillance Branch (CUHCB)*. (1) Conducts national, state, and local surveillance and surveys to identify new and to monitor recognized forms of violence and its consequences, analyzes incidence and prevalence data, and monitors trends in violence and its trajectory across the lifespan; (2) advises the Office of the Director, in DVP and

NCIPC, on the area of data and systems management and on surveillance and statistical analysis issues relevant to violence program planning and evaluation; (3) coordinates, manages, maintains and provides tabulations and maps from national surveillance systems and other data sources that contain national, state and local data on violence-related morbidity, mortality and economic costs; (4) develops and implements uniform definitions for public health surveillance of various forms of violence and related outcomes; (5) provides leadership for the development of surveillance research to inform policies, practice, and programs in the violence field; (6) provides expert consultation to federal, state, and local health agencies on surveillance system design, implementation, and evaluation, and use of surveillance data to describe the burden of violence; (7) provides information on violence surveillance to the scientific community and the general public through regular publication in peer-reviewed journals and CDC publications as well as through presentations to professional conferences and other stakeholder groups; (8) works with other branches to provide consultation, collaboration, and to ensure the use of surveillance data to inform research and prevention efforts, and; (9) in carrying out the above functions, provides leadership and collaborates with other divisions and Offices in NCIPC, other CIOs throughout CDC, and Federal, state, local, non-governmental, voluntary, and professional, organizations in all aspects of surveillance of violence and its consequences.

• *Research and Evaluation Branch (CUHCC).* (1) Plans, directs, conducts, and supports etiologic and epidemiologic research focused on causal factors, risk and protective factors, and psychosocial, cultural, and contextual determinants for violence and its consequences; (2) plans, directs, conducts, and supports applied research focused on the evaluation of strategies, policies, and interventions to prevent violent behavior and violence-related injuries and deaths; (3) evaluates the effectiveness and impact of violence prevention interventions, strategies, policies, and interventions as practiced or implemented by public health agencies and organizations at the national/regional and state/local levels; (4) conducts research to examine the context, processes, and factors that influence effective and efficient dissemination/diffusion, uptake/adoption, implementation, translation, and sustainability of violence

prevention strategies, policies, and interventions; (5) develops and evaluates methodologies for conducting research evaluation; (6) contributes to the research literature by publishing regularly in peer-reviewed journals and CDC-sponsored publications that include, but are not limited to, etiology and evaluation research and syntheses; (7) monitors activities of contracts, cooperative agreements, and grants to ensure operational objectives are being met; (8) serves as a resource, collaborates, and provides technical assistance in applying research and evaluation results and techniques to the ongoing assessment and improvement of violence prevention and control programs; (9) uses research findings to develop new strategies, policies, and interventions or improve the impact of existing strategies, policies, and interventions to prevent and reduce violent behavior, its risk factors, and its consequences, and; (10) in carrying out the above functions, collaborates with other components within NCIPC, CDC, PHS, and HHS and other federal agencies, national professional, voluntary and philanthropic organizations, and international agencies.

• *Prevention Practices and Translation Branch (CUHCD).* (1) Provides leadership and support in public health practice and the application of science for maximal benefit of violence prevention programmatic efforts; (2) plans, directs, conducts, and supports program evaluation of strategies, policies, and interventions to prevent violent behavior and violence-related injuries and deaths; (3) monitors and evaluates violence prevention programs and policies, and disseminates findings to promote program accountability and program improvement; (4) promotes an enhanced and sustained infrastructure for a public health approach to violence prevention at state, local, and tribal levels; (5) generates and moves practice based knowledge into program practice and research fields; (6) develops and evaluates methodologies for conducting program evaluation; (7) identifies findings, lessons learned, and evidence from the field and collaborates with internal and external partners to inform research, surveillance, and program evaluation that builds the evidence base for effective violence prevention; (8) provides support, training, and technical assistance that applies sound prevention principles and systematic processes to enhance public health practice, including program development, implementation,

improvement, and competence of personnel engaged in violence prevention and control research practices; (9) applies the best available evidence from translational science and continuous quality improvement to help communities select, adopt, adapt, implement, disseminate, sustain, and scale up programs, strategies, and activities that will lead to successful violence prevention outcomes; (10) works to reduce violence by supporting state and local violence prevention and control programs and promote the dissemination and application of science into program practice in the violence prevention field; (11) synthesizes and translates relevant research, evaluation findings, evidence, and trends and assures that communication and marketing technologies are applied to the development of practical tools, products, trainings, and guidance that enhances violence prevention programs, strategies, and activities; (12) communicates internally and externally the important work and progress of the staff, grantees, and partners; (13) plans, conducts, supports, and evaluates demonstration projects and programs to prevent and control violence; (14) proposes goals and objectives for national violence prevention and control programs, monitors progress toward these goals and objectives, and recommends and develops guidelines for priority prevention and control activities; (15) provides national leadership and guidance in violence prevention and control program planning, development, and evaluation; (16) develops and manages liaison and collaborative relationships with professional, community, international, federal, and other voluntary agencies involved in violence prevention activities, and; (17) in carrying out the above functions, provides leadership and collaborates with other divisions and offices in NCIPC, other CIOs throughout CDC, and federal, state, local, non-governmental, voluntary, professional, and international organizations in all aspects of public health practice as it relates to violence prevention.

• *Field Epidemiology and Prevention Branch (CUHCE).* (1) Conducts international surveillance and surveys to identify new and to monitor recognized forms of violence associated risk factors and consequences, analyzes incidence and prevalence data, and monitors trends in violence and its trajectory across the lifespan; (2) synthesizes and translates relevant research, evaluation findings, evidence,

and trends, and assures that communication and marketing technologies are applied to the development of practical tools, products, trainings, and guidance that enhance international violence prevention programs, strategies, and activities; (3) uses research findings to develop new strategies, policies, and interventions or to improve the impact of existing strategies, policies, and interventions to prevent and reduce violent behavior, its risk factors, and its consequences internationally; (4) serves as a resource, collaborates, and provides technical assistance in applying research and evaluation results and techniques to the ongoing assessment and improvement of violence prevention and control programs; (5) provides information on violence surveillance to the scientific community and the general public through regular publication in peer-reviewed journals and CDC publications as well as through presentations to professional conferences and other stakeholder groups; (6) disseminates scientific findings, evidence-based prevention strategies, and violence prevention guidelines through publication of research findings in professional journals and government reports, through participation in national and international meetings, seminars, and conferences, and through the development of communication initiatives; (7) establishes and sustains partnerships with other CDC CIOs and other international federal and non-government partners to improve the health and safety of youth by linking systematic measurement of violence with multi-sectoral, effective, scalable, and sustainable actions to reduce violence and its consequences; (8) leverages and applies science-based information to help organizations and government agencies to develop, evaluate, and improve programs and strategies to prevent violence-related injuries, health problems, and deaths; (9) provides expert consultation and technical assistance, consultation, training, and epidemiological, statistical, and other technical services to assist international and local health entities in the planning, implementation, application, evaluation, and overall improvement of violence monitoring and violence prevention programming, and; (10) in carrying out the above functions, collaborates with other divisions of NCIPC, CIOs, HHS agencies, other federal, state, and local departments and agencies, academic institutions, and voluntary, private sector, and

international organizations, as appropriate on all aspects of violence surveillance.

- *Division of Injury Prevention (CUHF)*. (1) Integrates injury prevention strategies with healthcare delivery; (2) develops and disseminates policies, recommendations, and guidelines for the prevention of injury and its consequences; (3) develops and implements evidence-based public health practices, policies, or programs that prevent or reduce unintentional and self-directed injuries; (4) identifies findings, lessons learned, and potential best practices from the field and collaborates with internal and external partners to conduct scientific investigations to examine the context, processes, and factors that influence the risk of injuries and successful implementation of prevention strategies; (5) plans, establishes, and maintains surveillance systems to monitor national trends in morbidity, mortality, disabilities, and cost of injuries and facilitates the development of surveillance systems by state and local agencies; (6) produces and disseminates new scientific knowledge to inform policies, practice, and programs in the injury field; (7) supports the development and enhancement of state, local, territorial, and tribal injury prevention programs that integrate evidence-based population health strategies, surveillance, and evaluation in collaboration with other public health and non-public health sectors to promote injury control and prevention; (8) provides expertise in statistics, computer programming, data science, economics, public health practice, surveillance, evaluation, and research to engage NCIPC and the injury prevention community; (9) leads translation and dissemination of injury prevention and control research findings and injury data to federal, state, local, territorial, and tribal public health agencies, and public and private sector organizations with responsibilities and interests related to injury prevention; (10) supports the development and enhancement of public health infrastructure for injury prevention at federal, state, local, and tribal levels through funding, workforce training, and outreach, and; (11) leads innovative data science activities to address injury data and information needs and inform research and prevention activities.

- *Office of the Director (CUHF1)*. (1) Plans, directs, coordinates, and evaluates the activities of the division; (2) provides administrative, fiscal, and technical support for division programs and units; (3) leads division strategic planning and priority setting; oversees

overall program performance, ensures scientific quality of activities, and implements operational policies to advance the center and agency mission; (4) collaborates with subject matter experts, program, and policy staff to develop strategic communication plans that meet agency, enter, and division priorities; (5) develops, implements, and evaluates communication strategies, campaigns, and materials to disseminate data and scientific findings, evidence-based prevention strategies, priority recommendations, programmatic successes, and guidelines through traditional and emerging communication channels; (6) develops and manages collaborative relationships with professional, community, international, governmental, and other non-governmental agencies, and tribal nations to advance injury prevention and control; (7) coordinates with the NCIPC Office of Policy and Partnerships to identify and proactively manage emerging policy issues; (8) advises division staff on policy issues and coordinates with staff to prepare briefing materials; (9) collaborates with other NCIPC divisions and offices and other CIOs throughout CDC to effectively partner on critical injury prevention programs; (10) prepares and monitors clearance of manuscripts for publication in scientific and technical journals and publications, including articles and guidelines published in the MMWR and other publications for the public; (11) prepares, tracks, and coordinates responses to all inquiries from Congress, the public, and HHS, and; (12) provides leadership for the development of research to inform policies, practice, and programs in the injury field.

- *Applied Science Branch (CUHFB)*. (1) Plans and directs strategies to collect, analyze, and interpret scientific findings from surveillance, behavioral, and epidemiologic research activities for use in evaluating trends, setting priorities, and developing intervention strategies for injuries; (2) plans, directs, conducts, and supports research to assess environmental, social, behavioral, and other risk and protective factors and to develop and evaluate intervention activities to prevent and control injuries; (3) leads and coordinates a national program for the prevention and control of non-occupational injuries that occur at home and in the community in collaboration with federal, state, local, territorial, and tribal agencies, and public and private sector organizations; (4) provides leadership, research, and expert consultation to federal, state, local, territorial, tribal, and non-

governmental partners in addressing unintentional and self-directed injuries; (5) plans, directs, and supports epidemiological analysis, applied research, and demonstration projects to advance the integration of injury prevention strategies with healthcare delivery; (6) provides technical assistance to local, state, territorial, and tribal agencies to advance the integration of surveillance and injury prevention strategies with healthcare delivery; (7) develops guidelines to reduce or mitigate the impact of injury as appropriate, and; (8) disseminates scientific findings, evidence-based prevention strategies, and injury prevention guidelines by publishing research findings in professional journals and government reports, participating in national and international meetings, seminars, and conferences, and developing communication initiatives.

- *Program Implementation and Evaluation Branch (CUHFC)*. (1) Coordinates and conducts research to examine the context, processes, and factors that influence effective and efficient adoption, implementation, dissemination, and sustainability of injury prevention strategies, policies, and interventions; (2) provides technical assistance in applying research and evaluation to the ongoing assessment and improvement of injury prevention and control programs; (3) supports training and outreach to increase the number and competence of personnel engaged in injury prevention and control research and practices; (4) works with local, state, territorial, and tribal public health programs to advance the use of surveillance, effective injury prevention strategies, and ongoing quality improvement activities for program planning and implementation to decrease the burden of injury; (5) collaborates with internal and external partners to disseminate effective injury prevention strategies; (6) develops and evaluates methodologies for conducting program evaluation; (7) works to generate practice-informed research and synthesize research findings for program application; (8) monitors and evaluates programs and policies and disseminates findings to promote program accountability and program improvement; (9) promotes an enhanced and sustained infrastructure for a public health approach to injury and violence prevention at state, local, territorial and tribal levels, and; (10) translates relevant research, evaluation findings, and other evidence into practical tools, products, and guidance that enhances injury

prevention programs, strategies, and activities.

- *Data Analytics Branch (CUHFD)*. (1) Plans, establishes, and maintains surveillance systems to monitor national and state-level trends in morbidity, mortality, disabilities, and costs of injuries; (2) analyzes and translates data into information that is disseminated to stakeholders for program planning, evaluation, and decision-making; (3) collaborates with and advises other divisions/offices in NCIPC, CDC CIOs, and external partners on traditional and emerging statistical, economic, surveillance, and data science methods; (4) collaborates with the NCIPC Office of Strategy and Innovation and the Office of Informatics, NCIPC divisions, and other CDC CIOs to increase efficiencies in collection, management, and usability of injury and violence data; (5) develops, maintains, and disseminates tabulations and maps from national, state, and local data on injury morbidity, mortality, economic costs, and risk and protective factors through CDC's WISQARS™ (Web-based Injury Statistics Query and Reporting system) and other NCIPC online tools; (6) develops, evaluates, and implements innovative statistical, economic, policy research, computer programming, and data science methods for application to injury surveillance, research studies, and program planning, and evaluation; (7) leads and collaborates with other scientists on epidemiologic studies and statistical and economic analyses and provides technical advice in the areas of study design, sampling, and the collection, management, analysis, and interpretation of injury and economic data; (8) produces high quality statistical, economic, and policy reports, publications, and presentations for dissemination, and; (9) leads and coordinates with the NCIPC Office of the Director and other divisions on innovative pilot projects and scaling up promising strategies to utilize non-traditional datasets and novel methods for data collection and analysis in public health.

- *Division of Overdose Prevention (CUHG)*. (1) Plans, establishes, evaluates, uses, and collaborates on surveillance systems to monitor local, state, and national trends in morbidity, mortality, risk and protective factors, and costs related to drug use and overdose and evaluates the effectiveness of prevention strategies; (2) plans, directs, conducts, and supports research focused on the causes, risks, and protective factors associated with drug use and overdose and identifies strategies at the federal, state, and local level, as well as in health systems, to

prevent drug use and overdose; (3) evaluates the effectiveness, costs, and impact of drug use and overdose-related interventions, strategies, policies, and programs as practiced or implemented by public health agencies and organizations at the federal, state, territorial, and local levels, including health systems and by law enforcement/public safety; (4) identifies, develops, evaluates, and implements programs and informs policies or guidelines to prevent drug use and overdose; (5) facilitates the translation, dissemination, and sustainability of practice- and research-tested findings into widespread local, state, and national public health and health system practice to prevent drug use and overdose; (6) provides technical assistance, consultation, training, and capacity building to federal, state, and local agencies, non-profit and international organizations, professional associations, and medical providers to prevent drug use and overdoses; (7) establishes and maintains relationships across HHS, CDC, NCIPC and its partners, including state, territorial, and local public health agencies, other federal agencies, the healthcare sector, professional organizations, and other constituents, including academic institutions and international organizations, that address drug use and overdose prevention, and; (8) develops or is actively involved in the development of drug use and overdose prevention educational materials, training courses, tools, and other communication materials, as appropriate, based on identified needs of stakeholders.

- *Office of the Director (CUHG1)*. (1) Plans, directs, and evaluates the activities of the division; (2) provides cross-cutting leadership and guidance in policy formation and program planning, development, implementation and evaluation for drug use and overdose prevention; (3) provides over-arching personnel, operational, administrative, fiscal, and technical support for division programs and units; (4) assures multi-disciplinary collaboration in drug use and overdose prevention activities; (5) provides leadership for developing research in etiologic, epidemiologic, and behavioral aspects of drug use and overdose prevention, and for coordinating division activities with others involved in related-work across NCIPC, CDC, HHS, and other stakeholders; (6) prepares, edits, and monitors policy review and general clearance of manuscripts for publication in peer-reviewed scientific and technical journals, including articles

and guidelines published in the MMWR, as well as communication products for a variety of audiences; (7) prepares, tracks, and coordinates controlled and general correspondence; (8) prepares responses and coordinates provision of materials requested by center and agency leadership, Congress, and HHS; (9) Plans, develops, conducts, and evaluates cross-cutting communication projects and campaigns to inform the media, health professionals, the public, and others about drug use and overdose prevention; (10) provides media, communication, and marketing support to the division; (11) serves as primary liaison between the division and relevant NCIPC Office of the Director, in the areas of communication, policy/partnership, science, administration/operations, informatics, and strategy/innovation; (12) designs, develops, and coordinates the publication of print and audiovisual materials such as fact sheets, newsletters, speeches and presentations, exhibits, social media messages, press releases, media advisories, and educational videos; (13) develops and evaluates messages, materials and health communication products to promote and disseminate scientific findings, evidence-based prevention strategies, priority recommendations, and guidelines through various platforms; (14) coordinates with NCIPC Office of Communication to execute and support NCIPC- and CDC-wide communication initiatives and policies related to overdose prevention; (15) coordinates with NCIPC Office of Policy and Partnerships to execute and support NCIPC- and CDC-wide policy and partner related initiatives related to overdose prevention; (16) collaborates with the Extramural Research Program Office on extramural research, policies, and procedures including peer review; (17) implements policies and procedures related to human subjects research protections, paperwork reduction act regulations, federal advisory committee act regulations, data sharing policies, and scientific authorship and misconduct; (18) supports scientific training opportunities, including the EIS training program, and; (19) collaborates, as appropriate, with non-governmental organizations, academic institutions, philanthropic foundations, and other stakeholders to achieve the mission of the division.

- *Epidemiology and Surveillance Branch (CUHGB)*. (1) Plans, establishes, and evaluates surveillance systems to monitor national, state, and local trends

in morbidity, mortality, and costs related to drug use and overdose; (2) develops and implements uniform definitions for public health surveillance of various overdose outcomes; (3) prepares routine surveillance reports of national, state, and local trends in drug use and overdose risk factors, behaviors, outcomes, and disparities, which includes the mapping of geographic variations; (4) uses surveillance systems to monitor overdoses and poisonings to create incidence rates to inform prevention programs and provide data for planning in the community and in health systems; (5) develops, designs, implements, and evaluates innovative surveillance strategies or systems that address gaps in existing CDC surveillance systems in collaboration with colleagues in NCIPC and other CIOs for application to overdose surveillance, epidemiologic studies, program evaluation, and programmatic activities; (6) plans and directs strategies to collect, analyze, and interpret scientific findings from surveillance, behavioral, and epidemiologic research activities for use in evaluating trends, setting priorities, and developing intervention strategies for overdose prevention; (7) prepares epidemiologic and scientific papers for publication in the peer-reviewed literature and for presentation at scientific and professional conferences; (8) proposes and serves as technical advisors and project officers for epidemiologic activities with state and local entities; (9) plans and conducts research projects that fill gaps in surveillance and investigates emerging and novel drug overdose threats, including toxicology; (10) serves as scientific and technical experts in drug overdose epidemiology and surveillance methodology to state and local health departments and to advisory groups at the national/international level; (11) supports training to increase the number and competence of personnel engaged in overdose epidemiology and surveillance, and; (12) prepares and produces high quality reports, publications, and other material for information presentation and dissemination by NCIPC staff to a wide-variety of stakeholders.

- *Health Systems and Research Branch (CUHGC)*. (1) Supports evaluation, applied research, and demonstration projects to determine the effectiveness of an intervention, improve the effectiveness of healthcare systems, and to support the understanding of how health systems can best be integrated with public

health prevention efforts to reduce or mitigate the impact of overdoses and related harms; (2) develops, implements, evaluates, and translates clinical guidelines and other materials for clinicians and health systems to reduce or mitigate the impact of overdoses and related harms; (3) collaborates with state, territorial, and local health departments to integrate applied research and evaluation findings, as well as quality improvement initiatives within health systems; (4) provides expert consultation to federal, state, local, and international health agencies on applied research, evaluation, and health system implementation strategies; (5) provides scientific technical assistance to health systems, states, and localities to increase their capacity to develop, implement, and evaluate system-level overdose prevention programs; (6) develops, implements, and evaluates tools and resources for use in electronic health records and health IT systems to address overdoses and helps support data integration across data systems; (7) contributes to the research literature, by publishing regularly in peer-reviewed journals and CDC-sponsored publications on topics that include, but are not limited to, programmatic, evaluation, health systems, or community based strategies, and; (8) supports dissemination of research, evaluation, translation, and program implementation to federal, state, and local health agencies, public and private sector organizations, and other national and international groups with responsibilities and interests related to overdose prevention.

- *Prevention Programs and Evaluation Branch (CUHGD)*. (1) Provides programmatic leadership and support for drug use and overdose prevention activities in states, territories, and local jurisdictions; (2) provides technical assistance and project officer support to grantees on implementation of evidence- and practice-based interventions with the greatest reach and impact in states, territories, and local jurisdictions, including sustaining and scaling up programs, strategies, and activities over time in collaboration with public safety/law enforcement and other stakeholders; (3) generates and promotes adaptation and adoption of novel evidence-based strategies to prevent drug use and overdose, including addressing vulnerable populations; (4) leverages epidemiology and surveillance data about drug overdose morbidity, mortality, and risk and protective factors to inform, tailor, and evolve

prevention strategies across the life course; (5) monitors and evaluates the outcomes of division investments in states, territories, and local jurisdictions using rigorous evaluation methods and widely disseminates findings to improve programmatic activities; (6) publishes the findings of programmatic evaluations in the peer-reviewed literature and other reports and participate in scientific and professional conferences; (7) serves as a resource, collaborates, and provides comprehensive technical assistance and training to states, territories, local jurisdictions and other partners to reduce drug use and overdose; (8) synthesizes relevant research, evaluation findings, evidence, and trends to develop practical guidance and resources that enhance overdose prevention programs, strategies, and activities; (9) uses research findings to develop new strategies, policies, and interventions or to improve the impact of existing strategies, policies, and interventions to prevent and reduce overdose, its risk factors, and its consequences; (10) collaborates with state, territorial, and local jurisdictions, public safety/law enforcement, and other partners to use data to drive decision-making and action, and; (11) provides direct support to states, territories, and local jurisdictions to prevent drug use and overdose.

IV. Delegations of Authority: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Alex M. Azar II,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1428]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on electronic drug product reporting for human drug compounding outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by September 16, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 16, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-1428 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80