CMS proposal to address antibiotic resistance: Key takeaways

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By Mari Edlin

It has been more than a year since President Obama released his national action plan to combat antibiotic-resistant bacteria and The Joint Commission unveiled its standard on antimicrobial resistance.

But now the issue is on the front burner: CMS issued a proposed rule in June, to reduce hospital-acquired conditions and promote the development of hospital-wide, infection prevention and control and antibiotic stewardship programs.

To participate in Medicare and Medicaid, hospital and critical access hospitals (CAHs) would need to meet new criteria, which include designating leaders of infection prevention and control to staff the stewardship programs, demonstrating appropriate use of antibiotics and showing a reduction in antibiotic-resistant infections.

The new rule also would require that hospitals and CAHs include the following in patient medical records:

- Details on all admissions, lengths of stay, transfers and discharges.
- Information to justify patient admissions, continued hospitalizations and diagnoses.
- Patients’ progress and responses to treatment and other services.

The proposed ruling is expected to go into effect by the end of 2017; the White House has called for all acute care hospitals to implement antibiotic stewardship programs by 2020.

New rule missing details, metrics

Kristi Kuper, senior clinical manager for Vizient, a nationwide network of community-owned healthcare systems and their physicians, says that having the endorsement of CMS will help redirect funding and resource allocation within hospitals toward the personnel, technology, education and training needed to improve antibiotic use, which is a critical mission.

Belinda Ostrowsky, MD, director, epidemiology, stewardship and infection prevention for Montefiore Health System, touts the new recommendations as a strong beginning even though there are no final details on how to best implement or assess stewardship programs with formal metrics. However, she is confident that resources from CDC and professional organizations are available to guide facilities.

Kuper agrees that the new ruling is missing specifics on what constitutes an antibiotic stewardship program, unlike The Joint Commission standard that she says is very descriptive of the key components of a stewardship—leadership support, accountability, drug expertise, specific actions, tracking antibiotic use, reporting and education.
She suggests that the new CMS ruling should include stronger language related to executive leadership support and more guidance/recommendations on antibiotic measurement.

On the other hand, she praises the new ruling for its coordination with a hospital’s quality programs and for leaving room to appoint a lead for the stewardship by not specifically naming who the professional should be.

She anticipates that the new ruling will lead to:

1. More antibiotic stewardship programs.
2. Increased awareness amongst clinicians, patients and hospital administrators about positive benefits arising from antibiotic use improvement.
3. Decreased incidence of infections, specifically those caused by multi-drug, resistant organisms.
4. Decreased incidence of Clostridium difficile (C. difficile), an infection that is associated with high morbidity and mortality.
5. Decreased frequency of adverse drug reactions associated with antibiotics.
6. Improvement in infection cure rates.

Donald Fry, MD, executive vice president, clinical outcomes for MPA Healthcare Solutions in Chicago, questions whether a rigid antibiotic stewardship program might force patients to receive inappropriate drugs in specific situations as exemplified by recommendations under CMS’ Surgical Care Improvement Project, which specifies preventive antibiotics despite which facilities patients are in, their condition or previous use of antibiotics.

“Antibiotic stewardship programs are useful, but cannot be inflexible and rigid,” he says. “All cases do not fit the specifications that are defined by a ‘one-size-fits-all’ mentality.”

Nicole Hodges, vice president, operations at MD Buyline, a Dallas-based source for evidence-based, clinical and technology research for healthcare systems, expects that at first guidelines will be broader and perhaps a bit more lenient to ensure that they are followed.

Ostrowsky also anticipates that guidelines will be somewhat flexible, enabling healthcare organizations to tailor a program to fit their local populations and microbiology, resources and physician prescribing habits.

Prevention is key

“It’s becoming necessary to being back older drugs found to be toxic because the bacteria have become resistant to our commonly used, newer ones,” Ostrowsky says. “These broad-spectrum drugs often kill some good bacteria while trying to kill the intended target and thus, the patient might be at risk for C. difficile.”

She says solutions to antibiotic resistance should focus on preventing infection rather than just treating it later through antibiotics. Similar to the proposed CMS rules, she recommends facilitating activities through a stewardship program that would cross the entire spectrum of care—both inpatient and outpatient—and be overseen by experts in infectious disease.

In that way, she believes these professionals can determine if a disease is really an infection and if so, which is the right drug to treat it—the right dose, interval and route of administration so that the bacteria are best targeted.

Montefiore walks the talk. The health system implemented an antibiotic stewardship in 2008, whose practical, systematic services incorporate a multidisciplinary team with procedures to help frontline clinicians make the right decisions about drugs, determine whether coverage is broad enough or if prior authorization is needed and prescriber education.
The program has implemented all the core elements recommended by CDC and over time, Ostrowsky says she has seen reductions in volume of antibiotics prescribed, an improvement in the appropriateness of antibiotics and reductions in *C. difficile* and costs.

Hodges says physician buy-in and oversight are integral to the success of a stewardship, as are prevention practices and prescriber and community education—things as simple as hand washing and gloves.

Her colleague at MD Buyline, Dennis Matricardi, clinical analyst, adds that including a microbiology lab expert and microbiology department members on a stewardship team with their ability to seek out resistant bacteria and patterns of resistance could help organizations meet new guidelines.

**Lack of financial support might slow development**

Matricardi is concerned that new antibiotics are slow to come to market. He says it is because drug manufacturers would prefer to spend their budgets and time on more profitable medications targeting common chronic conditions, such as heart disease and diabetes. “They take the same time to develop, but the latter are much more profitable,” he says.

The FDA approved seven antibiotics in 2014 and six over the past 10 months since March 2015. As of March 2016, there are an estimated 37 new antibiotics in the pipeline after a slowdown from 2003 to 2011. The bad news, however, no new class of antibiotics has been developed for treating systemic bacterial infections.

Hodges says that antibiotic resistance is an extremely complex issue causing “never-events,” and those costs cannot be recouped by hospitals.

She says that many larger hospitals probably already have antibiotic stewardships in place, but that financial constraints are holding back smaller organizations.