

The Honorable Andy Slavitt, Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health & Human Services  
Attention: CMS-3260-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

October 14, 2105

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1321 Duke Street  
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Via: Electronic Submission to Regulations.gov CMS-3260-P

**Re: Comments on Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities: Proposed Rule**

Dear Administrator:

The American Society of Consultant Pharmacists (ASCP) is the only international professional society devoted to optimal medication management and improved health outcomes for all older persons. ASCP's senior care consultant pharmacists members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, sub-acute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care.

ASCP is pleased to offer comments on the proposed rule relating to certain sections that speak to its expertise.

**Pharmacists in the Long-Term Care Facility:**

Consultant pharmacists are licensed healthcare professionals that coordinate pharmacy services to optimize medication management for residents with facility staff, prescribers and family/caregivers. Facilities contract with a consultant pharmacist to provide services that address the needs of each resident by conducting a Medication Regimen Review at least monthly (F428), as well as assisting in facility-level issues such as medication errors, medication storage, education of staff, and other quality initiatives to improve medication use and safety.

In order to provide optimal pharmacy services by a pharmacist, they need to have access to clinical information as well as the ability to communicate effectively with other members of the healthcare team. The technological challenges that currently exist in long-term care can be a barrier to access of the patient's electronic medical record, both on-site and remotely. The lack of incentives for the adoption of the electronic health record (EHR) and interoperability between systems are roadblocks in appropriately reviewing a resident's medical record and identifying potential "irregularities." This is critical when a resident has a change in condition, is admitted, or is discharged from a long term post acute care facility.

**Recommendations:** ASCP recommends that Pharmacists be added to the definition of Licensed Health Professional (**§483.5**). Additionally, ASCP recommends a phased in implementation of the provisions in this proposed rule to improve electronic systems consistent with the Office of the National Coordinator for Health Information Technology (ONC) interoperability roadmap.

#### **§483.21 Comprehensive Person-Centered Care Planning - New Section**

In February 2014, the Office of Inspector General issued a report entitled *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries* (<http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>). The report cited the critical early hours after admission into a skilled nursing facility, when many adverse events can occur due to a lack of adequate, person-centered care, including review of all medications. The concerns addressed in this report were discussed at length in subsequent "Call to Action: Raising Awareness for Reducing Adverse Events in Nursing Homes" stakeholder workgroup meetings, of which ASCP was a key participant. To this end, we support CMS's recommendation that facilities develop a baseline care plan for each resident within 48 hours of admission, as suggested by the workgroup.

**Recommendations:** ASCP recommends that pharmacists be included in the care planning process. Inclusion of the consultant pharmacist aligns the health care team in providing person centered care. In specific patient populations, such as older adults, these considerations become even more important due to multiple co-morbidities, medical complexity, and treatment burden (AGS, 2012). To determine realistic goals, the clinical value of a medication (i.e., benefit weighed against risk) needs to be assessed with the desired health and quality-of-life outcomes. We further recommend that the consultant and dispensing pharmacist be included in care plan process to ensure all medications are appropriate for the resident. This will allow for person-centered care to be provided and reduce adverse drug events. Finally, to ensure that the pharmacist can be a valuable member of this team, we recommend that the consultant pharmacist be notified upon admission, and at that time have access to the full medical record.

#### **§ 483.21(c) (2) (iii), (iv) Medication Reconciliation upon discharge:**

ASCP supports the proposed new requirement for a reconciliation of a resident's pre-discharge medications with their post-discharge medications. In the discharge planning process, we agree that the resident's discharge summary should include a completely reconciled medication list including all prescription medications, over-the-counter (OTC) medications, and any dietary supplements. As clinicians with extensive geriatric pharmacotherapy training, ASCP recommends that the consultant pharmacist and dispensing pharmacist should work together to ensure the discharge medication regimen is accurate and appropriate for the resident.

**Recommendations:** ASCP recommends that a consultant pharmacist be included in any patient's discharge plan from the facility to all other care settings. Adverse events associated with medication are a leading cause of hospital readmission. Further, if the resident is being discharged to independent living or to home, the first step in preventing these avoidable problems is ensuring that residents, family members, and care givers have a complete understanding of what medications have been prescribed. ASCP proposes that the consultant pharmacist provide a comprehensive medication review (CMR) during these key transitions in care. The CMR is an annual comprehensive, interactive consultation session conducted either person-to-person or via telehealth performed by a pharmacist, or other qualified provider resulting in a recommended medication action plan. The CMR is systematic process that includes: collecting patient information, identifying and prioritizing medication-related problems (MRPs), and creating a plan to resolve MRPs with the patient, caregiver, and/or prescriber. Other components include interactive face time of medication review and consultation in real-time conducted between the patient and/or other authorized individual (e.g. prescriber, caregiver) and the pharmacist or other qualified provider, as well as an educational service to address any questions the patient may have or concerns regarding their medications. This will both ensure the regimen is appropriate for the resident, and ensure that the resident will adhere to the regimen. ASCP encourages CMS to require Medicare Part D plans and other post-acute care providers to enlist consultant pharmacists to provide these services, which have been shown to improve quality of care and reduce medication-related problems (Tudor, 2012).

**§ 483.30(f)(2) Physician Delegation of Services:**

This section allows physicians to delegate dietary and therapy orders to "clinically qualified" personnel, but does not include pharmacists. Pharmacists have been granted the ability to enter into a professional collaboration relationship with physicians in some states. This section should specifically include pharmacists in the delegation of medication related to written orders when "acting within the scope of practice defined by state law." This may include lab work, or medication changes deemed appropriate and delineated by the individual prescriber in the collaborative practice agreement. This can technically already be done in more than 40 states that recognize collaborative practice agreements, however, it would be beneficial for the practice to be recognized in this section.

**Recommendation:** ASCP recommends that language be added that provides the physician with the ability to delegate to a qualified pharmacist the task of writing medication orders to the extent the pharmacist is authorized to do so under state law.

**§ 483.45 Pharmacy services:**

As stated in our comments in §483.21, we believe the consultant should be part of the proposed 48-hour care planning team upon entry to a skilled nursing facility. To ensure that the care plan is thorough, ASCP recommends that the care plan include a full, pharmacist-led medication regimen review (MRR).

ASCP supports having an MRR be performed when a resident returns to a facility or when a resident is transferred out of a facility to either home, or another care setting. As ASCP recently posited in *Call to Action* webinars and a series of regional National Partnership to Improve Dementia Care teleconferences, the consultant pharmacist must have access to the complete

electronic medical health record to perform an appropriate MRR. We do not support the idea of *any* clinician relying solely on the medication administration record (MAR) to make critical health care recommendations and decisions. As we reported on these webinars and conference calls, consultants encounter difficulties in receiving access to the full health record when not physically in the skilled nursing facility and often only the MAR is shared, making a comprehensive MRR difficult.

We ask that CMS modify verbiage in this area of the proposed rule to accurately explain why a consultant pharmacist might only have an MAR from which to perform an MRR, and why the consultant pharmacist should be supplied with electronic access to the electronic medical record when not in the facility. We understand implementation hurdles associated with interoperability of EHR, but we insist that interoperability be given top priority by CMS. Only through interoperability can the suggestions in the proposed rule be viable for skilled nursing facility clinicians. It should be further stressed that these interoperability and access concerns impact other members of the clinical team as well, since many care for residents at numerous SNFs and are not on-site in the facility during critical transition periods.

In the course of the MRR (whether the monthly MRR or the proposed transitional MRRs) the consultant pharmacist reviews all prescription medications, OTC medications, and dietary supplements, as well as recent lab data, and vital sign monitoring, including blood sugar readings in residents with diabetes, as well as clinical and psychosocial assessments and progress notes from physicians, nurses, and other consultants before making medication recommendations. In fact, these recommendations are more often based on optimal resident-centered care than on “irregularities.”

For example, a resident with hypertension who is treated with an antihypertensive medication might appear to be receiving appropriate treatment. Upon examination of vital signs, including blood pressure readings, this appropriate medication choice might need to be adjusted or removed to prevent a fall related to medication-induced hypotension. The proposed documentation requirements are a start, but do not adequately cover the reporting the consultant pharmacist performs with respect to the MRR process. The consultant pharmacist may indeed uncover “irregularities,” that is, drugs without indication, dangerous drug combinations, and drug redundancies (polypharmacy), but will also offer recommendations on appropriate strategies to ameliorate these concerns. Therefore, a more global description for the work a consultant does other than finding “irregularities” is suggested.

**Recommendations:** ASCP supports CMS’ proposed provisions for pharmacy services. While the expectation is that consultant pharmacists’ monthly review includes a review of the medical record, ASCP believes it is appropriate that in addition to current monthly MRRs, CMS require additional reviews of the medical record when specific circumstances dictate. ASCP also believes that the consultant pharmacist should be provided full access to the medical record in order to properly complete these reviews.

Examples of conditions that would trigger a chart review would include:

- **Upon admission to the facility:** This is a good opportunity for the pharmacist to inventory the resident’s diagnoses and related medication. Pharmacists are able to identify anomalies in the drug regimen and make recommendations to the prescriber to

ensure that the resident is receiving only those medications related to their diagnoses and to ensure that appropriate treatment and dosages are ordered.

- **Upon Transfer to another facility:** Continuity of care is enhanced when the receiving facility has full understanding of the resident's drug regimen. This requirement promotes that objective and ASCP supports these efforts.
- **Upon Return to the nursing facility:** As noted above, ASCP believes continuity of care will be enhanced when a consultant pharmacist has an understanding of the medical condition and current drug regimen of residents upon the return from another facility.
- **When the resident is prescribed antibiotics or psychotropic drugs:** Consultant pharmacists recognize the importance of ensuring that these drugs are used only when medically indicated. Consultant pharmacists have been active participants in CMS programs to reduce unnecessary use of antipsychotic drugs in nursing homes and are pleased with the success of this initiative. ASCP is also concerned about the potential for unnecessary use of antibiotics and agree that residents chart reviews are appropriate for residents with orders for these medicines.
- **When a drug is identified as a drug of concern by the QAA Committee:** ASCP agrees that this is an important consideration, and further encourage that the QAA committee solicit the advice of the consultant pharmacist to determine which drugs need to be subject to special surveillance.

**Concerns over Access to Medical Records:** As part of best practices, consultant pharmacists regularly review the full medical record. However, access to full medical records can be problematic due to a lack of interoperability, as mentioned above. ASCP supports the approach CMS has taken in the proposed rule and believes that consultant pharmacists are a valuable resource in the quest to improve quality of care in the nation's long-term care system.

Access to the resident's medical record, preferably in electronic format, is a critical component of success in this environment. While ASCP realizes that our concerns may be outside the scope of the current proposed rule, ASCP believes CMS should note the continuing struggle faced by pharmacists to get access to nursing home medical records. Ideally, medical records should be appropriately accessible in an electronic format that is platform-independent and completely interoperable. This alone would significantly enhance the value and efficiency of medication regimen review.

With respect to medication reconciliation at point of discharge to home, or community, the consultant pharmacists and the nursing facility do not have access to historical prescription drug events (PDE) available from the payors or prescription benefit managers (PBM). Patient medications are routinely changed during transitions of care due to formulary standards set by the various care settings and payors (hospital, nursing facility, and PBM). Requiring PBMs to make historical PDE information available to the consultant pharmacist would more efficiently reconcile patient medications at time of discharge to home. Providing historical PDE information to the consultant pharmacist will improve medication reconciliation at time of discharge by identifying and correcting medication dosing errors, duplicate therapy, and the quantity remaining from the last fill.

#### **§ 483.45(c)(4) Acting Upon Pharmacist Recommendations:**

ASCP agrees with CMS that it is very important to improve communication among the inter-professional team to ensure the safe use of medications for each resident. ASCP supports the proposal that the attending physician or prescriber not only review the consultant pharmacist's recommendations, but documents that this review has taken place, and in this written documentation, explains the rationale for accepting or rejecting the consultant's recommendations. This should be done at least once every 30 days, after the monthly MRR has been performed.

Until interoperability is implemented fully, giving electronic access to the medical record to all relevant providers, requiring a paper report to the medical director in addition to the current reporting would be a burdensome requirement.

**Recommendations:** ASCP suggests that the pharmacist's recommendations become part of the medical record which can be accessed and acted upon by the attending physician, facility's medical director and director of nursing. Due to the inter-professional nature of care provided in the long-term post-acute care (LTPAC) settings, there may be other providers who act upon the recommendations (e.g. dietician, nurse practitioner). Furthermore, CMS should consider avoiding the term "irregularities" which is currently defined as any drug that meets the definition of an unnecessary medication (paragraph d). This is narrowly focused on the negative implications of the medication. Often, pharmacists identify other medication related recommendations that improve disease or symptom control (e.g., pain management, diabetes), which may not be captured by this limited definition. Like other licensed health professionals, pharmacists should be able to order services (e.g. laboratory) and add, delete, or adjust medications that are in accordance with state law, including scope of practice.

#### **§ 483.45(d) Unnecessary Drugs and § 483.45(e) Psychotropic Drugs:**

In the regulatory guidance for F329, an "unnecessary medication" is defined as "in excessive dose (including duplicative therapy); or, for excessive duration, without adequate monitoring; or, without adequate indications for use; or, in the presence of adverse consequences which indicate the dose should be reduced or discontinued." Often a consultant pharmacist's written recommendations will concern the use of medications that are not necessary for the resident and may in fact be harmful for that person.

ASCP supports the proposal to broaden the definition of an unnecessary medication to include all medications given in the absence of medical necessity, including antipsychotic medications and other psychopharmacological agents. However, there is great concern with CMS's proposal to define all agents that can affect the brain (i.e., cross the blood brain barrier) as psychotropic agents. *Most* medications can affect the brain, but most medications are not appropriately considered psychotropic agents. ASCP supports broadening the definition to include medications that are given primarily to affect mental thought processing and behavior. Notably, medications used for chronic pain, such as opioids, can cause sleepiness and lightheadedness, but are not considered psychotropic medications as their intended effect does not affect mental thought processing or behavior. Pain management treatment must be evaluated on a frequent basis, and should not be subject to the rules and restrictions of the psychotropic medication drug class. When a patient is stable and the pain is controlled, it is counter-productive to good

pain management to require a gradual dose reduction (GDR) and is not in the best interest of the patient. The same argument could be made for some antiepileptic, antihypertensive medications, and antihistamines. ASCP is concerned that the CMS proposal to expand requirements to a broad definition of psychotropic medications may have the unintended consequence of preventing patients from appropriately accessing these medications. Additionally, such strong focus on psychotropic medications may direct proper oversight and attention away from non-psychotropic medications that could also be harmful to long-term and post acute care residents.

**Gradual Dose Reduction:** Gradual dose reduction (GDR), is an important tool in determining the appropriate dosage for residents or whether a prescribed medication can be discontinued completely. While the GDR can result in discontinuation of a specific medication therapy, the goal should not be to eliminate medication. There are many instances where it is medically necessary to treat a legitimate condition and the continued use of the medication is supported by sound medical rationale. ASCP is concerned that current GDR requirements may drive inappropriate reduction or discontinuation of some psychotropic medications.

**Recommendations:** ASCP recommends CMS modify GDR requirements so that residents who use psychotropic drugs receive GDR specifically in an effort to determine continued need for these drugs and behavioral interventions, unless clinically inadvisable based on medical evidence and FDA approved labeling with regard to dose. ASCP also recommends that CMS use the definition for “psychopharmacological” that is currently within the CMS State Operations Manual: “Psychopharmacological medication is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders. “

**PRN Medications Orders:** ASCP is concerned with the abundant use of pro re nata (prn) medication orders in skilled nursing facilities. Too often, if the resident has a standing order for the same type of medication in the prn order, the prn orders remain active in the resident’s chart long after the original reason for use has subsided; such as often happens with medications like acetaminophen. Having these unneeded prn orders in the chart can dramatically increase the chance for an adverse medication event, either through dosing errors, or perhaps through medication redundancies. However, setting a limit of 48 hours on all new prn orders for psychotropic medications could result in poor clinical outcomes in cases where the prescriber is unable to review the resident’s condition, and a beneficial medication is stopped prematurely.

**Recommendations:** ASCP suggests CMS consider a longer period of time, such as 7 days, so that medications are not stopped too soon. We believe a week will provide sufficient opportunity to implement non-pharmacological approaches and assess response and give all prescribers time to adequately assess the resident while preventing prn orders from lingering on the chart.

**Interdisciplinary Medication Stewardship:** While medication management and review is part of the role of the pharmacist, the provision of medications in the skilled nursing facility is not limited to the dispensing and consultant pharmacists. Nurses and nursing assistants routinely provide medications to residents, and physicians may assess the effectiveness of a medication while examining a resident. Any clinician in the facility can be responsible for a medication error. As such, ASCP has concerns with moving the broad category of unnecessary drugs, antipsychotics, other psychotropics, medication errors, and routine immunizations under F431.

**Recommendations:** ASCP suggests that a broader section focused on interdisciplinary medication stewardship be added to the current tags to better address this important area, with the consultant pharmacist an essential part of the clinical team.

**§ 483.75 Quality assurance and performance improvement:**

ASCP supports CMS' efforts to implement an effective Quality Assurance and Performance Improvement (QAPI) program in nursing facilities. ASCP further agrees that a focus on medication-related errors is an appropriate area of focus.

We support CMS' suggestion that a pharmacist be included in the facility's quality assessment and assurance (QAA) committee. The expertise of a consultant pharmacist may add considerably to the areas such as reduction of inappropriate use of psychotropic medicines, and education on the proper use of antibiotics and the reduction of unnecessary medications.

Consultant pharmacists frequently note that, despite medication regimen reviews that recommend changes to the resident's medication regimen, attending physicians do not always act (positively or negatively) on these recommendations, so the issues identified remain unresolved.

**Recommendations:** ASCP suggests that facilities develop QAPI programs which meet the needs of the residents. Medications are often an integral part of interventions and plans of care, which require ongoing inter-professional collaboration. This has been evident from the many success stories surrounding an emphasis on the improvement of treatment for residents with dementia as well as the national initiative to reduce the use of unnecessary antipsychotics.

**§ 483.80 Infection control:**

CMS' interest in improving infection control in nursing facilities is an important step in reducing unnecessary hospitalizations and combating antibiotic resistance. ASCP supports instituting an Infection Prevention and Control Programs (IPCP) in long-term care facilities. Indeed, the Centers for Disease Control (CDC) have cited the consultant pharmacist, along with the medical director and director of nursing, as one of the Antibiotic Stewardship Leaders in nursing facilities (<http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html>). Consultant pharmacists routinely review orders for antibiotics as part of the MRR to ensure they are appropriate for the resident to take, and review microbiology culture results to determine whether there may be microbial resistance to the selected agent. Consultant pharmacists can be very helpful in antimicrobial stewardship efforts by making the administrator, medical director, nursing director, and attending physicians aware of current antibiotic usage in the facility. Consultants, through the medication regimen review process (with necessary access to medical charts), have thorough knowledge of antibiotic use and the clinical indications that result in prescriptions for antibiotics.

We also support the institution of an Infection Prevention and Control Officer (IPCO) in each facility, and as the medication management specialists on the clinical team, we suggest that a pharmacist would be an ideal candidate for this newly created position. That said, we are concerned that CMS does not adequately explain what the ideal qualifications for the IPCO



should be. Indeed on a recent webinar with stakeholders, CMS merely said that there was an expectation that the IPCO carry “advanced training.” Many people have advanced clinical training in certain specialty areas, such as registered dietitians and occupational therapists, but little or no training in infection prevention or antimicrobial stewardship. Current language does not ensure that a qualified individual would act in this new role.

**Recommendations:** CMS must give clearer guidance on the expected qualifications of the IPCO in order to make this position a beneficial addition to the clinical staff at a skilled nursing facility. Additionally, ASCP recommends that CMS recognize the consultant pharmacist as an ideal candidate for this position.

### **Conclusion**

ASCP fully supports CMS’ acknowledgement of the valuable services provided by the consultant pharmacist and the expanded role outlined for the consultant pharmacist in the nursing facility. We have concerns that the immediate implementation of the rule as presented would put undue financial and infrastructural burden on nursing facilities. We believe the best approach to implementation would be a phased-in process, with established goals and metrics by which CMS can measure progress against the goals. With no increased reimbursement to the facility, and without the health information technology interoperability, implementation at all of the appropriate points of care would be difficult to achieve. It is also important to note that the cost of enhanced pharmacist services as proposed by CMS is not recognized in the current Medicare Part D pharmacy dispensing agreements. ASCP recommends that CMS include the cost of pharmacy services in the estimated facility implementation costs.

ASCP appreciates the opportunity to comment on this important proposal and looks forward to the opportunity to collaborate with CMS and other stakeholders in the long-term care community to advance the quality of care in the nation’s long-term care facilities.

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