



pharmacists advancing healthcare®

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June 26, 2014

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1607-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

**Re: CMS-1607-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers**

Dear Sir/Madam:

ASHP is pleased to submit comments in response to the Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals (Proposed Rule) issued by the Centers for Medicare & Medicaid Services (CMS) and published in the Federal Register on May 15, 2014.<sup>1</sup> ASHP is the national professional organization whose more than 40,000 members include pharmacists, student pharmacists, and pharmacy technicians who serve as patient care providers on healthcare teams in acute and ambulatory settings. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and advance healthcare.

**Specialized Pharmacy Residency Programs**

ASHP strongly recommends that CMS reinstate graduate medical education (GME) funding for second-year pharmacy residency programs and address this issue in Section V: Other Decisions and Proposed Changes to the IPPS for Operating Costs and Graduate Medical Education (GME). While the Agency cut funding in 2004, citing that these programs were not required for employment as a clinical pharmacist, ASHP surveys indicate otherwise. In fact, the overwhelming majority of institutions surveyed either requires or strongly favor pharmacy candidates who have completed residency programs.

An ASHP survey found that 80 percent of respondents would require a candidate with specialized residency training, if there was an adequate supply of specialized residency trained pharmacists. Additionally, almost 75 percent of respondents cite the loss of Medicare pass-

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<sup>1</sup> Federal Register Volume 79, Number 94, Pages 27978 – 28384.

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through funding for specialized residencies as making it more difficult to recruit specialized residency trained pharmacists at their institutions.

Second-year specialized pharmacy programs are vital to our health-care delivery system by providing pharmacists with essential clinical training that enables them to take on direct patient care activities, including participating on patient rounds, monitoring patient responses to their medicines, improving medication therapy outcomes and preventing adverse drug events (ADEs). These programs foster the skills required for pharmacists to care for highly-specialized and complex patients, effectively interact with specialized physicians and nurses, and conduct collaborative research. Similar to residencies in medicine, pharmacy residencies are intense, structured, patient-centered training that involve close work with preceptors and mentors. Their involvement not only provides improved patient outcomes, it can also result in reduced costs for their institutions and the health-care system. In a study published in the *American Journal of Health-System Pharmacy*, an intensive care unit clinical pharmacist saved a hospital as much as \$280,000 over a 4.5 month period by preventing potential ADEs and reducing costs.<sup>2</sup>

Further, ASHP believes that, for future roles involving specialized clinical activities, pharmacists will be required to have completed an ASHP-accredited second-year, specialized residency. With implementation of the Patient Protection and Affordable Care Act (PPACA) and other changes, the health care delivery system will evolve, particularly in hospitals and health-systems, making completion of these residencies a requirement for practice in these positions.

ASHP has adopted several policy positions that establish the need to complete a residency as a requirement for the clinical pharmacist in a hospital. The intent of the policy positions is to meet the changes in care delivery and the increasing reliance on the interprofessional patient care team.

- **Therefore, ASHP strongly recommends that CMS reinstate funding through the Medicare GME program for specialized pharmacy residency programs that was eliminated in 2003.**

### **Proposed Changes to the Hospital Readmission Reduction Program**

#### *Refinements to readmission measures and related methodology for FY 2015 and subsequent years*

ASHP strongly supports the use of the revised version of the CMS planned readmission algorithm version 3.0 for the AMI, HF, PN, COPD, and THA/TKA readmission measures. This

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<sup>2</sup> Kopp BJ, Mrson M, Erstad BL, and Duby JJ. "Cost implications of and potential adverse events prevented by interventions of a critical care pharmacist." *Am J Health-Syst Pharm*. 2007; 64:2483-2487.

algorithm is supported by the multi-stakeholder organization, the National Quality Forum (NQF). Also, the algorithm has undergone a validation study for use in the calculation of hospital readmissions. ASHP commends CMS on the use of the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) codes in creation of this measure to simplify and reduce the reporting burden. The Society agrees with the removal of CCS 211 Therapeutic Radiation and CSS 224 Cancer Chemotherapy to increase the accuracy of the algorithm that identifies planned readmissions. ASHP also agrees with the addition of CCS 99 Hypertension with Complications, and the changes to the CCS 149 Pancreatic Disorders to better identify unplanned readmissions.

Expanding the scope of applicable conditions for FY2016 and FY2017:

ASHP applauds CMS for addressing comments on delaying expansion of applicable conditions for 2016. The Society agrees with other commenters and CMS that institutions should be given time to become familiar with the 5 existing conditions AMI, HF, PNA, THA/TKA, COPD. ASHP conditionally supports the addition of All Cause Unplanned Readmissions following Coronary Artery Bypass Graft (CABG) to the readmission conditions for FY 2017. Similar to the recommendation by the NQF Measures Application Partnership, ASHP believes the CABG measure should undergo a vetting process through the multi-stakeholder organization and attain endorsement status prior to implementation.

- **As a member of the National Quality Forum (NQF), ASHP strongly recommends that CMS include only those measures that have been endorsed through the rigorous consensus-building process of the National Quality Forum. Consensus achieved during the measure development process, through broad acceptance and use of a measure, or through public comment does not incorporate the robust and comprehensive process used to establish NQF endorsement.**

Maintenance of technical specifications for quality measures:

ASHP commends CMS on the methodology outlined in the Hospital IQR program “Maintenance of Technical Specifications for Quality Measures” found in section IX.A.1.b. The Society believes this methodology gives CMS the ability to incorporate substantive changes to measures used in payment and reporting programs through future proposed rules and review period while preserving autonomy and flexibility to rapidly implement non-substantive updates to the measures from regular maintenance by measure developers.

Proposed inclusion of THA/TKA and COPD Readmission measures to calculate aggregate payment for excess readmissions beginning FY 2015. Changes to the calculation for the

aggregate payments for excess readmissions to include two additional readmission measures for COPD and THA/TKA

COPD exacerbations are a significant healthcare burden and are responsible for 1% of all emergency department visits. Over fifty percent of these emergency visits result in hospital admissions.<sup>3</sup> Further, appropriate medication use and adherence has been shown to be an independent modifiable risk factor to reduce COPD exacerbations.<sup>4</sup> The Society strongly supports the inclusion of a COPD readmission measures beginning FY 2015.

Establish an exceptions process to address hospitals with extraordinary circumstances

ASHP strongly agrees with other commenters and is in support of the creation of an extraordinary circumstance exemption (ECE) policy. Health-systems cannot control the frequency of disaster circumstances that will increase resource use and may result in high levels of hospital readmissions. This type of policy is a component of other payment and reporting programs and will support the efforts of acute care institutions to maintain the highest quality of care and efficient resource use for all patients during extraordinary circumstances such as disaster relief events.

**Proposed Changes to the Hospital Value Based Purchasing (VBP) Program.**

Most significantly, CMS proposes to remove six topped out measures and proposed change to truncated coefficient of variation criterion to determine whether a measure is topped out.

These measures are:

1. PN-6
2. SCIP-Card-2
3. SCIP-Inf-2
4. SCIP-Inf-3
5. SCIP-Inf-9
6. SCIP-VTE-2

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<sup>3</sup> García-Sanz M, Pol-Balado C, Abellás C, Cánive-Gómez J, Antón-Sanmartín D, González-Barcala FJ. Factors associated with hospital admission in patients reaching the emergency department with COPD exacerbation. *Multidisciplinary Respiratory Medicine*. 2012;7(1):6. doi:10.1186/2049-6958-7-6.

<sup>4</sup> Ozyilmaz E, Kokturk N, Teksut G, Tatlicioglu T. Unsuspected risk factors of frequent exacerbations requiring hospital admission in chronic obstructive pulmonary disease. *Int J Clin Pract*. 2013;67(7):691-697. doi:10.1111/ijcp.12150.

ASHP agrees with the methodology provided on calculations to determine whether a measure is topped out, specifically the truncated coefficient of variation criterion. ASHP agrees with the proposal to alter the threshold from “less than 0.10” to “less than or equal to 0.10”. However the Society strongly suggests that these identified “topped-out” measures remain available in other reporting programs. The Society believes that reporting these six specific measures have attributed to recent increases and emphasis on improved healthcare quality in hospitals. Each of these measures has a significant impact on local improvement efforts and the Society strongly encourages CMS to continue to use and apply these measures to other reporting programs.

#### New Measures for FY 2017

ASHP supports the inclusion of two new measures on Methicillin Resistant Staphylococcus aureus Bacteremia (NQF #1716) and Clostridium difficile Infection (NQF #1717) as well as the proposed adoption of the current CLABSI measure. The Society understands the need to use the current specification of the CLABSI measure. ASHP urges CMS and NQF to rapidly incorporate reliability-adjusted Standardized Infection Ratio (SIR) calculation for this CLABSI measure because it provides a more robust calculation to identify differences among hospital rates.

ASHP applauds CMS for considering incorporation of a care transition measure (CTM-3) into the Hospital VBP Program. The incorporation of this measure develops a ninth dimension of the HCAHPS survey in the Patient and Caregiver Centered Experience of Care/ Care Coordination (PEC/CC) domain for FY 2018. This measure is a significant first step in addressing shared accountability and quality of care during transitions of care periods and discharges from the health-system setting. The Society agrees that initially the normalization approach should be used for this care transition measure and calculation of total performance score.

#### **Proposed Changes to the Hospital Acquired Condition Reduction Program**

##### General Selection of Measures and updates on AHRQ PSI-90 and CDC NHSN CLABSI and CAUTI measures

ASHP supports the proposed selection and implementation schedule of quality measures included in the Hospital Acquired Condition (HAC) Reduction Program. The Society believes that the AHRQ PSI-90 composite for domain 1 and CDC NHSN measures CAUTI and CLABSI for domain 2 are sufficient starting points to address the potential harm experienced in acute care facilities. ASHP agrees with the proposal to add the CDC NHSN Surgical Site Infection measure

for FY 2016. According to the CDC the overall surgical site infection rate is 1.9% with an associated mortality rate of 3%. An emphasis on domain 2 measures is important to prevent negative sequelae and outcomes. In addition, the organization strongly supports the proposed addition of CDC NHSN Methicillin Resistant Staphylococcus aureus (MRSA) Bacteremia and C. difficile measures for FY 2017. These measures will address the increasing incidence infection in hospital settings.

#### Proposed maintenance of technical specifications

ASHP agrees with the proposed method of maintaining and updating the technical specifications of the quality measures for the HAC Program. This methodology includes adoption of a sub-regulatory process for non-substantive changes released by measure developers, and will aid in rapidly incorporating updates to quality measures.

#### Future considerations for electronically specified measures

ASHP strongly encourages proposals to incorporate standardized electronic composite measures of all-cause harm in the HAC reduction program in future years. The Society believes an electronic all-cause harm measure could augment existing claims-based measures and provide actionable information to institutions to prevent harm at the point of care. ASHP suggests that a potential measure be incorporated as a third domain and share a weighting component with domain 2. The scheduled incorporation of such a measure should be tested for feasibility and reliability prior to inclusion in the performance score and payment penalty.

### **Proposed Changes to the Hospital Inpatient Quality Reporting (IQR) Program**

ASHP encourages information and recommendations set forth in the NQF Measures Application Partnership 2014 Recommendations on Measures for more than 20 Federal Programs. ASHP is an inaugural member of the NQF and believes the methodology and consensus development process of this multi-stakeholder organization greatly contributes to the effectiveness of quality reporting programs through input on the measures under consideration. ASHP agrees with the proposed validation strategy for electronic clinical quality measures for the Hospital IQR Program, including the desired attributes and planned process. ASHP supports the larger scale pilot of the validation strategy prior to proposing requirements for the FY2017 payment determination. The Society understands that there are challenges to moving from chart abstracted measures to electronic clinical quality measures – particularly standardization and collection of electronic clinical documentation within workflows. The organization strongly

supports, similar to other commenters, a data validation strategy prior to implementation of electronic clinical quality measures.

Removal and Suspension of Hospital IQR Program Measures:

ASHP agrees with the proposal to modify the definition of a “topped out” measure. This modification changes the operator for the truncated coefficient of variation (CV) from strictly “less than” to “less than or equal to” to designate a topped out measure. The organization understands that several important measures will be retained as electronic clinical quality and supports the list of chart abstracted measures proposed for removal for the FY 2017 payment determination.

Overview of Measure and Rationale for Examining Payments for a 30-day Episode of Care:

The Society strongly supports the proposal to include the Severe Sepsis and Septic Shock: Management Bundle Measure NQF#500. The Surviving Sepsis Campaign is an international initiative for appropriate management of sepsis and septic shock and reduces the harm associated with these episodes.<sup>5</sup> A bundled measure can greatly influence goal oriented management.

Possible Future Electronic Clinical Quality Measures:

ASHP strongly supported proposed inclusion of measures addressing adverse drug events. Specifically Adverse Drug Events – Hyperglycemia (NQF # 2364; CMS #701a) and Adverse Drug Events Hypoglycemia (NQF # 2363; CMS #701b). The Measures Application Partnership conditionally supported these measures in its 2014 Recommendations on Measures for More Than 20 Federal Programs final report. These measures relate to the appropriate management of diabetes and have just recently been endorsed by the NQF. Optimizing medication therapy in hospital settings greatly reduces negative sequelae associated with adverse events.

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<sup>5</sup> Dellinger RP, Levy MM, Rhodes A, et al. Surviving sepsis campaign: international guidelines for management of severe sepsis and septic shock: 2012. Crit Care Med. 2013;41(2):580-637. doi:10.1097/CCM.0b013e31827e83af.

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Page 8

The Society appreciates this opportunity to provide comments. Please contact me if you have any questions or if you would like further detail on the surveys that ASHP has conducted supporting our position that CMS should reinstate second-year pharmacy residency programs. I can be reached by telephone at 301-664-8806, or by e-mail at [ctopoleski@ashp.org](mailto:ctopoleski@ashp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher J. Topoleski". The signature is fluid and cursive, with a large initial "C" and "T".

Christopher J. Topoleski

Director, Federal Regulatory Affairs