American Hospital Association

FALL 2010

*Dedicated to keeping our critical access hospital (CAH) members informed about pertinent issues, this edition of **CAH Update** looks at recent legislative activities following the historic passage of the Patient Protection and Affordable Care Act (ACA). On the regulatory front, we examine the multiple proposed and final rules from the Centers for Medicare & Medicaid Services (CMS), including regulations for the inpatient and outpatient prospective payment systems (PPS), physician fee schedule (PFS) and the definition of "meaningful use" and certification standards for electronic health records (EHRs). In addition, we review rules that affect CAHs from the Health Resources and Services Administration (HRSA) and 340B drug discount pricing.*

LEGISLATIVE ADVOCACY: MOVING FORWARD

Several provisions of the ACA that extended critical Medicare policies are scheduled to expire in the next several months. Moving forward, renewing these "extenders" is an advocacy priority. The AHA urges Congress to address the following:

- Extend the work geographic index floor and revise the practice expense geographic adjustment under the Medicare physician fee schedule.
- Extend the exceptions process for Medicare therapy caps.
- Extend the bonus payments made by Medicare for ground and air ambulance services in rural and other areas.
- Extend the physician fee schedule mental health add-on, which increases the payment rate for psychiatric services delivered by physicians, clinical psychologists and clinical social workers by 5%.

In addition, there are other advocacy issues that have surfaced as part of rulemaking or that were missed in the ACA, such as certified registered nurse anesthetist (CRNA) services. We support

the *Rural Access to Nurse Anesthesia Services Act* (H.R. 3151/S.1585), which would permit pass-through payment for reasonable costs of CRNA services in CAHs despite the reclassification of such hospitals as urban hospitals, including hospitals located in "Lugar" counties, and for on-call and standby costs for such services.

Appropriations

The AHA supports equitable funding for rural health programs. On July 29, the Senate Appropriations Committee voted to approve a bill allocating $74.66 billion in discretionary funding to federal health and human services programs for fiscal year 2011. The Labor-HHS-Education appropriations bill includes $141.4 million for the National Health Service Corps, $5.1 million for rural physician training grants, $57.3 for Rural Health Care Services Outreach grants, $41.2 million for Medicare Rural Hospital Flexibility grants, and $40 million for two medical home demonstrations.

LABOR-HEALTH AND HUMAN SERVICES-EDUCATION AND RELATED AGENCIES APPROPRIATIONS - FY 2011
(Amounts in millions)

SELECT RURAL PROGRAMS (in millions)	President's Budget FY 2011	House FY 2011 approved	Senate Committee FY 2011
Telehealth	$8.0	$15.0	$12.0
Rural Health Outreach Grants	$55.0	$56.6	$57.3
Rural Health Policy Development	$10.0	$10.2	$10.0
Rural Hospital FLEX grants	$39.0	$41.2*	$41.2
State Offices of Rural Health	$9.0	$9.7	$10.0
Delta Health Initiative	$0	$0	$0
Denali Commission	$0	$0	$0
National Health Service Corps	$169.0	$141.8	$141.4
Nurse Loan Repayment and Scholarships	$125.0	$125.0	$94.0

*includes $15.0 million in small hospital improvement program grants

BEYOND HEALTH CARE REFORM: REGULATORY POLICY

CAHs will be affected by several rules recently promulgated by CMS, HRSA, the Federal Communications Commission (FCC) and the Internal Revenue Service (IRS). Key CAH provisions of three major rules – IPPS, OPPS and PFS – are discussed below. Other regulations affecting small or rural hospitals also are reviewed including final rules for health information technology (IT). A more detailed analysis of CMS' regulations and their impact on CAHs is discussed in the AHA's Regulatory Advisories, available at www.aha.org.

FY 2011 IPPS Final Rule

On July 30, CMS issued its hospital IPPS final rule for fiscal year (FY) 2011. **The rule includes a number of provisions relevant to CAHs**. Details on the final rule may be found at http://www.aha.org/aha/advisory/2010/108020-regulatory-adv.pdf.

The rule finalizes three policies related to CAHs:

- The rule finalizes CMS' proposed "clarification" of its policy concerning when provider taxes are considered allowable costs under Medicare. Although the AHA voiced its strong opposition to this "clarification," which is actually a change in policy, CMS finalizes its proposal. Specifically, Medicare contractors will determine the allowability of provider taxes on a case-by-case basis, based on reasonable cost principles, and will determine if a reduction of the allowable tax expenses is necessary to account for payments providers receive that are associated with the assessed tax.
- Effective for cost-reporting periods beginning on or after October 1, 2010, once a CAH has elected to receive payments under “the optional method” (also known as “Method 2”), the election will remain in place until it is terminated. CAHs will no longer have to re-elect the optional method annually. If a CAH is being paid under the optional method and wishes to terminate that election, it must submit a request in writing to its fiscal intermediary or Medicare Administrative Contractor at least 30 days prior to the start of the next cost-reporting period.
- The rule ensures CAHs will be paid 101% of reasonable costs for all outpatient services they provide, regardless of the billing method elected. In FY 2010, CMS set outpatient service reimbursement for CAHs electing Method 2 at 100% of cost instead of at 101% of cost. The provision in this rule is retroactive, meaning CAHs will continuously receive the 101% reimbursement, despite CMS’ previous policy.

Payments for CRNA Services - Certain hospitals located in rural areas are eligible for reasonable-cost based reimbursement for CRNA services. Under the existing regulations, neither hospitals that have reclassified from urban to rural, nor hospitals that are located in “Lugar” counties, are eligible to receive this cost-based reimbursement. Lugar counties are certain counties that are rural, but adjacent to one or more urban areas, and are treated as being located in the urban area. However, effective for cost-reporting periods beginning on or after October 1, 2010, CMS will make hospitals (including CAHs) that have reclassified from urban to rural eligible for CRNA cost-based reimbursement. CMS will not make hospitals or CAHs that are located in Lugar counties eligible for CRNA cost-based reimbursement.

Payment for Transfers - CMS will expand the post-acute care transfer policy as it relates to transfers to non-inpatient PPS hospitals. The current transfer policy applies to patients who are transferred between inpatient PPS hospitals. The final rule expands the policy so that it also applies to transfers between inpatient PPS hospitals and hospitals that would otherwise be eligible to be paid under the inpatient PPS, but that do not have an agreement to participate in the Medicare program, and also to transfers between inpatient PPS hospitals and CAHs.

CY 2011 Outpatient PPS and Ambulatory Surgical Centers Proposed Rule

On July 2, CMS released the OPPS and ambulatory surgical center (ASC) proposed rule for calendar year 2011. In addition to updating OPPS and ASC payment weights and rates, the

proposed rule includes both OPPS and inpatient PPS changes enacted by the ACA. Details are available in the AHA July 28 Regulatory Advisory.

Physician Supervision - In response to concerns raised by the AHA and other hospital and rural health groups, CMS proposes to permit a modified level of physician supervision for a few specified hospital outpatient therapeutic services, beginning in 2011. CMS identifies a set of 16 "nonsurgical extended duration therapeutic services" - these are procedures with a significant monitoring component that can extend for a sizable period of time, are not surgical, and typically have a low risk of complication. The list of services to which this revised policy applies includes observation services, various intravenous and subcutaneous infusions and various therapeutic, prophylactic or diagnostic injections.

CMS proposes that these services require direct supervision only for the initiation of the service followed by general supervision for the remainder of the service. CMS would adopt the same definition of "general supervision" currently used for certain diagnostic services.

In our August 31 comment letter to CMS, we urged the agency to adopt a more comprehensive and clinically appropriate approach to supervising outpatient therapeutic services. In addition, we recommended that CMS extend the direct supervision enforcement moratorium for CAHs through 2011 and also apply the moratorium to other small and rural hospitals

Physician Self-Referral - CMS proposes to implement AHA-supported changes enacted in ACA to the “whole hospital” and “rural provider” exceptions in the physician self-referral law that will prohibit their use by new physician-owned hospitals and limit the ability of existing physician-owned hospitals to expand their capacity.

Cardiac and Pulmonary Rehab Services - In the proposed rule, CMS clarifies that a CAH outpatient department is considered a covered setting for cardiac, pulmonary and intensive cardiac rehabilitation programs, provided that the program meets all of the regulatory requirements including direct supervision of all services by a physician.

CY 2011 Physician Fee Schedule Proposed Rule

On June 25, CMS released the Medicare PFS proposed rule for CY 2011. The rule makes annual payment updates mandated by law and implements certain provisions of the ACA. A final rule is expected by November 1 and will take effect January 1, 2011. Details of the proposed rule may be found at http://www.aha.org/aha/advisory/2010/100806-regulatory-adv.pdf.

PCIP/HSIP Bonus for CAHs under the Optional Method - The ACA provides for a 10% primary care incentive payment (PCIP) for certain primary care services delivered by a primary care practitioner for five years, beginning January 1, 2011. The PCIP will be available only to primary care practitioners in the specialties of family medicine, internal medicine, geriatric medicine, pediatric medicine, nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) who furnish 60% of their services in these codes. In addition, qualifying practitioners providing care in a health professional shortage areas (HPSAs) will receive the PCIP on hospital visit codes that are typical of primary care medicine, though only 10% of these visits will count toward the 60% threshold above.

In addition, the ACA provides a 10% HPSA surgical incentive payment (HSIP) for certain major procedure codes delivered by general surgeons in a HPSA for five years, beginning January 1, 2011. In the rule, CMS proposes to use CY 2009 PFS claims data to determine those practitioners who are eligible for the PCIP in CY 2011. In order for NPs, CNSs and PAs to be eligible, they must be billing for their services under their own National Provider Identifier (NPI) and not furnishing services incident to physicians' services.

Payment is made to the eligible primary care practitioner or, where the physician has reassigned his or her benefits to a CAH paid under the optional method, to the CAH based on an institutional claim. HPSA surgical incentive payment is made to the surgeon or, where the surgeon has reassigned benefits to a CAH paid under the optional method, to the CAH based on an institutional claim.

The PCIP and HSIP will be made quarterly. For those CAHs paid under the optional method, in which they bill on behalf of practitioners for their professional services, CMS will make quarterly payments directly to the CAH. An eligible primary care physician in HPSAs may receive both a 10% HPSA bonus and PCIP. Also CAHs that use Method 2 or the optional method would receive their 101% facility payment (as of the ACA) plus 115% for physician payments plus 10% for the new PCIP or HSIP bonus.

Disclosure Requirements for In-Office Ancillary Services - The ACA requires that for services furnished on or after January 1, 2010, physicians referring patients for radiology services under an exception to the physician self-referral ("Stark") law must inform patients in writing at the time of referral of any ownership interest in certain imaging services to which the physician refers the patient, and of the availability of other suppliers who may provide such services. They also must furnish a written list of suppliers who provide the services in the area where the patient resides.

CMS proposes that hospitals and CAHs do not qualify as "suppliers" of imaging services. The AHA believes that including hospitals and CAHs on the written notice would benefit patients in choosing an alternative entity for imaging services and would provide patients with more options.

Medicare Telehealth - CMS maintains a specific list of services that can be billed as telemedicine services for patients presenting to an eligible provider in a designated rural area. The "originating site," where the patient presents, may bill Medicare for a facility fee, while the physician providing the service through telecommunications from a "distant site" is paid the amount allowed by the Medicare fee schedule.

In the rule, CMS reviews requests to expand the list, and proposes to add the following services: individual and group kidney disease education services; individual and group diabetes self-management training services, with a minimum of one hour of in-person instruction to ensure effective injection training; group medical nutrition therapy; and group health and behavior assessment and intervention services. For inpatients, CMS proposes to add subsequent hospital care services to the list of approved telemedicine services, with the limitation of one telehealth visit every three days. For post-acute settings, to add subsequent nursing facility care services that are not federally mandated, with the limitation of one telehealth visit every 30 days.

Ambulance Add-On - The rule implements the ACA's extension to the existing add-on payment for ground ambulance services – a 3% add-on for rural areas and a 2% add-on for urban areas – through December 31. It also extends through December 31 the "super rural" ambulance add-on. These provisions are retroactive to January 1, 2010.

Final Rules on "Meaningful Use" and Certification Criteria

CMS on July 28 published a final rule defining "meaningful use" of electronic health records (EHRs). At the same time, the Office of the National Coordinator (ONC) for Health Information Technology issued a final rule that sets certification criteria, standards and implementation specifications for EHR technology. Taken together, these regulations set EHR adoption requirements that hospitals and physicians must meet under the *American Recovery and Reinvestment Act of 2009* (ARRA) to qualify for additional Medicare and Medicaid incentive payments beginning in 2011 and to avoid significant payment penalties in 2015 and later years.

Details of the final rules on meaningful use are available at http://www.aha.org/aha/advisory/2010/100813-regulatory-adv.pdf.

CMS Meaningful Use – The meaningful use definition requires hospitals adopt and meaningfully use certified EHRs to meet 14 "core," or mandatory, objectives and an additional five objectives chosen from a "menu set" of 10 options, of which at least one must address public health objectives. The rule requires hospitals to immediately use Computerized Provider Order Entry (CPOE). This requirement can be complicated, costly to implement, and takes time to do right. Each meaningful use objective has associated functionality measures to ensure that objectives are met.

CMS has modified some measures to permit an eligible hospital or CAH to indicate that the objective/measure does not apply to them because, for example, they have no patients or an insufficient number of actions to calculate the measure, and the agency has identified specific exclusions where they exist. CMS will only require attestation to remove the measure from consideration, which reduces the number of objectives required to demonstrate meaningful use. CMS' final regulation also includes a related measure for the final privacy and security objective, which is to conduct or review a security risk analysis, implement security updates and correct identified security deficiencies.

For hospitals and CAHs that want to qualify for incentive payments in fiscal year 2011, they must begin meaningful use of certified EHR technology on or before July 2, 2011. In subsequent years, CMS proposes using a full-year reporting period based on the federal fiscal year.

Hospitals will be required to report on all quality measures for which they have any applicable patients of any payer, not just for measures applicable to their Medicare patients. This requirement is different than for the pay-for-reporting program, for which hospitals need only report on quality measures for which they have at least five eligible patients in a given calendar quarter. Clinical quality measures adopted for the Medicare EHR incentive program also will apply to the Medicaid EHR incentive program. Therefore, hospitals including CAHs participating in the Medicaid incentive program are required to report on the 15 measures finalized in this rule.

ONC Certification - In a separate rule, ONC finalized a definition of certified EHRs and an initial set of certification criteria, standards and implementation specifications for EHRs. The certification criteria follow the Stage 1 meaningful use objectives laid out by CMS and also require specific steps to protect the privacy and security of health information. The certification criteria apply to EHR products, not providers.

Hospitals and physicians must use certified EHRs to qualify for the Medicare and Medicaid payments. ONC provides a multi-stage definition of "certified EHR technology." In essence, providers must use either a "complete EHR," or a combination of EHR modules, which can be "any service, component, or combination thereof that can meet the requirements of at least one" of the certification criteria adopted by the Secretary. Providers who choose to combine multiple EHR modules are responsible for ensuring that the modules work together and that, together, they meet all of the certification criteria.

Incentive Payments - As specified in the *American Recovery and Reinvestment Act* (ARRA), CAHs also are eligible for Medicare incentive payments for FYs 2011 through 2015, but cannot receive payments for more than four years. CMS proposes to provide incentive payments to CAHs as distinguished by provider number on the cost report, which is the CMS Certification Number of the main provider. CAH incentive payments will be based on costs incurred during the CAH's cost-reporting period. CMS will reimburse qualifying CAHs for the Medicare share of their reasonable costs incurred for the purchase of certified EHR technology.

The Medicare share for CAHs will be calculated using the same methodology as for subsection (d) hospitals, plus 20 percentage points (not to exceed 100%). CMS proposes that the reasonable costs for the purchase of certified EHR technology would mean 100% of the reasonable acquisition costs, excluding any depreciation and interest expenses associated with the acquisition, incurred for the purchase of depreciable assets, such as computers and associated hardware and software, necessary to administer certified EHR technology. CAHs would be able to fully depreciate these costs in a single year, as well as include any past costs that have not yet been depreciated. The incentive payments are in lieu of any payments that would otherwise be made to CAHs for these costs.

Payments to CAHs will be processed as interim payments subject to reconciliation. To obtain payment, a CAH must attest to being a meaningful user and submit documentation to its FI or MAC to support the costs incurred for its health IT system. Once the FI or MAC reviews the documentation and determines the allowable amount, the payment contractor will make the initial incentive payment, which will be subject to a reconciliation process. CMS anticipates that the initial payments will generally be made within two months of the determination of the allowable amount.

For each year payment is received, eligible CAHs will need to maintain evidence of qualification to receive incentive payments for six years, and produce it in the event of an audit.

Per the ARRA, CMS states that, unless significant hardship is demonstrated, CAHs that are not meaningful users by FY 2015 will be subject to Medicare payment reductions. CAHs may receive a hardship exemption for a maximum of only five years.

In a change from the proposed rule, CMS has included CAHs as eligible for Medicaid EHR incentive payments, if they meet the volume thresholds and other Medicaid requirements. In general, hospitals must have 10% Medicaid patient volume. Medicaid payments to CAHs will follow the same formula as for other acute-care hospitals, which is based on the Medicare payment formula for subsection (d) hospitals.

Conditions of Participation for Telemedicine Credentialing and Privileging in CAHs

Currently, Medicare's Conditions of Participation (CoP) require the governing body of a hospital to make all privileging decisions based on the recommendation of the hospital's medical staff after the medical staff has thoroughly reviewed the credentials of practitioners applying for privileges. Similarly, each CAH is required to have its privileging decisions made by its governing body or the individual responsible for the CAH. This requirement is applied regardless of whether the services are to be provided onsite at the hospital or through a telecommunications system.

The proposed CoP do not address how hospitals might more easily credential and privilege physician groups in a way that ensures the safe provision of telemedicine services. The AHA urges CMS to develop a similar process whereby hospitals can use the credentialing and privileging information from practitioners who fulfill the Medicare Conditions of Coverage.

Other Regulations

The 340B Drug Pricing Program - Under the 340B drug program, drug manufacturers are required to provide outpatient drugs at a reduced price. The 340B price defined in the statute is a ceiling price, meaning it is the highest price a covered entity would have to pay for a given outpatient drug. Entities can negotiate below ceiling prices with manufacturers. As a result, 340B prices have been found to be roughly 50% of the Average Wholesale Price. On August 2, the HRSA Office of Pharmacy Affairs began enrolling new-covered entities eligible for the 340B drug pricing program as a result of the ACA. There will be a rolling admission process for these new entities which include CAHs, rural referral centers (RRCs), and sole community hospitals (SCHs) as well as free-standing children's and cancer hospitals. Rolling admission process for new covered entities will close on September 30. Entities wishing to enroll after that date must wait for the next enrollment period.

The new-covered entities eligible for 340B are:

- Free-standing children's hospitals with a disproportionate share hospital (DSH) adjustment > 11.75%;
- Free-standing cancer hospitals with a DSH adjustment > 11.75%;
- SCHs and RRCs with DSH adjustment ≥ 8%; and
- CAHs.

All of the new-covered entities must either be publicly owned or be a private, nonprofit hospital with a contract with state or local government to provide health care services to low-income populations not eligible for Medicaid or Medicare. Eligible CAHs, RRCs and SCHs also may be members of GPOs. The new enrollment forms are available from HRSA.

Rulemaking on Designation of MUPs/HPSAs - The ACA mandates negotiated rule-making for the definition of Medically Underserved Populations (MUPs) and primary care HPSAs. Revisions to the criteria or process for designating MUPs/HPSAs will affect the providers, programs and communities in rural and urban areas that depend on these designations for federal funding. More than 34 federal programs use these shortage designations for eligibility and funding criteria.

HHS Secretary Sebelius recently announced the appointment of a committee comprised of 28 members who represent programs that are most affected by these designations. Those programs include:

- Community Health Centers,
- Rural health clinics and health care practitioners,
- Special populations with unique health care needs, and
- Technical experts in the area of research in health care access and statistical methods.

The AHA's John Supplitt, senior director of the Section for Small or Rural Hospitals, was appointed as a committee member.

FCC National Broadband Plan - Recently the FCC issued a proposed rule on reforms to the universal service support programs for rural health care providers. The agency proposes to make the following broad categories of changes:

- Create a "Health Infrastructure Program" that will largely codify the existing Rural Health Care Pilot Program. It will fund up to 85% of the costs of new and upgraded infrastructure for rural health care institutions and providers to connect to medical institutions in more urbanized areas.
- Replace the current Internet Access Fund in the RHC program with a "Broadband Services Program." This will fund up to 50% of the monthly recurring cost of dedicated broadband connections for health care providers.
- Expand eligibility for the Rural Health Care programs to include administrative offices and data centers that support eligible health care providers, skilled nursing facilities and dialysis centers.
- Establish annual caps and priority rules, in light of the expanded support programs proposed in the item.
- Eliminate the "mandatory offset rule," which currently requires telecommunications service providers in the rural health care program to take their reimbursements as credits against their required USF contributions rather than direct payments.
- Implement performance measures in the Rural Health Care support programs, including "meaningful use criteria," and data gathering and analysis programs.

In our September 8 comment letter to the FCC, we urged the agency to streamline its application and eligibility requirements for funding to help rural health care providers develop and use broadband services. In addition, we strongly opposed any requirement tying eligibility for broadband funds to meaningful use criteria for EHRs, which could further the digital divide between urban and rural hospitals.

Additional Requirements for Tax-Exempt Hospitals - Schedule H of IRS Form 990 is required to be completed by an organization that operates at least one facility that is, or is required to be, licensed, registered or similarly recognized by a state as a hospital. The ACA applies several new requirements to section 501(c)(3) hospital organizations in addition the requirements otherwise applicable for tax exemption. The IRS has requested comments on four new requirements it imposes on hospitals seeking to qualify for and maintain tax-exempt status and that, if the hospital organization operates more than one hospital facility, each of those facilities also must comply with the new requirements. The requirements are for a health needs assessment, a financial assistance policy, a limitation on charges, and billing and collections. Although the community health needs assessment requirement is effective for tax years beginning after March 23, 2012, the remaining three requirements are effective immediately.

In a July 22 comment letter, the AHA urged the IRS to seek formal legislative action to establish a "reasonable cure" period for any failure to meet the new requirements, such as the later of 90 days or the end of the fiscal year in which the failure is discovered.

Save the Date!
24th Annual Rural Health Care Leadership Conference
January 30 — February 2, 2011
Pointe Hilton Squaw Peak Resort
Phoenix, AZ

Webcast
Tuesday, October 5

Accountable Care Organizations (ACOs)
Want to learn more about accountable care organizations (ACOs)? Plan to participate in our October 5 webcast featuring a discussion on ACOs with input from Dr. Steven Hester, CMO of Norton Healthcare in Louisville. We also will provide a federal update. AHA's Town Hall Interactive webcasts occur at 4 p.m. ET.

To register or to view the webcast, go to www.aha.org/townhall

Visit the Section for Small or Rural Hospitals Web site at http://www.aha.org/smallrural

For more information, contact John Supplitt, senior director, Section for Small or Rural Hospitals, at (312) 422-3306 or jsupplitt@aha.org.