Quality and Compliance: CMS Attempts To Add To Its Quality-Based Initiatives

Dec 23 2008

Practice Area: Health Law

With the recent election and changes in administration, health care reform continues to be a hot topic. President-Elect Obama has promised to issue an economic recovery blueprint this week, with approximately one-fifth of the package reportedly slotted toward health care. Given this amount of financing, health care reform is a key issue. Senator Max Baucus issued a White Paper last month that sets out reform goals, many of which may be included as part of President-Elect Obama's final health care plan.

One of the central goals set out in Senator Baucus's White Paper, and emphasized repeatedly through various initiatives of the Centers for Medicare and Medicaid Services ("CMS"), is using payment incentives to reduce costs and increase quality of care. Recently, CMS added to its growing line of quality initiatives by issuing three proposed National Coverage Determinations (the "NCDs") that seek to deny Medicare coverage for three specific "never events." "Never events" are medical errors that are serious, preventable and costly. The proposed NCDs will deny coverage for wrong patient, wrong body part, and wrong surgical or invasive procedures. All three of these errors are included in the National Quality Forum's (the "NQF") current list of 28 never events.

This *Bulletin* is intended to briefly alert providers to the proposed NCDs and provide a general overview of recent developments in CMS's ever-expanding set of quality initiatives.

Quality and Compliance
Purportedly in response to the Institute of Medicine's 1999 report, "To Err is Human: Building a Safer Health System," CMS has made great effort in reducing the costs to the Medicare system associated with poor quality health care. Because quality issues are reportedly so pervasive, CMS has developed value-based purchasing ("VBP") tools. VBP consists of initiatives designed to improve health care quality and reduce costs, largely by tying reimbursement to the quality of care and quality data reporting. By creating these links, CMS intends VBP to align the interests of providers with quality and encourage highvalue health care.

CMS considers the following "tools" as part of its VBP initiative:

- Payment incentives
- Measuring performance
- Publicly reporting performance results
- Applying national and local coverage policy decisions
- Enforcing conditions of participation
- Providing direct support through Quality Improvement Organizations ("QIOs").

The idea is that Medicare has become an active, rather than passive, purchaser of higher quality and more efficient health care services. CMS continues to expand the VBP concept across the entire spectrum of care, including inpatient care, outpatient care and physician offices. While the implementation may differ for each unique setting and payment structure, CMS desires to align the incentives across each setting to achieve consistency and efficiency.

Proposed NCDs
The proposed NCDs fit within CMS's VBP framework. Wrong patient, wrong body part, and wrong surgical or invasive procedures result in higher costs and lower quality of care, but are preventable. In the proposed NCDs, CMS takes the position that these never events are not reasonable and necessary for the treatment of the patient's medical condition. Because a service must be reasonable and necessary for Medicare payment, these procedures will not, in general, be covered by Medicare if the NCDs are finalized.

CMS has proposed definitions for each of the incorrect surgeries and invasive procedures to identify the events that are not covered. CMS has also defined the scope of "surgical and other invasive procedures" for each of the events. The definitions and scope are each consistent with the NQF's definitions in its list of never events, but with some modification to the scope to avoid confusion with the current use of "surgery" in Medicare law and guidance.

If the NCD's become final, CMS intends to issue policies addressing non-covered surgery in the Medicare Benefit Policy Manual.

Hospital-Acquired Conditions
In addition to these proposed NCD's, CMS has added two new preventable hospital-acquired conditions ("HACs") and expanded the surgical site infection HAC for 2009.

A HAC is a condition (such as a surgical site infection) that is not present on the patient's admission to the hospital but is developed during the inpatient stay. Because evidence suggests an enormous volume and cost burden of HACs, Congress has sought to align payment incentives to encourage hospitals to avoid these complications. While providers obviously strive to prevent HACs, the inpatient prospective payment system (the "IPPS") contained little incentive for hospitals to prevent these conditions. Many MS-DRGs, for example, are subdivided into two or three groups with correspondingly higher payments based on the presence of a complicating condition ("CC") or a major complicating condition ("MCC"). In many cases, an HAC could qualify as a CC or MCC, resulting in higher reimbursement under the IPPS, regardless of whether the HAC was acquired during the inpatient stay.

Because of this alleged disincentive to avoid HACs, Congress instructed CMS to identify at least two HACs which (a) are costly or high in volume; (b) result in an assignment of a higher paying DRG when the condition is present as a secondary diagnosis; and (c) are reasonably preventable with evidence-based guidelines. Following Congress's mandate, CMS originally selected eight HACs, but has since expanded this number to 10 for the fiscal year 2009. Medicare does not pay the hospital an additional amount under the IPPS if these selected HACs are not present on the patient's admission. Instead, Medicare pays the hospital as if the HACs are not present.

HACs are different from the NCDs proposed above in that they only apply to hospital payments for inpatient stays; the proposed NCDs would apply to Medicare payments to hospitals, physicians and any other health care providers and suppliers involved in the erroneous surgeries. For further background on "never events," see Vol. VI, Issue 48, American Health Lawyers Association, Hospitals and Health Systems (Dec. 19, 2008).

Healthcare-Associated Conditions
In line with its HAC initiative, CMS also desires to address the sizable volume of encounters and preventable injuries in hospital outpatient settings each year, and the growth in hospital outpatient care, by adapting this same concept to the outpatient setting. Specifically, CMS would adjust OPPS payments for illness, injuries and preventable complications, known as healthcare-associated conditions, developed during an outpatient encounter.

Unlike the IPPS payment methodology, CMS pays for outpatient services at a single rate, whether or not a complication is present. CMS must therefore explore other options to create financial incentives for providers to avoid preventable conditions in the outpatient setting. CMS has suggested that one such option could be a flat rate reduction in payment when a condition is present. Moreover, a professional who has failed to prevent a condition in one setting may be financially responsible for the treatment of the condition in a second setting. Other challenges to implementing an outpatient initiative include selecting preventable conditions, identifying whether a condition was present on encounter, and attributing liability for the condition among potentially responsible providers.

Pay for Reporting
Another quality-based initiative introduced by CMS is pay for reporting. Pay for reporting ("P4R") involves the creation of financial incentives to induce providers to report data on quality of care measures to CMS. While P4R initiatives do not penalize hospitals for poor quality care, CMS considers P4R to be a VBP initiative. P4R initiatives are already underway for hospital inpatient care, hospital outpatient care and physician services. Since FY 2005, CMS requires many hospitals (some types are excluded) to report data on inpatient quality of care to receive the full annual IPPS payment update (this is known as the "RHQDAPU" program). Hospitals must report data on 27 of 30 quality of care measures (hospitals do not have to report on three outcome measures) or incur a 2% reduction in their annual payment update for fiscal year 2009. CMS has added fifteen inpatient measures (two of which were added in the 2009 OPPS/ASC Final Rule) and retired another (pneumonia oxygenation assessment), for a total of 44 measures for 2010. Hospitals must report on 28 of the measures toreceive the full update for 2010. The other 16 measures will be calculated by CMS based on Medicare claims data, reducing some of the burden on hospitals.

CMS similarly requires many hospitals to report data on the quality of outpatient care to receive the full annual update to the OPPS payment rate. These hospitals must report data on seven quality of care measures in 2008 or incur a 2% reduction for payments in 2009. CMS has added four outpatient imaging efficiency measures for a total of 11 measures for which hospitals must report outpatient quality data to receive the full update for 2010.

Certain professionals who voluntarily report on select professional services receive a bonus payment of 1.5% for 2008 and 2% for 2009. Finally, CMS also opted to defer rulemaking for ambulatory surgery center quality data reporting until a later date.

Value-Based Purchasing Plan
In addition to the above VBP initiatives, the testing and development of a more comprehensive VBP plan for many Medicare hospital services is underway (critical access hospitals and others are excluded). Congress required CMS to design and implement the VBP plan for inpatient hospital services beginning in fiscal year 2009. Pursuant to its congressional mandate, CMS submitted its proposed plan to Congress on November 21, 2007 (the "Plan"). The Plan differs from previous initiatives in that it expands on pre-existing initiatives to include pay for performance ("P4P"). P4P generally ties payment to the actual quality of care, such as the achievement of performance goals or benchmarks. The proposed Plan, includes:

- A performance assessment model with various quality "domains" (i.e. process of care, patient experience, and outcome measures, etc.) to calculate a total performance score;
- Options to translate the score into an incentive payment;
- Potential criteria to select performance measures, and possible measures;
- A phased approach to transition from the RHQDAPU program to the Plan;
- A redesign of the current data transmission and validation infrastructure;
- Potential enhancements to the Hospital Compare website; and
- An approach to monitoring the impact of the Plan.

CMS is also, pursuant to a more recent Congressional mandate in 2008, developing a VBP program for physicians and other professional services.

Conclusion
Major health care reform is on the horizon, and quality remains central to this effort. The three proposed NCDs are but one initiative among others in CMS's rapidly evolving VBP framework. Given the publication of the three proposed NCDs, it is possible CMS could seek to issue additional NCDs for other HACs. Moreover, this *Bulletin* only focuses on hospitals and health systems. VBP is present in other practice settings, and such settings will receive additional attention as CMS expands its VBP initiatives. Consequently, all providers should prepare for further scrutiny regarding quality of health care.
