HHS Retrospective Regulatory Review

Update – January 2012

Since the President's Executive Order on Improving Regulation and Regulatory Review, HHS has made significant progress in its retrospective review activities. To date, we published eight proposed rules and nine final rules on the list of regulations identified for retrospective regulatory review. An additional four proposed rules and three final rules are targeted for publication during the first quarter of 2012.

Two of the proposed rules we published are expected to result in significant savings to the health industry. The first, a major revision to the *Medicare Conditions of Participation for Hospitals*, is likely to result in an estimated savings of close to $5 billion over five years. The second, *Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction*, may result in cost savings that approach $200 million during the first year. HHS is working to finalize these rules.

Some of the key cost savers of these proposed rules include:

- Permit laboratory services to operate on-site at critical access hospitals, *saving roughly $15.8 million per yea*r.
- Allow hospitals to determine the total number of directors needed for the various outpatient services that a hospital offers, *saving $300 million per year*.
- Allow hospitals to set their own policies regarding the duties and privileges of Advanced Practice Registered Nurses, Physician Assistants, and other licensed nonphysician practitioners in accordance with their state laws and scope-of-practice acts. This reform *should save hospitals roughly $330 million per year*.
- Permit hospital nursing service care plans to be integrated into the hospital's overall interdisciplinary care plan, thereby eliminating the requirement that nursing staff develop two care plans. *Estimated savings are roughly $110 million per year.*
- Allow hospitals to use standing medical orders approved by the hospital's clinical leadership to advance the practice of evidence-based medicine and ensure more consistent care for all patients. *This reform should save $90 million per year.*
- Remove certain Medicare reenrollment bars and revocations for incidental failures to comply with Medicare requirements such as a failure of a provider or supplier to respond timely to a re-validation request or failure to submit a Medicare claim for a consecutive 12-month period. *Expected savings are $10 million per year.*

Other rules recently published as final will make provider practice more efficient and less burdensome. One rule, the Home Health Prospective Payment System Rate Update for Calendar Year 2012 (0938-AQ30), removes the previous regulatory requirement that the physician who conducts the face-to-face visit with a Medicare home health patient prior to recertification must be the same physician who completes the recertification. Yet another final rule, Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and

Practitioners (0938-AQ05), allows hospitals to more easily credential and provide privileges for physicians and other practitioners who provide telemedicine services.

Still other rules give patients easier access to information about their health care. One such final rule, Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage (0938-AP93), removes the requirement that an ambulatory surgery center provide the patient or the patient's representative with verbal and written notice of the patient's rights prior to the date of the procedure. Now those centers can give patients that information on the day of the procedure, thereby saving time and travel costs for the patient. Another proposed rule, Patients' Access to Laboratory Test Reports (0938–AQ38), permits patients to more easily access their clinical lab test results. This rule, coupled with the Fiscal Year 2012 Physician Fee Schedule final rule (0938-AR06) that removes the requirement for the physician to sign every order for a clinical lab test, will save costs and increase efficiency in the system.

Additional rules propose to provide much needed relief to states. For example, the Disallowance of Claims for Federal Financial Participation (FFP) and Technical Corrections (0938-AQ32) rule proposed to revise the repayment schedule for states that received more Medicaid funds than they were entitled to receive. The proposal provides three options for states to elect a repayment schedule that recognizes the unique fiscal pressures states are experiencing and allows for a longer repayment period. A second rule, the Medicaid Home & Community Based Services Waiver final rule (0938-AP61) will permit states greater flexibility to design and operate fewer Medicaid waiver programs for home and community based services by designing packages based on need rather than diagnosis.

In a rule providing greater flexibility, efficiency, and modernization in the child support enforcement programs (970-AC50), states will be able to submit and accept information electronically, maintain electronic records, and accept electronic signatures in these programs. States will also have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible. Finally, states will have greater flexibility to close unenforceable cases and redirect resources to more productive efforts and, in some cases, close and transfer appropriate cases to a tribal child support program.

In another major undertaking, retrospective review will result in major modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's requirements for distribution of Notices of Privacy Practices (0991-AB80).

Finally, the Department is undertaking a major review of FDA's Bar Code Rule for Drugs. Under the current rule, drug manufacturers must use a certain type of bar code to identify the drug, but recent changes in technology have resulted in the availability of multiple types of bar codes and bar code readers on the market. FDA will conduct an extensive economic review to determine if the rule should be modified to permit a wider range of bar code uses in light of these changes in technology that have occurred since the rule went into effect. To that end, FDA published a notice in the Federal Register requesting comment on this matter by February 23, 2012. Those comments will help FDA determine whether and how to proceed with a major revision to this rule.

In addition to these regulatory changes, the Department established an Analytics Team based in the Office of the Assistant Secretary for Planning and Evaluation to share information, make the quality of analysis more consistent across the Department, and ensure the integration of such analysis into regulatory decision-making to improve the quality of regulation. The Analytics Team has already had a significant impact on several of the regulations developed as a result of the retrospective review activity.

The Department also established a webpage on its HHS.gov/Open website devoted to retrospective review activities: http://www.hhs.gov/open/execorders/13563/index.html. This is the first step in the long-term development of a single portal access point for all regulatory information across the Department.

Finally, the Department is moving forward with a Public Participation Task Force to develop innovative ideas for involving the public in the regulatory process. In two major efforts to involve the public thus far, the Department published an Advance Notice of Proposed Rulemaking to solicit public comment on revising the Common Rule, the signature rule on protection of human subjects that has not been revised for more than 20 years, and a second Notice inviting comment on whether and how the pharmaceutical bar code rule should be revised.

A full list of the regulations for which a review is complete or which are currently under development follows. HHS is committed to the President's vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The Department conducted its initial inventory of significant regulations that have been in effect for at least five years without revision when it developed the initial list of candidate rules targeted for review. HHS is continuing to take inventory of its existing, significant regulations to identify potentially outdated regulations, which can be integrated into the retrospective regulatory review plan on an ongoing basis.