

Medication Practices at Center Of Hospital and Nursing Home Proposals

Discharge and Pharmacy Requirements to Change

Stephen Barlas

The Centers for Medicare and Medicaid Services (CMS) is proceeding with two separate but parallel rulemakings that make changes to discharge policies at hospitals and long-term care (LTC) facilities, which are typically skilled nursing facilities (SNFs). The first updates the conditions of participation (COPs) for hospitals;¹ the second does the same for LTC facilities, though they are not formally called COPs.² In both instances, there is a focus on medication reconciliation. The LTC proposal goes further, however, instituting significant changes in pharmacist responsibilities for residents still in nursing homes.

The separate revamps stem from the congressional passage of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), which requires hospitals, including, but not limited to, acute care hospitals, critical access hospitals (CAHs), long-term care hospitals, inpatient rehabilitation facilities, home health agencies (HHAs), and SNFs, to take into account quality measures and resource use measures to assist patients and their families during the discharge planning process.

The hospital proposal significantly expands the reach of those COPs by including outpatients in the discharge requirements. Whether a patient is 75 years old with multiple chronic conditions hospitalized for a heart attack or a 25-year-old athlete hospitalized because of a minor incident on the football field, the same requirements would apply. "We are concerned that the range of patients who would be required to have a full discharge evaluation and plan, rather than a robust set of discharge instructions, is too extensive," says Ashley Thompson, Senior Vice President of Public Policy Analysis and Development at the American Hospital Association (AHA).

There is no question the new requirements in both instances, if finalized, will impose some fairly heavy costs on hospitals and nursing homes, both of which have criticized the reach of the proposed rules. Pharmacists are unhappy specifically with the hospital proposal, which does not indicate that pharmacists should be in the thick of medication plan analysis or follow-up as patients leave hospitals. The proposed changes put the coordination of the discharge plan in the hands of "a registered nurse, social worker, or other personnel qualified in accordance with the hospital's discharge planning policy."

According to Christopher J. Topoleski, Director of Federal Legislative Affairs for the American Society of Health-System Pharmacists:

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.

The absence of pharmacists from the proposed rule is concerning given that both CMS and the U.S. Department of Health and Human Services have recognized the value of pharmacists and their services in previously released reports, final rules, and Medicare conditions of participation.

The LTC proposal, on the other hand, is heavy on new responsibilities for pharmacists, who generally come into play in a consulting role, though larger nursing homes or chains may have pharmacists on staff. Here, the CMS focuses on eliminating the prescribing of "unnecessary" drugs and expands the scope of current restrictions beyond "antipsychotics" to "psychotropics," bringing many more pharmaceuticals under review. There is a particular emphasis on opioids, use of which the federal government has been trying to diminish via various policies, a concern shared by Congress. The Senate Select Committee held a hearing on opioid use among the elderly through



Stephen Barlas

the Medicare Part D outpatient drug plan, for example. The focus was not on nursing home residents, however, just Part D recipients broadly. President Obama has proposed a number of initiatives as part of his 2017 budget aimed at reducing opioid use among the elderly, such as limiting pharmacies the elderly could use.

However, the expansion of current LTC restrictions to all anti-psychotics is unpopular in many quarters. "The AGS [American Geriatrics Society] strongly disagrees with CMS' language and approach to 'psychotropic' medications in the proposed rule," says Steven R. Counsell, MD, President of the AGS. "Most importantly, the proposed definition of psychotropic drug as 'any drug that affects brain activities associated with mental processes and behavior' is inappropriately broad and vague."

The two CMS proposed rules are intertwined with CMS medication reconciliation initiatives that have the same goal: to make sure any patient leaving any health/medical facility where he or she has received pharmaceuticals gets adequate medication-procedure follow-up at whatever facility he or she is going to, whether that be the home, a nursing home, an HHA, or a community-based services provider. The rationale is that better discharge planning, particularly medication reconciliation, leads to fewer hospital readmissions. The CMS has been paying more attention to hospital readmissions since the Patient Protection and Affordable Care Act gave the agency the authority to penalize and reward hospitals based on readmission rates. In October 2015, an article by a professor and researchers at the Yale School of Public Health stated: "Nearly 20% of Medicare beneficiaries experience an unplanned hospital readmission, with an estimated cost to the American public of about \$26 billion per year."³

Medication Practices at Center of Hospital and Nursing Home Proposals

Hospital COPs

The current hospital discharge planning requirements were established in 1994 and were last updated in August 2004. Hospitals do not have to prepare a discharge plan for all inpatients, much less execute one, and there are no specific requirements for what has to be covered in a discharge plan if one is prepared. The hospitals simply must identify patients who *may* need a discharge plan. Beyond that, pretty much anything goes. There are no medical reconciliation requirements. That loose approach does not fit well with the CMS' efforts to reduce hospital readmissions and reduce Medicare and Medicaid costs. Hence, the IMPACT Act's provisions requiring hospital discharge plan upgrades.

Some hospitals use self-developed or industry-generated criteria for identifying patients who may need a discharge plan. Others use predetermined clinical factors such as age, comorbidities, previous hospitalizations, and available social support systems to identify patients who may need a discharge plan. Additionally, hospitals use any number of other factors, such as physician preference; nursing, social work, and case management experience and history; current workload; and common practice to develop the discharge plan. Finally, some hospitals develop discharge plans for every inpatient, regardless of any of the factors previously mentioned. As a result of these and other differences among hospitals, there is considerable variation in the extent to which there are successful transitions from acute care hospitals.

Not surprisingly, policies on medication reconciliation are all over the place. Hospital patients discharged back to their home may be given literature to read about medication usage and required therapies, prescriptions for post-hospital medications and supplies, and referrals to post-hospital resources. The CMS says:

Inadequate patient education has led to poor outcomes, including medication errors and omissions, infection, injuries, worsening of the initial medical condition, exacerbation of a different medical condition, and rehospitalization. Lack of patient education concerning medicine storage, disposal, and use may also be a factor in overdoses, substance use disorders, and diversion of controlled substances.

The potential new requirements for hospitals compared to the 2004 version appear to be the difference between night and day. In the proposed rule, hospitals and CAHs would be required to create discharge plans for all inpatients as well as some outpatients, including observation patients; same-day patients receiving anesthesia or moderate sedation; emergency department (ED) patients identified by ED practitioners as needing a discharge plan; and other categories of outpatients recommended by the medical staff and specified in the hospital/CAH discharge planning policies approved by the governing body. The "plan" is differentiated from discharge "instructions," which would include a standard set of information covering the following areas: instruction on post-discharge care at home, warning signs of the need to seek immediate care, medications required after discharge, medication reconciliation, and written instructions for follow-up care or referrals. The discharge evaluation that CMS proposes would require hospitals to evaluate patients on at least eight factors, includ-

ing diagnosis, comorbidities, anticipated ongoing care needs, readmission risk, patient access to non-health care services, relevant psychosocial history, communication needs, and patient goals and treatment preferences.

That process would have to start within 24 hours of the patient's admission, a time frame that has been singled out by many groups as too strict. Alyssa Keefe, Vice President of Federal Regulatory Affairs for the California Hospital Association (CHA), says, "Implementation of the requirements as written, particularly the initiation of a plan within 24 hours of admission/registration for all inpatients and several categories of outpatients, will require significant increases in staffing in our member hospitals and, as discussed in these comments, will not necessarily result in improved patient care outcomes."

"The AHA agrees that all inpatients should have a discharge plan, as well as some, but not all, observation and same-day patients who receive anesthesia or moderate sedation," says the AHA's Thompson. "Patients undergoing diagnostic procedures, such as colonoscopies, likely require a clear, comprehensive set of discharge instructions, but not a full discharge evaluation and plan. Further, we do not believe all outpatients need a medication reconciliation, especially outpatients undergoing diagnostic procedures, unless their medications or drug therapies or regimens are changed during the visit."

Medication Reconciliation

Some of the medication reconciliation procedures the CMS is proposing as part of the new hospital discharge process don't appear to be overly onerous. A list of the name, indication, and dosage of each medication would be required, along with any significant risks and side effects of each drug as appropriate to the patient. The medications would have to be reconciled, which is probably a new layer of work that hasn't been done previously by some, maybe many, hospitals.

A couple of new requirements may give hospitals pause because of the staffing and resource implications. The discharge implementer would have to help a departing patient determine where he or she will refill prescriptions obtained in the hospital once he or she leaves the hospital. That would include helping patients figure out which drugs are covered by their health plan, and which pharmacies they need to go to—is the patient's insurance network an issue?—to get a particular prescription refilled. The CMS is also considering requiring patients' inpatient physicians to consult with their state's prescription drug monitoring plan (PDMP) to reconcile patient use of controlled substances as documented by the PDMP, even if the practitioner is not going to prescribe a controlled substance.

That possibility has not gone over well. The CHA's Keefe explains:

We are concerned about CMS' consideration of a requirement to consult with the state PDMP database, which would be an unnecessary step for most patients and would slow down the discharge process. Moreover, access to the database is limited to certain authorized users. In some settings, the individual who is directly responsible for the development of the discharge plan may not have direct access to the PDMP, and coordinating with other practitioners will be impractical and unnecessary. Rather, consultation should

Medication Practices at Center of Hospital and Nursing Home Proposals

occur on a case-by-case basis, determined by factors identified in the medication reconciliation or medical history.

Long-Term Care Facilities

The LTC standards have not been comprehensively reviewed and updated since 1991, and the makeover in pharmacy services would be stark. There is a brief mention of a requirement to reconcile medications as part of a discharge summary. But the more significant upgrades revolve around drug reviews for residents. There would be a new requirement that a pharmacist review a resident's medical chart at least every six months. That review would also have to be performed in other circumstances: 1) when the resident is new to the facility, 2) when a prior resident returns or is transferred from a hospital or other facility, and 3) during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic, or any drug the Quality Assessment and Assurance Committee has requested be included in the pharmacist's monthly drug review. The pharmacist would have to write a report after the review listing, at a minimum, the resident's name, the relevant drug, and the *irregularity* identified. That report would be sent to the attending physician, the facility's medical director, and its director of nursing. Irregularity would mean a drug given under any of these circumstances:

1. In excessive dose (including duplicate drug therapy)
2. For excessive duration
3. Without adequate monitoring
4. Without adequate indications for its use
5. In the presence of adverse consequences that indicate the dose should be reduced or discontinued

The physician would then document in the resident's medical record that he or she has reviewed the identified irregularity and what, if any, action he or she has taken to address it. If there will be no change in the medication, the attending physician would document his or her rationale in the resident's medical record. The CMS wants to define "irregularities" to mean "unnecessary drugs."

There has been a lot of attention, including congressional hearings, given to what some view as unnecessary prescribing of antipsychotic drugs to nursing home residents. The nursing home industry has worked to reduce those rates. The American Health Care Association (AHCA), which represents nursing homes, launched its metric-based Quality Initiative in 2012 and later joined the CMS in supporting the National Partnership to Improve Dementia Care in Nursing Homes. In 2014, the AHCA and CMS set goals to decrease the use of antipsychotics in skilled nursing centers by a total of 30% by December 2016. Today, 54.6% of AHCA member centers have achieved the initial goal of a 25% reduction, while 48.9% have achieved the goal of a 30% reduction.

But the CMS is now setting its sights beyond antipsychotics. It would make a major threshold change by expanding the current pharmacy requirements that apply only to antipsychotics to psychotropic drugs. A psychotropic drug would be considered any drug that affects brain activities associated with mental processes and behavior.

The expansion of pharmacist surveillance of psycho-

tropic drugs worries hospice officials and others. J. Donald Schumacher, President and CEO of the National Hospice and Palliative Care Organization (NHPCO), says the new focus on psychotropic drugs would impose significant burdens on facilities and on the attending physicians of patients who need these drugs. "NHPCO has serious concerns about the effects these proposed rules would have on hospice patients who reside in facilities, and on their continued access to medications that are essential to their comfort and well-being at the end of life," he adds.

The pharmacy requirements would prohibit psychotropic drugs from being dispensed to residents who have not used them previously unless medically necessary. Moreover, residents taking psychotropic drugs would have to receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue use of these psychotropic drugs.

According to Schumacher:

The proposed rule would drastically decrease hospice patients' quality of life by restricting or discouraging access to medications that provide significant relief of symptoms like hallucinations, nausea, vomiting, and pain. For example, based on the current regulatory restrictions regarding antipsychotic drugs and the implications of their use on facilities' *Star Ratings*, hospice clinicians are already forced to recommend longer-acting atypical antipsychotics because facilities refuse to allow use of shorter-acting drugs like haloperidol, which can be used on an 'as needed basis' and safely discontinued when a crisis has passed. The proposed regulations will make this situation much worse.

Costs

The complexities of both of the new hospital and long-term care facility requirements will force the adoption of new procedures, refinements of existing ones, and, in many instances, the hiring of new staff. There will be a cost impact on every provider. The CMS estimates that hospitals will incur one-time costs of \$17 million just for combing through the new requirements and understanding them. The total annual costs for complying with the new requirement to prepare discharge plans for outpatients would be \$107 million.

The rule anticipates that the per-facility cost of the rule will be \$22,000 annually for hospitals and \$6,400 for critical access hospitals. According to the AHA's Thompson:

However, these figures greatly underestimate the cost of implementation. The proposed rule would require hospitals and CAHs to hire additional staff, including clerical staff, social workers, and RNs, to accommodate the increased number of discharge plans required. Some hospitals have told us that they would need to double their staff of discharge plan coordinators in order to meet the rule's proposed requirements, including one hospital that anticipates it will need to hire about 15 additional people. Another hospital anticipates hiring a discharge planning coordinator at a cost of \$60,000 annually.

The costs to nursing homes from the LTC rule would greatly surpass those to hospitals. The CMS forecasts first-year costs of \$700 million. "Although CMS estimates a first-year, per-facility cost of \$46,491 to implement all changes in the

continued on page 237

Medication Practices

continued from page 230

proposed rule, our members have indicated that the proposed addition of an antibiotic stewardship program and other pharmacy requirements would cost that much alone,” says Tom Nickels, Executive Vice President of AHA. “Second, some of the regulatory impact analyses are inadequate, such as the suggestion that it would take only eight hours to develop or update training programs covering eight separate subjects, and there is no accounting for the *implementation* of the full training requirements.”

“How are care centers supposed to pay for this?” asks Mark Parkinson, President and CEO of the AHCA. “Either the federal government should pay or high-cost requirements should be implemented at the back end of a reasonable phase-in period. New requirements often look good on paper, yet only drain scarce funds away from resident care, quality-of-life activities, staff job creation, and salaries.”

REFERENCES

1. Centers for Medicare and Medicaid Services. Medicare and Medicaid programs; revisions to requirements for discharge planning for hospitals, critical access hospitals, and home health agencies. *Fed Regist* 2015;80(212):68126–68155.
2. Centers for Medicare and Medicaid Services. Medicare and Medicaid programs; reform of requirements for long-term care facilities. *Fed Regist* 2015;80(136):42168–42269.
3. Bradley EH, Brewster A, Curry L. National campaigns to reduce readmissions: what have we learned? The Commonwealth Fund. October 1, 2015. Available at: www.commonwealthfund.org/publications/blog/2015/oct/national-campaigns-to-reduce-readmissions. Accessed February 25, 2016. ■