



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

August 15, 2016

[Submitted electronically to <http://www.regulations.gov>]

Centers for Medicare & Medicaid Services

Re: Medicare & Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule

Dear Sir/Madam:

APhA is pleased to submit these comments regarding the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care (hereinafter, the "Proposed Rule"). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician office practices, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates CMS's efforts to reduce readmissions and the incidence of hospital-acquired conditions, improve antibiotic use and enhance patient and workforce protections by modernizing CAH's Conditions of Participation (CoP). We thank CMS for the opportunity to provide pharmacists' perspectives on its Proposed Rule and appreciate CMS's inclusion of pharmacists in the proposed Antibiotic Stewardship (AS) program and its continued emphasis of a team-based approach to care. As CMS is aware, antibiotics are among the most commonly prescribed drugs, yet approximately half are not needed or not optimally prescribed.¹ Antibiotic resistant infections have a significant annual impact on patients causing 23,000 deaths annually and upwards of \$35 billion in excess direct health care costs.² Thus, increasing pharmacist involvement in antibiotic stewardship and patient care can decrease expenditures and streamline care. APhA offers the following recommendations and concerns regarding the AS program, staffing evaluations, the quality assessment and improvement (QAPI) program and medical record access discussed in the Proposed Rule.

¹ Executive Office of the President, President's Council of Advisors on Science and Technology. Report to the President on Combating Antibiotic Resistance. 2014. Available at:

https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf.

² *Id.*

I. Condition of participation: Infection prevention and control and antibiotic stewardship programs

As longtime advocates for the pharmacist's role in antibiotic stewardship, APhA applauds CMS's inclusion of pharmacists as potential leaders of the proposed AS programs. Research has consistently demonstrated that pharmacists' involvement in AS programs can improve medication appropriateness and cure rates, and reduce treatment failures, rates of infection, antibiotic prescribing and dosing errors—ultimately limiting antibiotic resistance and reducing costs.^{3,4,5,6,7} Although the Proposed Rule identifies only physicians or pharmacists as the leads of AS Programs⁸, the regulatory language in §485.640(b)(1) is broader than a physician or pharmacist since it states “an individual, who is qualified through education, training or experience is appointed as the leader of the antibiotic stewardship program...”⁹ Because it appears from Proposed Rule's background information that CMS's intent is to only have physicians and pharmacists lead AS programs, APhA recommends that CMS clarify practitioners eligible under this provision by specifying that only a pharmacist or physician may lead an AS Program.

To improve transparency and foster team-based decision-making, APhA supports CMS's requirement that the hospital, when selecting the leader of the AS program, base its decision “on the recommendations of the medical staff leadership and pharmacy leadership.”¹⁰ A similar structure exists for infection prevention and control programs where appointment is based recommendations from medical staff leadership and nursing leadership.¹¹ Since implementation of the two aforementioned programs are required CoP elements, we are concerned that CAHs and hospitals may select a single individual to lead both programs. Given the robust demands of each program and CMS's decision to require both, APhA encourages CMS to discourage hospitals and CAHs from having the same individuals lead both programs.

APhA also appreciates that the Proposed Rule would grant hospitals and CAHs with “the flexibility to align their programs with the guidelines best suited to them,” and that CMS is “intentionally building flexibility into the regulation by proposing language that requires hospitals to demonstrate adherence to nationally recognized guidelines rather than any specific

³ Cairns, K.A., Jenney A.W.J., Abbott, I.J., Skinner, M.J., Doyle, J.S., Dooley, M. & Cheng, A.C. (2013). Prescribing trends before and after implementation of an antimicrobial stewardship program. *The Medical Journal of Australia*, 195(5), 262-266. Available at: <https://www.mja.com.au/journal/2013/198/5/prescribing-trends-and-after-implementation-antimicrobial-stewardship-program>

⁴ Diaz Granados, C.A. (2012). Prospective audit for antimicrobial stewardship in intensive care: impact on resistance and clinical outcomes. *American Journal of Infection Control*, 40(6), 526-529. Available at: [http://www.ajicjournal.org/article/S0196-6553\(11\)00972-2/abstract](http://www.ajicjournal.org/article/S0196-6553(11)00972-2/abstract)

⁵ Di Pentima, M.C., Chan, S. & Hossain, J. (2011) Benefits of a pediatric antimicrobial stewardship program at a children's hospital. *Pediatrics*, 128(6), 1062–1070. Available at: <http://pediatrics.aappublications.org/content/128/6/1062>

⁶ Newland, J.G., Stach, L.M., De Lurgio, S.A., Hedican, E., Yo, D., Herigon, J.C., Prasad, P.A., Jackson, M.A., Myers, A.L. & Zaoutis, T.E. (2012). Impact of a Prospective-Audit-With-Feedback Antimicrobial Stewardship Program at as Children's Hospital, *Journal of Pediatric Infectious Diseases Society*, 1(3), 179-186. Available at: <http://jpid.oxfordjournals.org/content/early/2012/07/30/jpids.pis072.full>

⁷ Bartlett, J.M. & Siola, P.L. (2014). Implementation and first-year results of an antimicrobial stewardship program at a community hospital, *American Journal of health-System Pharmacists*, 71, 943-949. Available at: <http://www.ajhp.org/content/71/11/943>

⁸ See Department of Health and Human Services, 81 Fed. Reg. 39447, 39457, 39475 (June 16, 2016) (to be codified at 42 C.F.R. pts. 482 & 485) stating “Antibiotic stewardship programs are led by physicians and pharmacists who have direct knowledge and experience with antibiotic prescribing.”

⁹ 81 Fed. Reg. 39447, 39457, 39463, 39477, 39479.

¹⁰ *Id.*

¹¹ 81 Fe. Reg. 39477

guideline or set of guidelines for infection prevention and control and for antibiotic stewardship.”¹² While the Proposed Rule highlights joint guidelines from the Infectious Disease Society of American (IDSA) and the Society for Healthcare Epidemiology of America (SHEA),^{13,14} which recommend an onsite infectious diseases (ID) physician and ID-trained pharmacist as core members of the AS program, research has demonstrated that effective alternative models for institutions unable to implement an AS Program (e.g., due to limited resources) may involve a remote ID pharmacist, or pharmacy resident and student pharmacists.^{15,16} Accordingly, in line with CMS’s recognition of the need for flexibility, APhA suggests that CMS allow hospitals and CAHs to implement alternative practices that are evidence-based, rather than restricting them nationally recognized guidelines.

II. Condition of participation: Staffing and staff responsibilities

APhA agrees with the intent of CoP related to the review and evaluation of health care practitioners in effort to improve patient care. However, we are concerned that pharmacists are not specifically included as a type of practitioner whose clinical privileges and performance will be periodically evaluated. Specifically, §485.631(d)(1) & (2) require evaluation of the “quality and appropriateness of the diagnoses and treatment,” furnished by nurse practitioners, clinical nurse specialists, physician assistants and doctors of medicine or osteopathy. Given the value pharmacists bring as medication experts and the importance of their role in AS Programs, pharmacists should be explicitly included as health care practitioners whose performance is periodically evaluated so as to measure and depict their contributions within the health care team.

In addition, APhA suggests that CMS expand the pool of practitioners eligible to perform these reviews. As currently drafted in the Proposed Rule,¹⁷ pharmacists are not involved in the evaluation of other health care practitioners. To advance team-based care, CMS should expand the practitioners eligible to evaluate CAH staff and doctors of medicine and osteopathy to reflect the current health care environment and evolving roles health care providers, such as pharmacists. A more holistic approach to evaluations is consistent with current trends in employee appraisals that consider multiple strategies and perspectives.¹⁸ Doing so will enhance the quality and robustness of the review as the evaluation will reflect more diverse expertise and interactions.

III. Condition of Participation: Quality assessment and performance improvement program

¹² 81 Fed. Reg. 39447, 39454, 39455, 39457.

¹³ See Barlan, T.F., Cosgrove, S.E., Abbo, L.M., MacDougall, A., Scheutz, A.N., Septinus, E.J., Srinivasan A., Dellit, T.H., Falck-Ytter, Y.T., Fishman, N.O., Hamilton, C.W., Jenkins, T.C., Lipsett, P.A., Malani, P.N., May, L.S., Moran, G.J., Neuhauser, M.M., Newland, J.G., Ohl, C.A., Samore, M.H., Seo, S.K. & Trivedi, K.K. (2016). Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Disease Society for Healthcare Epidemiology of America, *Clinical Infectious Disease*, 62, e51-e77. Available at: <http://cid.oxfordjournals.org/content/early/2016/04/11/cid.ciw118.abstract>.

¹⁴ 81 Fed. Reg. 39447, 39455 stating “While the CDC guidelines represent one set, there are other sets of nationally recognized guidelines from which hospitals might choose, such as those established by SHEA and IDSA.”

¹⁵ Laible, B.R., Jawad, N., Assimacopoulos, A.P. & Schut, J. (2010). Implementation of a pharmacist-led antimicrobial management team in a community teaching hospital: use of pharmacy residents and pharmacy students in a prospective audit and feedback approach, *Journal of Pharmacy Practice*, 23(6), 561-535. Available at: <http://jpp.sagepub.com/content/23/6/531>.

¹⁶ Wood, Z.H., Nicolsen, N.C., Allen, N. & Cook, P.P. (2015). Remote antimicrobial stewardship in community hospitals, *Antibiotics (Basel)*, 4(4), 605-616. Available at: <http://www.mdpi.com/2079-6382/4/4/605>.

¹⁷ 81 Fed. Reg. 39478

¹⁸ Aggarwal, A. & Thakur, G.R.M. (2013). Techniques of Performance Appraisal- A Review, *International Journal of Engineering and Advanced Technology*, 2(3), 617-621.

APhA is pleased that CMS recognizes the importance of incorporating quality indicator data in hospital QAPI programs, including patient care data submitted to or received from quality reporting and quality performance programs. Since hospitals and CAHs are already collecting such data, APhA recommends that CMS encourage hospitals and CAHs to report data that reflect pharmacy-driven interventions and services, such as data used for Pharmacy Quality Alliance measures that are endorsed by NQF. Reporting such measures will make certain hospitals and CAHs incorporate quality and performance measures that more comprehensively assess the full array of opportunities to improve care, including the impact of better utilizing pharmacists' expertise.

In addition to encouraging care models that harness pharmacists' skillset, we appreciate CMS promoting hospital and CAH development and implementation of IT systems and information exchanges that include other providers, such as pharmacists. CMS encourages hospitals to "use IT systems, including systems to exchange health information with other providers" and to use certified health IT to "ensure that they are transmitting interoperable data that can be used by other settings."¹⁹ APhA supports CMS's recommendation and suggests the agency take additional steps to incentivize hospital and CAH inclusion of other providers, such as pharmacists, and other settings, such as pharmacies, in efforts to optimize interoperable IT systems and information exchanges. Additionally, we recommend IT system and exchange funding be available to all members of the health care team to help advance patient care as they move between settings.

IV. Condition of participation: Medical record services

APhA welcomes efforts to enhance the medical record to benefit patient care. Pharmacists in all settings play a crucial role in monitoring patient progress, for example, pharmacists' expertise enables them to effectively evaluate and report pharmacokinetic changes and adverse drug reactions.²⁰ However, pharmacists often do not have access to a patient's medical record, limiting both their ability to report and provide coordinated care. While the Proposed Rule's requirement to document medication responses and services will add to the medical record, the medical record will still be incomplete if the pharmacist, including a patient's community pharmacist, is unable to access or add to these records.

In addition, improving pharmacists' access to medical records may limit hospital and CAH readmissions, especially given the Proposed Rule's requirement to include discharge information in the medical record. Pharmacists' access to medical records, including discharge information, helps patients transition between care settings and reduce hospital readmissions.²¹ CMS should consider policies that encourage and facilitate pharmacists' access to medical records to achieve the Proposed Rule's goal to reduce readmissions.

APhA appreciates the opportunity to provide the pharmacist's perspective on the proposed changes to the conditions of participation for hospitals and CAHs. Like CMS, we support efforts to modernize care settings to respond to emerging public health issues, such as hospital-acquired conditions and antibiotic resistant bacteria, and believe that pharmacists are playing a crucial role in improving patient care, which can be expanded and more beneficial.

¹⁹ 81 Fed. Reg. 39447, 39453.

²⁰ Ansari, J.A. (2010). Drug Interaction and Pharmacist. *Journal of Young Pharmacists*, 2(3), 326-331. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2964764/>.

²¹ Sen S., Bowen J.F., Ganetsky V.S., Hadley D. Melody, D., Otsuka S, Vanmali R. & Thomas, T. (2014). Pharmacists implementing transitions of care in inpatient, ambulatory and community practice settings. *Pharmacy Practice*. 12(2), 439-447.

Pharmacists are medication experts on a care team and have a proven ability to limit risks associated with overprescribing antibiotics. We applaud CMS's recognition of the pharmacist's capabilities and encourage ongoing efforts to better incorporate and utilize pharmacists in variable care settings. If you have any questions or require additional information, please contact Jenna Ventresca, JD, Associate Director of Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government
Affairs