sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2). The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	19	1	19	40	760
HDE Application—814.104	3	1	3	320	960
HDE Amendments and resubmitted HDEs—814.106	6	5	30	50	1,500
HDE Supplements—814.108	110	1	110	80	8,800
Notification of withdrawal of an HDE—814.116(e)(3)	1	1	1	1	1
Notification of withdrawal of Institutional Review Board approval—814.124(b)	1	1	1	2	2
Periodic reports—814.126(b)(1)	35	1	35	120	4,200
Total					16,223

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	247	1	247	2	494

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification of emergency use—814.124(a)	22	1	22	1	22

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

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, *i.e.,* fiscal years 2014 through 2016. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 35 respondents with approved HUD applications. Under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 247.

The number of respondents has been adjusted to reflect updated respondent data. This has resulted in an overall decrease of 2,971 hours to the total estimated annual reporting burden. There have been no program changes and the estimated Average Burden per Response has not changed for any of the information collections since the last OMB approval.

Dated: October 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22320 Filed 10–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by November 15, 2017, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by November 15, 2017. Nominations will be accepted for current vacancies and for those that will or may occur through November 30, 2017.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov*; by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002; or by Fax: 301–847–8640.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*; by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002; or by Fax: 301–847–8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm*.

FOR FURTHER INFORMATION CONTACT: *For questions relating to participation in the selection process:* Kimberly Hamilton, Advisory Committee Oversight and Management Staff (ACOMS), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, 301–796–8220 email: *kimberly.hamilton@fda.hhs.gov*.

For questions relating to specific advisory committees or panels, contact the appropriate Contact Person listed in table 1.

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2426, Silver Spring, MD 20993–0002, phone: 301–796–2721, email: *Lauren.Tesh@fda.hhs.gov*.	Antimicrobial Advisory Committee.
Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993–0002, phone: 301–796–6875, email: *Patricio.Garcio@fda.hhs.gov*.	Clinical Chemistry and Clinical Toxicology Devices Panel.
Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993–0002, phone: 301–796–6683, email: *Evella.Washington@fda.hhs.gov*.	Ear, Nose and Throat Devices Panel, Immunology Devices Panel.
Pamela Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993–0002, phone: 301–796–5433, email: *Pamela.Scott@fda.hhs.gov*.	Medical Devices Dispute Resolution.
Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993–0002, phone: 301–796–0400, email: *Aden.Asefa@fda.hhs.gov*.	Neurological Devices Panel.
LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2428, Silver Spring, MD 20993–0002, phone: 301–796–2855, email: *LaToya.Bonner@fda.hhs.gov*.	Endocrinologic and Metabolic Drugs Advisory Committee.
Karen Strambler, Center for Food Safety and Nutrition, Food and Drug Administration, FDA College Park, CPK1, Rm. 1C008, College Park, MD 20740, phone: 240–402–2589, email: *Karen.Strambler@fda.hhs.gov*.	Food Advisory Committee.
Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2430, Silver Spring, MD 20993–0002, phone: 301–796–0889, email: *Cindy.Chee@fda.hhs.gov*.	Gastrointestinal Drugs Advisory Committee, Pulmonary-Allergy Drugs Advisory Committee.
Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, phone: 301–796–4043, email: *Jennifer.Shepherd@fda.hhs.gov*.	Medical Imaging Advisory Committee.
Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, phone: 301–796–2894, email: *MoonHee.Choi@fda.hhs.gov*.	Non-Prescription Drugs Advisory Committee, Peripheral & Central Nervous Systems Advisory Committee.
Marieann Brill, Office of the Commissioner, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993–0002, phone: 240–402–3838, email: *Mariann.Brill@fda.hhs.gov*.	Pediatrics Advisory Committee.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2.

TABLE 2—COMMITTEE DESCRIPTIONS, TYPE OF CONSUMER REPRESENTATIVE VACANCY, AND APPROXIMATE DATE NEEDED

Committee/panel/areas of expertise needed	Type of vacancy	Approximate date needed
Antimicrobial Advisory Committee—Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties.	1—Voting	November 30, 2017.
Clinical Chemistry and Clinical Toxicology Devices Panel—Doctors of medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1—Nonvoting	Immediately.
Ear, Nose and Throat Devices Panel—Otologists, neurologists, and audiologists	1—Nonvoting	Immediately.
Immunology Devices—Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1—Nonvoting	Immediately.
Medical Devices Dispute Resolution—Experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills.	1—Nonvoting	Immediately.
Neurological Devices Panel—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	1—Nonvoting	Immediately.
Endocrinologic and Metabolic Drugs Advisory Committee—Knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties.	1—Voting	Immediately.
Food Advisory Committee—Knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, and other relevant scientific and technical disciplines.	1—Voting	Immediately.
Gastrointestinal Drugs Advisory Committee—Knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics.	1—Voting	Immediately.
Pulmonary-Allergy Drugs Advisory Committee—Knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics.	1—Voting	Immediately.
Medical Imaging Advisory Committee—Knowledgeable in the fields of nuclear medicine, radiology, epidemiology, statistics, and related specialties.	1—Voting	Immediately.
Non-Prescription Drugs Advisory Committee—Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties.	1—Voting	Immediately.
Peripheral and Central Nervous System Drugs Advisory Committee—Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties.	1—Voting	Immediately.
Pediatrics Advisory Committee—Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. The core of voting members shall also include one representative from a pediatric health organization and one representative from a relevant patient or patient-family organization and may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one nonvoting member who is identified with industry interests.	1—Voting	Immediately.

I. Functions and General Description of the Committee Duties

A. Antimicrobial Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

B. Certain Panels of the Medical Devices Advisory Committee

Reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area: (1) Advises on the classification or reclassification of devices into one of three regulatory categories; (2) advises on any possible risks to health associated with the use of devices; (3) advises on formulation of product development protocols; (4) reviews premarket approval applications for medical devices; (5) reviews guidelines and guidance documents; (6) recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (7) advises on the necessity to ban a device; and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

C. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human

drug products for use in the treatment of endocrine and metabolic disorders.

D. Food Advisory Committee

Make recommendations on emerging food safety, food science, nutrition, and other food-related health issues that FDA considers of primary importance for its food and cosmetics programs. Reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues; (2) the safety of new foods and food ingredients; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

E. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases.

F. Pulmonary-Allergy Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

G. Medical Imaging Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

H. Non-Prescription Drugs Advisory Committee

Review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

I. Peripheral and Central Nervous System Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

J. Pediatrics Advisory Committee

The Committee advises and makes recommendations to the Commissioner of Food and Drugs regarding: (1) Pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes; (5) pediatric labeling changes; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur; (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary of Health and Human Services (Secretary) directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate an affiliation with and/or active participation in consumer or community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, a signed copy of the *Acknowledgement and Consent* form available at the FDA Advisory Nomination Portal (see **ADDRESSES**), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations must also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to

permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22344 Filed 10–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Standards for the Children's Hospitals Graduate Medical Education Payment Program's Quality Bonus System

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

ACTION: Request for public comment.

SUMMARY: This notice seeks public comment on establishing a quality bonus system for the Children's Hospitals Graduate Medical Education (CHGME) Payment Program. The CHGME Support Reauthorization Act of 2013 states that the Secretary may establish a quality bonus system, whereby the Secretary distributes bonus payments to hospitals participating in the program that meet standards specified by the Secretary. The goal of this notice is to seek comment to assist HRSA in the development of the standards, payment structure, and outcome measures for the CHGME Quality Bonus System.

DATES: Submit written comments no later than December 15, 2017.

ADDRESSES: Written comments should be submitted to Malena Crawford, Public Health Analyst, HRSA, by email (*MCrawford@hrsa.gov*) or by fax (301–443–0162).

FOR FURTHER INFORMATION CONTACT: Malena Crawford, Public Health Analyst, HRSA, 5600 Fishers Lane, Rockville, MD, 20852, (301) 443–7334.

SUPPLEMENTARY INFORMATION: The CHGME Program supports graduate medical education (GME) in freestanding children's hospitals. The program supports the training of primary care pediatricians and pediatric medical and surgical subspecialists. The CHGME Support Reauthorization Act of 2013 makes up to 25 percent of the total amount appropriated annually in excess of $245 million, but not to exceed $7,000,000, available to provide payments to newly qualified hospitals, as defined in section 340E(h) of the Public Health Service Act. The statute additionally states that the Secretary may establish a quality bonus system for CHGME hospitals using any remaining funds after payments are made to newly qualified hospitals. In FY 2017, Congress appropriated $300 million to the CHGME Program. Of this, approximately $4 million in payments were made to newly qualified hospitals. If funding levels and mechanisms remain constant, it is estimated that approximately $3 million may be available annually for the CHGME Quality Bonus System. If the total amount available for the CHGME Quality Bonus System in a fiscal year is less than $2 million, HRSA does not plan to implement the CHGME Quality Bonus System in that year to minimize administrative burden on the hospitals. In this case, the funds would be disbursed to all eligible hospitals (including those newly qualified) according to the CHGME formula payment methodology.

HRSA understands the complexities involved in designing a GME quality improvement initiative. The CHGME Quality Bonus System would be the first of its kind for any federal GME payment program and responds to changes occurring in the larger health care arena. For example, the Accreditation Council for GME, one of the prevailing GME accrediting bodies, recently implemented new GME program requirements around patient safety and quality improvement. Many GME programs and stakeholders are working towards establishing GME quality related outcome metrics, but currently no widely accepted metrics exist that have the ability to distinguish between the quality of training provided at different hospitals and training programs. Additionally, clinical outcomes alone may not be appropriate measures for establishing a GME quality improvement initiative. HRSA would like to begin to develop approaches to measure and assess the quality of GME programs using existing data sources initially and then develop new and improved data sources as we learn which are most informative and useful.

Quality Bonus Payment in FY 2019—Proposal for Public Comment

HRSA is proposing a multi-step implementation in recognition of the changing landscape and the need for additional data. For FY 2019, HRSA proposes a quality bonus system that will initially recognize high-level engagement of CHGME hospitals in state and regional health care transformation, as well as engagement of resident trainees in these activities. HRSA is seeking public comment on the timeline, eligibility, standards, documentation, and payment structure as described below. HRSA is also proposing areas for comment for FY 2020 and beyond.

Timeline: HRSA anticipates implementing the proposed CHGME Quality Bonus System standards in FY 2019 payments (project period October 1, 2018, through September 30, 2019).

CHGME Hospital Eligibility: HRSA proposes to include all eligible CHGME hospitals, including those newly qualified, as eligible entities for the CHGME Quality Bonus System.

Quality Bonus System Standards: The proposed standards are: (1) Demonstration of engagement in state- or regional-level initiatives by a children's hospital to transform pediatric health care to improve access, quality, and cost effectiveness of health care; and (2) demonstration of resident trainee engagement in these activities.

HRSA has identified several initiatives involving CHGME hospitals that require a significant level of engagement. These include federally funded efforts such as: Participation in a state Medicaid initiative to improve access, quality, and cost effectiveness of pediatric health care (*e.g.,* a Centers for Medicare & Medicaid Services State Innovation Model Award or other Health Care Innovation Award with a state or regional impact); participation in the HRSA Maternal and Child Health Bureau's Health Care Delivery System Innovations for Children with Medical Complexity Collaborative Improvement and Innovation Network (CoIIN); or, participation in HRSA's Federal Office of Rural Health Policy Rural Health Network Development Grant Program.