100. Kathleen Cooper-Loher, Marshfield, Wisconsin, Court of Federal Claims No: 18–0769V
101. Kerstina Alexander on behalf of M.A., Deceased, Woodbridge, Illinois, Court of Federal Claims No: 18–0770V
102. Henry Milligan, Jr., Orlando, Florida, Court of Federal Claims No: 18–0771V
103. Cheryl Thompson, South Bend, Indiana, Court of Federal Claims No: 18–0772V
104. Olivia Gallegos, Fresno, California, Court of Federal Claims No: 18–0773V
105. Jacie Albanez and Mario Albanez on behalf of N.A., San Diego, California, Court of Federal Claims No: 18–0774V
106. Scott Kelbick, Avondale, Arizona, Court of Federal Claims No: 18–0775V
107. Elizabeth Phenneger, Spokane, Washington, Court of Federal Claims No: 18–0776V

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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: Final response.

SUMMARY: HRSA published a notice in the **Federal Register** on October 11, 2017, soliciting feedback on the establishment of the Children's Hospitals Graduate Medical Education Payment (CHGME) Program's Quality Bonus System (QBS). In particular, HRSA requested feedback on the Fiscal Year (FY) 2019 and beyond multi-step implementation of the system, including demonstration of engagement in state or regional-level initiatives, documentation, and payment structure. This notice summarizes and responds to the comments received during the 60-day comment period.

ADDRESSES: Additional information about the CHGME is available at *https://bhw.hrsa.gov/grants/medicine/chgme.*

FOR FURTHER INFORMATION CONTACT: Malena Crawford, Project Officer, Children's Hospitals Graduate Medical Education Payment Program, Division of Medicine and Dentistry, HRSA at *MCrawford@hrsa.gov* or (301) 443–7334.

SUPPLEMENTARY INFORMATION: The CHGME statute was amended in 2013. The amendments permit up to 25 percent of the total amount appropriated annually in excess of $245 million, but not to exceed $7,000,000, 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 2018, Congress appropriated $315 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 in FY 2019, it is estimated that approximately $3 million may be available annually for the CHGME QBS.

On October 16, 2017, through a **Federal Register** Notice (FRN), HRSA announced a 60-day public comment period to solicit input on the CHGME QBS proposed standards. HRSA proposed a multi-step implementation beginning in FY 2019 that initially will 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 sought public comment on the timeline, eligibility, standards, documentation, and payment structure as described in the FRN. HRSA also requested comment on proposed QBS measures, potential data sources, and tiering of QBS payments for FY 2020 and beyond. HRSA received feedback on the following program components in response to the FRN:

- QBS Goals
- Qualifying Initiatives for the FY 2019 QBS
- Measures and Metrics
- Payment Structure
- Documentation, Reporting Requirements and Reducing Reporting Burden
- Implementation Timeline for FY 2020 and Beyond

HRSA carefully reviewed the comments received and used them to guide the development of the FY 2019 CHGME QBS and to inform future iterations of the CHGME QBS. Final guidance for the FY 2019 CHGME QBS will be published in the FY 2019 CHGME Notice of Funding Opportunity (NOFO).

Comments on the Proposed Standards of the Quality Bonus System

HRSA received 17 responses to the request for comments. Thirteen commenters are current CHGME hospitals and four are state/national associations. Comments are summarized below.

QBS Goals

Summary of Comments

Nearly all commenters supported establishing the CHGME QBS to recognize and reward quality training programs for residents supported by the CHGME program and agreed with the approach to recognize engagement in initiatives geared towards transforming pediatric health care to improve access, quality, and cost effectiveness. However, many commenters questioned whether there was enough information about these initiatives to establish a baseline, draw comparisons between children's hospitals, and make judgements about relative performance. Several suggested the proposed approach could be enhanced by starting with documentation of transformation activities in which residents are involved. Specifically, one commenter recommended ''that HRSA work to identify current residents' engagement in quality initiatives and how residents can further engage on broader based initiatives before transitioning the Quality Bonus Program to other criteria in FY 2020 and beyond.'' A few commenters also requested that HRSA offer more clear and specific goals for the multi-step implementation of the QBS.

Response

After considering feedback from stakeholders, the revised goal of the QBS will be to recognize hospitals for quality improvement & GME transformation efforts in high priority focus areas and build standards to increase engagement and involvement of residents in broader initiatives. HRSA will implement a baseline phase for CHGME QBS in FY 2019. Information collected during this baseline phase will be used to establish QBS standards for implementation in FY 2021. In order to qualify for the QBS payment, CHGME awardees must submit documentation in the FY 2019 reconciliation application describing the hospital's initiatives, resident curriculum, and direct resident involvement in the following areas: Integrated care models, telehealth/HIT, population health, social determinants of health, and additional initiatives to improve access

and quality of care to rural/underserved communities.

Qualifying Initiatives for the FY 2019 QBS

Summary of Comments

Many commenters recommended expanding the list of initiatives that would qualify for the QBS and mentioned a number of other initiatives that children's hospitals are currently involved in, which included national and regional non-federal collaboratives. One commenter recommended recognizing initiatives that address pediatric health disparities (*e.g.,* childhood obesity, immunizations, access to care, poverty, food insecurity, population health, child abuse, opioid overuse) at the local and regional levels, initiatives that positively impact the health of surrounding communities, hospital quality improvement projects, and other quality-related programs that meet the goals of the Healthy People 2020. Another commenter recommended recognizing resident participation in medical homes and clinically integrated networks.

Several commenters recommended that HRSA start by compiling a list of the quality improvement and transformation efforts that residents currently engage in to identify focus areas for increased engagement and involvement. A few commenters expressed concerns that resident engagement in these initiatives may be limited due to training requirements that require rotating to a variety of clinical sites and normal resident turnover in training programs that typically last between 3–5 years.

Response

HRSA considered the commenters' recommendations for qualifying initiatives for FY 2019 and has revised the FY 2019 QBS qualification requirements taking into consideration the comments received. As mentioned above, in order to qualify for the FY 2019 QBS payment, CHGME awardees must submit documentation in the FY 2019 reconciliation application describing the hospital's initiatives, resident curriculum, and direct resident involvement in the following areas: integrated care models, telehealth/HIT, population health, social determinants of health, and additional initiatives to improve access and quality of care to rural/underserved communities. In all areas, CHGME awardees will be required to highlight initiatives aimed at improving access and quality of care to rural and/or underserved communities. More details will be included in the FY 2019 CHGME NOFO.

Measures and Metrics

Summary of Comments

Several commenters recommended focusing the QBS measures and metrics on the CHGME program and its goals, including measures regarding the quality of resident training. Commenters offered a number of potential measures and metrics that ranged from residency training characteristics, graduate outcomes, clinical learning environment outcomes, and health care transformation activities. One commenter recommended developing measures and metrics to evaluate how well training programs prepare graduates to improve the quality of care provided to local communities and integrate quality improvement into their clinical practice. They also recommended that quality measures could evaluate the quality of training settings, including commitment to caring for underserved populations, and impact on addressing healthcare problems in the community.

A few commenters recommended that HRSA more critically evaluate future QBS measures and metrics. Specifically, one commenter stated that they were ''particularly concerned about the proposed plans for FY 2020. Currently, there are no ''off the shelf'' measures that can be used to determine the quality of training programs. We recommend a thorough stakeholder process be convened with pediatric experts and CHGME hospitals to outline the best path forward.''

A number of commenters cautioned that it is hard to tie patient outcomes to resident training. A few other commenters discouraged using graduate outcomes as a QBS measure, suggesting that hospitals are unable to control the specialty choices and future practice locations of residents. Several commenters also cautioned against using metrics relating to hospital outcomes which could not be directly tied to training. They recommended only using measures that were within a hospital's control. The following chart highlights other suggested measures and metrics from commenters:

ADDITIONAL QBS MEASURES AND METRICS RECOMMENDED BY COMMENTERS

Residency Training
Quality of resident training.
Volume of trainee-led initiatives and participation in larger hospital initiatives.
Percentage of training time spent in rural and underserved locations.
Graduate Outcomes
Percentage of graduates practicing in underserved areas.
Practice patterns and competency levels of graduates.
Clinical Learning Environment Outcomes
Value of clinical care.
Number of unnecessary medical tests, treatments, and procedures.
Rates of medical complications (hospital-acquired infections, unplanned extubations).
Rates of surgical complications (surgical site infections).
Hospital readmission rates.
Chronic disease management (treatment compliance and percentage at goal).
Health Care Transformation Activities
Number of faculty and resident publications.
Number of health care transformation initiatives.

Commenters also identified existing sets of measure that could be reviewed to identify potential candidates for use in the QBS such as the American Board of Family Medicine's (ABFM) Certification Survey Questionnaire, the ABFM's National Family Medicine Residency Graduate Follow-up Survey, the Children's Hospital Association approved activities such as Solutions for Patient Safety, the American College of Surgeons' Pediatric National Surgical Quality Improvement Program, and the Accreditation Council for Graduate Medical Education's (ACGME) milestones and measures.

Response

HRSA appreciates the recommendations for potential QBS measures and metrics and recognizes the concerns regarding appropriate measures and metrics expressed by the commenters. HRSA will be reviewing all the sets of measures that were identified, as well as individual measure that were suggested for potential incorporation into the next phase of the QBS. Following the initial baseline phase of the QBS as detailed above in Qualifying Initiatives for the FY 2019 QBS response section, HRSA plans to conduct an environmental scan of GME quality measures, analyze the data collected during the baseline year, develop quality measures for GME programs in the above areas, and manage an organized stakeholder engagement process on potential QBS

standards and measures for future iterations.

Payment Structure

Summary of Comments

Most commenters agreed with the tiered payment method but highlighted the importance of clearly messaging that funding tiers are not indicative of different levels of quality or engagement for the first phase of the CHGME QBS. One commenter offered, ''the bonus payments would have a more significant effect in transforming the quality of CHGME programs if the payments were funded at a level larger than $3 million and were in excess of current program funding.''

Response

HRSA will continue to message clearly that the FY 2019 CHGME QBS payment tiers are not reflective of the quality of the initiatives. The payment tiers were developed taking into account the size of the training programs and CHGME payments typically awarded. In future years, once the data sources were better developed HRSA would work to develop a payment structure that takes into account both the size of the program and quality. As noted earlier, the amount of funding available for the QBS is provided for in statute and the $3 million funding amount is an estimation, assuming funding levels and mechanisms remain constant.

For FY 2019, QBS payments will be disbursed with the CHGME FY 2019 reconciliation payments. CHGME hospitals that submit the required documentation with the FY 2019 reconciliation application will receive a portion of the available funds for the CHGME QBS payment. Amounts will be distributed according to a three-tiered payment structure detailed in the **Federal Register**, 82 FR 48102.

HRSA expects that future quality measures will likely be a combination of both quantitative and qualitative measures, where payment will be directly linked to the level of achievement of an individual hospital. We will continue to seek additional input from stakeholders and experts on the appropriate measures and metrics for future iterations of the CHGME QBS.

Documentation, Reporting Requirements and Reducing Reporting Burden

Summary of Comments

Several commenters indicated that HRSA already collects quite a bit of information through the annual report and recommended that HRSA build on its existing reporting requirements to minimize reporting burden. These commenters suggested that new reporting requirements would add an administrative burden and deter maximum participation in the QBS. One commenter questioned whether HRSA would publicly share the QBS data.

Response

HRSA agrees that participation in the QBS should not be overly burdensome and will work to create reasonable documentation requirements. HRSA acknowledges that it is already collecting some quality-related data in the annual CHGME performance measures and is developing ways to improve these fields. In addition, as part of the further development of the QBS, HRSA will be reviewing the different sets of data that children's hospitals already report to identify if any of the measures could be used as part of the QBS. A long-term goal would be to have transparency regarding the QBS data and HRSA will make sure to include that topic in stakeholder discussions. Any new data collection form(s) that are developed will require Office and Management and Budget (OMB) approval. Stakeholders will be able to provide public comments on any new data collection form(s) developed.

Implementation Timeline for FY 2020 and Beyond

Summary of Comments

Half of commenters recommended a longer timeline to phase in the full FY 2020 and beyond QBS proposed framework, in order to ensure a thorough stakeholder engagement process in which pediatric experts are adequately involved in establishing metrics and measures, identifying quality outcomes, and evaluating QBS standards.

Response

HRSA recognizes concerns about the QBS implementation timeline. We understand that there are many important factors that must be taken into account when implementing the QBS, and each requires thorough and well-informed consideration. In addition, QBS-related data collection must align with existing reporting and payment schedules for the CHGME Payment Program. The first phase of the CHGME QBS is planned to start in FY 2019, and we have taken into consideration feedback collected through this FRN. The data collected during the FY 2019 QBS will give HRSA an indication of the current experiences across our children's hospitals so that we can establish reasonable parameters and measures moving forward. In addition, HRSA is examining using existing reporting requirements to establish components of the QBS for FY 2020 and beyond. HRSA will continue collaborating with stakeholders and experts to inform future phases and measures for the CHGME QBS. As new QBS measures will affect a fiscal year payment, any updates or changes will be included in that year's NOFO.

Conclusion

HRSA appreciates the comments and recommendations received and has used them to guide the development of the FY 2019 CHGME QBS and inform future iterations of the CHGME QBS. Final guidance for the FY 2019 CHGME QBS will be published in the FY 2019 CHGME NOFO. If you have questions or concerns about comments that were not addressed in this notice, please contact *MCrawford@hrsa.gov.*

Dated: June 19, 2018.

George Sigounas,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Survey of Organ Donation Attitudes and Practices, OMB No. 0915–0290—Reinstatement With Change

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. The ICR is for reinstatement with change of a previously approved information collection, assigned OMB control number 0915–0290, which expired on March 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 26, 2018.