



August 15, 2016

[Submitted electronically to www.regulations.gov]

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Docket CMS — 3295 — P for “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule.”

ASHP is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed changes to the Medicare and Medicaid conditions of participation (CoPs) for hospitals and critical access hospitals (CAHs) (the “proposed rule”). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization’s more than 43,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 70 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP thanks CMS for the opportunity to comment on the proposed changes to hospital and CAH CoPs. We believe that pharmacists have a responsibility to take prominent roles in antimicrobial/antibiotic stewardship (AS) programs and to participate in the infection prevention and control (IC) programs of hospitals and health systems.¹ While ASHP is generally supportive of CMS’s IC and AS proposals, to ensure robust programs we encourage CMS to consider the following comments as it finalizes the hospital and CAH CoPs.

- **AS Program Leadership:** ASHP commends CMS for recognizing that pharmacists are essential to successful AS programs and thanks CMS for citing ASHP’s AS and IC guidance. CMS states in the proposed rule that AS programs “are led by physicians and pharmacists who have direct knowledge and experience with antibiotic prescribing.”² However, although CMS includes a clinical pharmacist’s time in calculating the cost of an AS program, CMS does not explicitly require that a pharmacist lead these programs. We encourage CMS to strengthen this requirement by requiring that, at minimum, a pharmacist be an integral part of the AS program team. AS programs focus heavily on antibiotic use and require careful coordination with

¹ ASHP, Antimicrobial Stewardship Resources, “ASHP Statement on the Pharmacist’s Role in Antimicrobial Stewardship and Infection Prevention and Control”, *available at* <http://www.ashp.org/DocLibrary/BestPractices/SpecificStAntimicrob.aspx>.

² 81 Fed. Reg. 39457 (June 16, 2016).

disparate members of the healthcare team/departments. Pharmacists function as the medication experts on the healthcare team as well as, in many instances, the de facto care coordinators. As such, pharmacists are uniquely positioned to take on the clinical, organizational, and collaborative demands of overseeing AS programs.

It is important to note that, while we assert that pharmacists are essential to successful AS programs, we fully concur that robust AS programs require “internal coordination among all components responsible for antibiotic use and reducing the development of resistance.”³ We believe that physicians, nurses, laboratory personnel, and others should be engaged in creating, implementing, and monitoring AS programs, but we recommend that AS programs be housed within the pharmacy department. This would align with The Joint Commission’s medication management standards⁴ related to responsibility for antibiotic stewardship, while facilitating outreach to other departments.

- **IC and AS Leadership Recommendations:** CMS proposes to “require hospitals to seek out and consider the recommendations of medical staff leadership and nursing leadership” in making appointments to AS and IC program teams.⁵ We support this requirement and suggest that CMS expand it to include recommendations from other departments or divisions — including pharmacy, laboratory medicine, pathology, and quality assurance/performance improvement — that are integral to the success of AS and IC programs. Although our understanding is that CMS did not intend for the above language to be prescriptive, we are concerned that some stakeholders could read it narrowly, precluding vital feedback from individuals outside the medical staff and nursing leadership.
- **AS and IC Program Funding:** Comprehensive AS and IC programs require sufficient financial support. CMS suggests that the cost savings associated with these programs will more than offset their costs⁶, but we are concerned that the savings numbers will vary over time and by hospital/CAH. Specifically, we are concerned that CMS posits some cost savings on reduced drug acquisition costs. While the majority of facilities will likely see decreased drug acquisition costs following the introduction of an AS program, increasing drug prices will likely consume these savings, eventually eliminating them. Additionally, CMS’s cost savings estimates were derived from a very small number of studies. We are concerned that these effects may not be entirely replicable in every hospital and CAH and, therefore, should not be the prime justification for AS program implementation. Creating unrealistic expectations about the level of cost savings associated with AS programs could endanger AS programs that do not produce equivalent cost savings.

³ *Id.* at 39456.

⁴ See The Joint Commission, “Prepublication Standards – New Antimicrobial Stewardship Standard” (June 22, 2016), available at https://www.jointcommission.org/assets/1/6/HAP-CAH_Antimicrobial_Prepub.pdf (Establishing new standards under MM.09.01.01, which take effect January 1, 2017).

⁵ 81 Fed. Reg. 39456.

⁶ *Id.* at 39472

Aside from ongoing administration costs, to build effective programs, hospitals and CAHs will likely need to invest in personnel education costs, including support for staff pharmacists hoping to obtain AS stewardship certification. Thus, we urge CMS to explore additional funding mechanisms for IC and AS programs. In particular, ASHP recommends that CMS enhance financial incentives to stimulate creation of postgraduate infectious diseases/antimicrobial stewardship pharmacy residency programs, which will increase the number of pharmacists trained to perform AS and IC work.

Finally, ASHP supports the use of telemedicine networks to allow under-resourced small and rural hospitals to access to national experts when needed to optimize patient's care. We urge CMS to allocate resources and funding to support the development of telemedicine network options.

- **AS Program Metrics:** As noted above, ASHP supports the creation of robust AS programs. ASHP shares CMS's view that AS programs should be evidence-based; however, we question the inclusion of "growth of antibiotic resistance in the hospital overall" as a performance metric.⁷ Although we believe that resistance should be monitored, measuring success based on overall resistance could skew program assessment. Many external factors beyond the AS program's control contribute to resistance patterns within a hospital/CAH, including transfer of patients from nonaffiliated facilities.

Additionally, the Centers for Disease Control and Prevention (CDC), the Pew Charitable Trusts, the National Quality Forum (NQF) and others are currently pursuing the use of more targeted metrics including Standardized Antimicrobial Administration Ration (SAAR) and Antibiotic Utilization (AU) models. Both ASHP staff and ASHP expert infectious disease members have been providing input on the potential implementation of these models into ASHP programs. This is still an evolving process, but we encourage CMS to consider these models as AS and IC program outcome measures are developed and implemented.

In addition to our comments on the AS and IC sections of the proposed rule, members have raised questions regarding the provision of nutrition services under § 485.635(a)(3)(vii). ASHP's understanding is that CMS's proposed changes broaden the regulatory language to allow any clinician who "meets his or her respective State laws, regulations, or other appropriate professional standards" to prescribe a therapeutic diet, regardless of the clinician's title.⁸ We respectfully request that CMS further clarify the provision in its final rule and indicate whether our interpretation is correct.

As CMS finalizes the hospital and CAH CoPs, ASHP is eager to assist CMS in any way possible. Please contact me at jschulte@ashp.org or (301)-664-8698 if you have any questions or wish to discuss our comments further.

⁷ *Id.* at 39457.

⁸ *Id.* at 39461.

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Sincerely,

A handwritten signature in black ink that reads "Jillanne M. Schulte". The signature is written in a cursive style with a prominent loop at the end of the last name.

Jillanne M. Schulte, JD
Director, Federal Regulatory Affairs