

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]

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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 (CoLIN); or, participation in HRSA's Federal Office of Rural Health Policy Rural Health Network Development Grant Program.

In addition to the partnerships above, HRSA is seeking comment on state or regional initiatives to consider when establishing the qualifying standards for the CHGME Quality Bonus System, as well as suggestions for how to distinguish between levels of engagement and performance in a meaningful way.

Documentation: To receive a quality bonus payment based upon engagement in state- or regional-level pediatric health care transformation, CHGME hospitals would be required to submit a letter from the lead organization, which could include the project director for a HRSA-supported program or the state Medicaid Director, confirming participation by the children's hospital in the program and delineating the roles and responsibilities of the children's hospital in the program activities. In addition, CHGME hospitals would be required to submit a brief narrative statement describing how CHGME trainees are integrated into state- or regional-level pediatric health care transformation activities and the expected benefits for trainees and the health systems served by the children's hospital. HRSA is seeking comment on this proposed approach including opportunities to limit burden and streamline the documentation to determine whether applicants meet standards and distinguish among levels of engagement and performance.

Payment Structure: HRSA proposes that CHGME hospitals that meet the standards receive a portion of the available funds for the CHGME Quality Bonus System. HRSA proposes a three tiered payment structure to recognize the different annual payment levels received by CHGME hospitals. Hospitals that meet the Quality Bonus Systems standards will be evenly divided into three tiers based on their combined direct and indirect fiscal year payment amounts, as calculated per the established CHGME program formulas:

Tier 1: Hospitals that qualify for the quality bonus payment that are in the lowest third among hospitals that qualify for the quality bonus payment of calculated CHGME annual payments will receive a base payment.

Tier 2: Hospitals that qualify for the quality bonus payment that are in the middle third will receive two times the base payment.

Tier 3: Hospitals that qualify for the quality bonus payment that are in the highest third will receive three times the base payment.

The base payment rate would be determined from the total amount available and the number of hospitals that qualify for the CHGME Quality

Bonus System in a fiscal year. HRSA would also seek to recognize the hospital's level of engagement or performance in the bonus amount. HRSA is also interested in gathering views and suggestions on whether any of the existing information that hospitals already report to the Centers of Medicare and Medicaid Services, HRSA, accrediting bodies, and others could be used to measure the performance of GME programs and related health outcomes for FY 2019 or subsequent years. This could be individual measures or combinations of measures that are reported to different entities.

Quality Bonus Payment in FY 2020 and Beyond—Areas for Public Comment

In future years, HRSA will refine the CHGME Quality Bonus System to reflect the feedback received from stakeholders, as well as advancements in the development of standardized GME quality measures. To that end, HRSA also is requesting comments on several areas of the Quality Bonus System that will be implemented in FY 2020 and beyond. For long-term implementation, HRSA seeks public comments on the following areas:

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 Measures: HRSA is seeking comment on appropriate GME outcome measures that can assess and distinguish performance in meaningful ways. HRSA is considering several GME outcome measures including resident specialty outcomes (e.g., number of graduates in high need pediatric specialties), resident service outcomes (e.g., service to high need rural or underserved communities), and children's hospital quality outcomes. As noted above, these measures could be existing measures that hospitals already report or new ones that would be developed or improved for use in determining quality bonuses.

Data Sources: HRSA is seeking comment on available data sources on which to base the Quality Bonus System. HRSA is requesting comment on data sources that are publicly available, will streamline reporting requirements, and will limit burden on CHGME programs.

Tiering of Quality Bonus Payments: HRSA is requesting comments on payment structures to recognize hospitals according to their level of engagement and/or outcomes while also taking into account the different size of GME programs. The goal is for payment

structures to recognize the quality of hospitals' programs considering the different circumstances in which different children's hospitals operate (e.g., patient severity, size of training programs, number of specialties trained, etc.).

Frequency of Review: HRSA plans to review and update the CHGME Quality Bonus System standards regularly to reflect changes in GME and advances in measuring GME outcomes.

Dated: October 5, 2017

George Sigounas,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). This meeting will be open to the public but advance registration is required. Please register online at <http://www.achdncmeetings.org/> by 12:00 p.m. Eastern Time on November 6, 2017. Information about the ACHDNC can be obtained by accessing the following Web site: <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html>.

DATES: The meeting will be held on Wednesday, November 8, 2017, 9:30 a.m. to 5:00 p.m. Eastern Time and Thursday, November 9, 2017, 9:30 a.m. to 3:00 p.m. Eastern Time (meeting times are tentative).

ADDRESSES: This meeting will be held in-person at 5600 Fishers Lane, 5th Floor Pavilion, Rockville, MD 20857. The meeting will also be accessible via Webcast. Instructions on how to access the meeting via Webcast will be provided upon registration. Please note, the 5600 Fishers Lane building requires security screening on entry. Visitors must provide a driver's license, passport, or other form of government-issued photo identification to be granted entry into the facility. Non-US Citizens planning to attend in person will need