Summer 2012

The Section for Small or Rural Hospitals of the American Hospital Association represents and advocates on behalf of more than 1,630 rural hospitals, including 975 critical access hospitals (CAHs). ***CAH Update*** *provides our members updates on legislative and regulatory activities, as well as on Section programs and services.*

Hospitals Take to the Hill

By the end of the year, Congress must make some tough decisions that will critically affect America's hospitals, including what to do with the Medicare physician payment fix, Medicare extenders, and other expiring tax provisions. And on Jan. 3, automatic Medicare cuts contained in last year's *Budget Control Act* kick in.

Hospitals need to ensure that Congress does not impose arbitrary payment cuts to providers, but instead offers real solutions to our nation's fiscal problems. *You have the ability to make a difference.* Plan to attend one of the AHA's Advocacy Days this fall. You'll have the opportunity to meet with your legislators and talk to them directly about the challenges facing your patients and your community. *Save these dates:* Sept. 11, Nov. 29, and Dec. 11. Contact Michael McCue, director of Member Relations/Grassroots Events, at 312-422-3319 or mmccue@aha.org for additional information.

Taking Action … Introducing 'We Care, We Vote'

In this critical election year, the debate over the national deficit and what to do about it has taken on

particular urgency. The hospital field is more than 5 million strong, and legislators - and potential legislators - need to understand that we care - not just for patients, but about the health and well-being of our communities and our nation. And we vote.

At www.aha.org/wecarewevote, you'll find resources to help you encourage your employees to register and vote. We offer sample newsletters, complimentary "We Care, We Vote" posters and table tents and legal guidance. You'll also find a guide to help you engage candidates for office to gauge their positions on health care and the deficit and to educate them on the challenges ahead for the hospital field. In addition, you'll find resources to help enhance your interactions with lawmakers so that you can be a more effective advocate for your patients, your hospital and your community.

AHA encourages you to work together with your organization's leadership to engage your extended hospital family at this important time. **The time is now to work together toward long-term solutions that will set these programs on a path toward future sustainability.** Our patients and communities deserve the care they need to always be there. Join our Partnership for Action and become an advocate for rural hospitals.

AHA Legislative Update and Advocacy Agenda for Rural Hospitals

Extenders: As the legislative year winds down, the AHA is focused on ensuring all hospitals have the resources they need to provide high-quality care and meet the needs of their communities. That means:

- Advocating for appropriate Medicare and Medicaid payments;
- Working to extend expiring Medicare provisions;
- Improving federal programs to account for special circumstances in rural communities; and
- Seeking adequate funding for annually appropriated rural health programs.

In February, Congress passed the *Middle Class Tax Relief and Job Creation Act of 2012*, which contained many provisions important to rural hospitals and beneficiaries. The AHA sent letters to every member of the House and Senate in support of renewing the expiring Medicare and rural extenders, and we encourage you to continue reach out to your lawmakers on these important programs as well.

The specific extenders are:

- Payments for the technical component of certain physician pathology services.
- Ambulance add-on payments.
- The outpatient hold-harmless provision for rural hospitals and Sole Community Hospitals.
- Medicare cost payments for clinical diagnostic laboratory tests furnished in certain rural areas.
- Section 508 hospital wage index reclassifications.
- The Medicare-dependent hospital program.
- The enhanced low-volume adjustment for inpatient prospective payment system hospitals.

In addition, the letters express support for *the R-HoPE Act* (H.R.3859/S.1680), which would extend several of the provisions including the outpatient hold harmless and the direct billing for the technical component of pathology services, and for *the Rural Hospital Access Act* (H.R.5943/S.2620), which extends the Medicare-dependent hospital program and enhanced Medicare low-volume adjustment until Sept. 30, 2013.

Fiscal Year 2013 Federal Budget

President's Budget: In February, President Obama released a budget outline for fiscal year (FY) 2013. The outline, which is similar to a proposal the White House released last September, calls for cutting Medicare by about $268 billion and Medicaid by $52 billion over 10 years. This budget proposal, as well as other deficit and spending reduction bills, will put rural hospitals at risk of cuts in several areas.

The administration proposes changes to payments for rural providers. Starting in FY 2013, it would reduce CAH payments from 101 percent to 100 percent of reasonable costs. In addition, effective in FY 2014, it would eliminate the CAH designation for hospitals that are less than 10 miles from the nearest hospital. Together, the administration estimates these rural proposals would save approximately $2 billion over 10 years.

Rural health programs such as the Medicare Rural Hospital Flexibility Grant Program, Rural Health Outreach and Network Development, State Offices of Rural Health, Rural Telehealth, Rural Policy Development and other health care programs are vital to ensuring that needed services remain available in America's rural communities. The president's FY 2013 budget proposes a $15 million cut to rural programs.

House Budget: In May, the U.S. House of Representatives today voted 218-199, mainly along party lines, to approve a Republican budget reconciliation package that would cancel $98 billion in automatic defense spending cuts scheduled for January 2013 and replace them with across-the-board cuts to other discretionary and mandatory programs. The legislation retains the 2% across-the-board cut to Medicare spending under the *Budget Control Act*, adds more stringent eligibility reviews for Medicaid enrollees and caps damages on medical liability awards, among other provisions. The Senate is not expected to take up the measure, and the administration has said the president would veto it.

Regulatory Policy Priorities

Capital leases allowable cost for CAH EHR incentive payments: After extensive meetings and discussions on the issue with the AHA, CMS announced in July that it has agreed to change its policy and to now allow CAHs to include the cost of capital leases for certified electronic health record (EHR) technology in their Medicare EHR incentive payments. A capital lease "is essentially the same as a virtual purchase agreement" and "meets the intent of the statute and regulation to qualify the leased asset as a purchased asset," CMS states in a new Frequently Asked Question on its website. "Therefore, the

CAHs' incentive payment may include the 'cost' of such leased asset, which must be based on the fair market value of the asset…at the date the lease was initiated."

IOM Recommendations on Examining Rural Payment Programs and Medicare Extenders: On July 17, the Institute of Medicine (IOM) issued a report that includes a recommendation that CMS re-examine rural hospital payment programs, such as the critical access and Medicare-dependent hospital programs, to determine whether they are effective at ensuring adequate access to appropriate care. In our Rural Hospital Policy Update AHA explains our disappointment that that the IOM believes that these programs have not helped improve the access challenges beneficiaries face in rural America. In contrast, these and other adjustments have helped improve rural hospitals' financial stability significantly; resulting in fewer rural hospital closures and thereby helping ensure rural beneficiaries are able to access care.

AHA urges HUD not to increase hospital mortgage insurance premiums: The AHA urged the Department of Housing and Urban Development to withdraw its proposal to increase premiums for the Hospital Mortgage Insurance Program by 20 basis points in fiscal year 2013, which would raise the program's financing costs by 30-40 percent. In comments submitted to the agency, AHA said the proposal "could put the program out of reach for many community hospitals in need of affordable financing. As a result, many necessary renovations, refinancings or new construction projects will not be feasible, threatening access to high-quality health care services for those least able to afford it." In addition, the proposed increase is unnecessary to maintain the program's positive financial balance.

MedPAC June Report to Congress: On June 15, the Medicare Payment Advisory Commission (MedPAC) issued a report to Congress that includes a chapter on health care provided to Medicare beneficiaries living in rural America. As stated in our Rural Hospital Alert, the AHA is disappointed to see that, in many ways, this chapter presents an incomplete picture. For example, it does not consider the fact that physicians serving rural beneficiaries are older on average than those serving urban beneficiaries. Specifically, the report does not draw the obvious next conclusion that once these physicians begin to retire in earnest, access to care in rural areas may be severely impacted, and ongoing monitoring is warranted.

In addition, the report states that, in general, payments to rural health care providers are adequate because payment adequacy indicators were similar in urban and rural areas. However, comparing urban and rural areas is not a good indicator of whether payments are adequate – margins are, and both urban and rural hospitals have negative Medicare margins. Finally, although the report shows that rural hospitals have a much higher Medicare utilization than urban hospitals, it does not discuss the implication of this higher Medicare utilization combined with negative Medicare margins. These two factors taken together mean that rural hospitals are still at a disadvantage because they are disproportionately affected by Medicare payments that remain below the cost of care.

CMS reminds providers of pathology billing change effective July 1:

The Centers for Medicare & Medicaid Services is reminding health care providers that independent laboratories may no longer bill Medicare directly for the technical component of physician pathology services furnished to hospital patients on or after July 1, when a statutory moratorium allowing the practice expires. This was addressed in the March 2012 CMS MedLearn Matters. AHA supports passage of the *Physician Pathology Services Continuity Act* (H.R. 2461), which would allow Medicare to continue paying independent laboratories directly for the technical component. Eliminating direct payment to independent labs would be especially burdensome for small and rural hospitals, which often lack the surgical volume necessary to support in-house services and instead rely heavily on independent labs for physician pathology services.

Enrollment and Re-Certification of CAHS in the 340B Drug Pricing Program:
Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement with the Secretary of Health and Human Services. By signing, the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities, including CAHs which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of section 340B(a)(5) of the PHS Act which prohibits:

a. a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate; and,
b. a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate and to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) developed a registration process for covered entities to enable it to address those mandates.

In the July 20 Federal Register, HRSA announced its "Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program." HRSA has submitted a request to the Office of Management and Budget (OMB) for its review. To enroll and certify the eligible federally funded grantees (including the newly enrolled CAHs), the OPA requires entities to submit administrative information (e.g. shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate grantee level or entity level authorizing officials and state/local government representatives. The purpose of this registration information is to determine eligibility for the 340B Drug Pricing Program. To maintain accurate records, 340B statute also requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program.

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are also required to submit general information about the arrangements and to certify that signed agreements are in place with those contract pharmacies.

Electronic Health Record Incentive Program

On Aug. 23 CMS released a final rule defining "meaningful use" of electronic health records for Stage 2 of the Medicare and Medicaid EHR Incentive Programs. The Office of the National Coordinator for Health Information Technology also issued a companion final rule that sets certification criteria, standards and implementation specifications for EHR technology. Taken together, these regulations raise the bar on the EHR adoption requirements that hospitals and physicians must meet under the 2009 *American Recovery and Reinvestment Act* to qualify for additional Medicare and Medicaid incentive payments and to avoid significant payment penalties in FY 2015.

The AHA is disappointed that CMS has set an unrealistic date by which hospitals must achieve meaningful use to avoid penalties. The rule establishes statutory Medicare payment penalties beginning in FY 2015 for prospective payment system (PPS) hospitals that fail to meet meaningful use. By law, the reductions are applied to PPS hospitals' market-basket update. The penalty is a 25 percent reduction to the market-basket update in FY 2015, 50 percent in FY 2016, and 75 percent in FY 2017 and beyond. Statutory penalties also apply to CAHs that fail to meet meaningful use. For CAHs, the penalties would reduce cost-based payments from 101 percent to 100.66 percent in FY 2015, 100.33 percent in FY 2016, and 100 percent in FY 2017 and beyond. CMS finalized its proposal that any CAH that is not a meaningful user in FY 2015 will incur the penalty for its cost-reporting period that begins in FY 2015.

Members-only webinar. AHA will host a live members-only webinar Sept. 5 on the final rule for Stage 2. Robert Anthony, a health specialist in CMS's Office of E-Health Standards and Services, will review the Stage 2 requirements and timelines for implementation, incentive payments and penalties for health care providers that fail to achieve them. The event will be moderated by Chantal Worzala, AHA director of policy. To register for the webinar, from 2:30-4 p.m.ET, click here. For more information, contact AHA Member Relations at (800) 424-4301.

To learn more, see the Aug. 23 AHA Special Bulletin and look for an upcoming AHA Regulatory Advisory with an in-depth analysis.

Drug Shortages

With drug shortages becoming increasingly frequent, the AHA surveyed its members to find out how the shortages have impacted day-to-day patient care. The AHA survey of 820 hospitals revealed that almost 100 percent of hospitals reported a shortage in the last six months and nearly half of the hospitals reported 21 or more drug shortages. The number of drug shortages has tripled in the last six years and they are having an impact on patient care.

The Food and Drug Administration Safety and Innovation Act (S. 3187, H.R. 5651) includes important reforms that require manufacturers to notify the FDA in advance if there will be a discontinuance or interruption in the supply of a drug; codify FDA's authority to more quickly approve manufacturer applications to make drugs that are in short supply; lift caps set by the Drug Enforcement Administration on narcotic ingredients to ensure sufficient supply for vital anesthesia, pain management and other critical uses; and improve communication with providers and patients as to the reason for and length of potential shortages. The legislation also creates a user fee program that will help speed FDA approval of generic drugs. In July, President Obama signed the Act into law.

Outpatient Prospective Payment System

On July 6, the Centers for Medicare & Medicaid Services (CMS) released the outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule for calendar year (CY) 2013. In addition to updating OPPS and ASC payment weights and rates, the proposed rule includes no enforcement in CY 2013 of the direct supervision policy for outpatient therapeutic services provided in critical access hospitals (CAHs) and in small rural PPS hospitals with 100 or fewer beds;

AHA appreciates the extended delay in enforcement in CAHs and small rural PPS hospitals. However, we remain concerned that hospitals will have difficulty implementing CMS's requirements. We believe that more changes are needed, including those contained in the *Protecting Access to Rural Therapy Services Act of 2011* (S. 778). The bill would mandate a default standard of "general supervision" for outpatient therapeutic services and obtain provider input to identify specific procedures that require direct supervision; ensure that for CAHs the definition of "direct supervision" is consistent with the CAH conditions of participation; and prohibit enforcement of CMS's retroactive reinterpretation of the "direct supervision" requirements. We will continue to advocate for these and other changes. A summary of the proposed rule may be found in an AHA Regulatory Advisory.

Medicare Physician Fee Schedule

In April, CMS released Transmittal 2457 with changes to outpatient therapy services – physical therapy, occupational therapy and speech-language pathology – effective Oct. 1. These changes are required by *The Middle Class Tax Relief and Job Creation Act of 2012*. The transmittal affects therapy services provided in hospital outpatient departments (HOPDs), outpatient rehabilitation facilities, comprehensive outpatient rehabilitation facilities, skilled nursing facilities and medical offices. Services provided in critical access hospitals are excluded.

The AHA strongly opposed expanding the therapy caps to services provided in HOPDs. This provision expires on Dec. 31, 2012. While AHA continues to support an extension of the therapy cap exceptions process for calendar year 2013 and beyond, AHA will urge Congress to extend the exceptions process without expanding the cap to therapy services provided in hospital outpatient settings. A summary of the transmittal can be found in an AHA Regulatory Advisory.

In July, CMS released the Medicare physician fee schedule proposed rule for calendar year (CY) 2013. Without congressional action, the PFS rule would reduce Medicare physician payments by an estimated 27% on Jan. 1.

Primary Care and Care Coordination: CMS proposes to explicitly pay physicians and qualified non-physician practitioners (NPP) for post-discharge transitional care management services in the 30 days following a hospital, skilled nursing facility, outpatient observation or community mental health center discharge. This would include non-face-to-face care management provided by clinical staff members.

Certified Registered Nurse Anesthetists (CRNA) and Pain Management Services: The rule would allow CRNAs to independently bill Medicare for chronic pain management services (rather than "incident to" a physician or NPP) as long as the CRNA is able to furnish these services in accordance with state scope of practice laws.

CMS Proposes Claims-Based Data Collection Strategy for Therapy Services: The rule includes a proposal to collect data on patient function related to physical and occupational therapy, and speech language pathology services. Beginning on Jan. 1, CMS must implement a claims-based data collection strategy that is designed to assist in reforming the Medicare payment system for outpatient therapy services. Such strategy shall be designed to provide for the collection of data on patient function during the course of therapy services in order to better understand patient condition and outcomes.

A summary of the rule can be found in the July 27 AHA Regulatory Advisory. Comments on CMS's proposed rule are due Sept. 4.

Home Health Prospective Payment System

The home health rule, also released this July, provides a net increase of 0.1 percent ($20 million) in Medicare payments for home health services over CY 2012 levels. The increase reflects a 2.5 percent market-basket update which, in addition to other adjustments, is offset by mandatory cuts under the ACA and a 1.32 percent coding offset, which is part of a multi-year offset.

Face-to-Face Encounter: CMS proposes to allow NPP in the inpatient setting to conduct the face-to-face encounter required to certify the need for home care.

New Provider Sanctions: The proposed rule adds further sanctions for agencies that fall out of compliance with Medicare conditions of participation, including monetary penalties, payment suspension and temporary management. Due to the CMS and state-level infrastructure changes that would be required to implement the new sanctions, the proposed sanctions would take effect one year after the final rule is issued.

A summary of the rule can be found in the Aug. 6 AHA Regulatory Advisory. Comments are due Sept. 4.

MEDICARE CONDITIONS OF PARTICIPATION

In May, CMS released a final regulation to revise a number of the existing Conditions of Participation (CoP) for hospitals and CAHs. A summary of the CoP rule can be found in an AHA Regulatory Advisory.

One of the most relevant changes for CAHs in this regulation would be to eliminate the requirement that CAHs must furnish diagnostic and therapeutic services, laboratory services, radiology services, and emergency procedures directly by CAH staff. This would allow CAHs to provide such services under arrangement. This change will better enable CAHs to address staffing challenges, provide high quality care to their patients, and provide CAH patients better access to care.

INTERNAL REVENUE SERVICE SECTION 501(R) FOR TAX-EXEMPT HOSPITALS

In June, the Department of the Treasury and the Internal Revenue Service (IRS) released long-anticipated proposed regulations implementing three of the four new requirements created by the ACA for tax-exempt hospitals**:** adoption of a written financial assistance policy and a policy relating to emergency medical care; limitations on the amounts a hospital charges to individuals eligible for financial assistance for emergency or other medically necessary care; and limits on engaging in extraordinary collection actions before making reasonable efforts to determine an individual's eligibility for financial assistance. The new requirements are found in Section 501(r) of the Internal Revenue Code. The provisions of Section 501(r) became effective for tax years beginning after March 23, 2010, except for the community health needs assessment requirement, which is effective for tax years beginning after March 23, 2012.

A summary of the rule can be found in an AHA Legal Advisory. AHA submitted comments to OMB on the regulations' regulatory burden, which we stated will vastly exceed the 11.5 hours estimated by the IRS. AHA members reported to the association that they will have to spend anywhere from 250 hours annually to more than 2,000 hours annually to satisfy the detailed requirements of the regulations. In addition, the AHA will submit comments to Treasury and the IRS on the proposed regulation, which are due Sept. 24. Look for a model comment letter for AHA members to use when they also submit comments.

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

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