CAH UPDATE

Sitka Community Hospital
Sitka, AK

William Newton Hospital
Winfield, KS

Summer 2015

The AHA and its Section for Small or Rural Hospitals represents and advocates on behalf of more than 1,600 rural hospitals, including 975 critical access hospitals (CAHs). *CAH Update* gives our members news on legislative and regulatory activities, as well as on Section programs and services. This issue of *CAH Update* reviews the federal budget for fiscal year (FY) 2016, AHA's advocacy agenda and actions, and rulemaking and regulations emerging from various agencies, such as the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA).

AHA WEBINARS ON PHYSICIAN RECRUITMENT AND INTEGRATED NETWORKS

The AHA is hosting two webinars for its hospital members in September. On September 15, leaders from CHI-Mercy Medical Center in Williston, ND a 25-bed CAH and the Family Medicine Residency Program at the University of North Dakota (UND) School of Medicine and Health Sciences will share a story of how the two have combined resources to establish a university-sponsored family medicine residency program in Williston. To register, click HERE.

On September 23, leaders from Stratus Healthcare will share their ambitious strategy to preserve hospital independence and keep health care local while preparing for integrated delivery and transitions of care. 16 health systems comprised of 30 community hospitals including 6 rural are collaborating on this ambitious strategy. To register and discover what they are doing and why, click HERE.

AHA TASK FORCE ON ENSURING ACCESS IN VULNERABLE COMMUNITIES

The AHA Board has announced a new 30-member task force that will work to confirm the characteristics of vulnerable rural and urban communities and identify strategies and federal policies to help ensure access to care in these areas. The Task Force on Ensuring Access in Vulnerable Communities is comprised of two subcommittees – one for rural and one for urban communities. Ray Montgomery, president and CEO of Unity Health White County Medical Center in Searcy, Ark., will chair the Rural Subcommittee. The task force is planning meetings and conference calls beginning in September and will concluding in spring 2016 with a report to the Board. New information will follow related to the task force as it begins its work.

THE FY 2016 BUDGET

In February, President Obama released his FY 2016 budget; he requested $431.3 billion in reductions to Medicare, of which $349.8 billion would come from providers including CAHs and $83.8 billion would come from structural reforms. His budget proposes $128 million for rural health programs, including $59 million for rural health outreach grants, $26 million for rural hospital FLEX grants and $14.9 million for telehealth.

In June, the House Appropriations Committee voted 30-21 to approve legislation that would provide $153 billion in discretionary funding for the departments of Labor, Health and Human Services, Education and related agencies in FY 2016, $3.7 billion less than this year. The bill would provide $71.3 billion for HHS programs, an increase of $298 million from FY 2015. Funding levels include more than $6 billion for HRSA.

In June the Senate Appropriations Committee voted 16-14 to approve legislation that would provide $153.2 billion in discretionary funding for the departments of Labor, HHS, Education and related agencies in fiscal year 2016, $3.6 billion less than this year. According to the committee, the legislation eliminates discretionary funding for the Affordable Care Act (ACA) and Independent Payment Advisory Board, and would prevent using discretionary funds to support state-based health insurance exchange operations and the ACA Risk Corridor program. The bill would provide $70.4 billion for HHS programs, $646 million less than in FY 2015. Among other provisions, the HHS funding includes $150.6 million for rural health programs.

Health Resources and Services Administration
FY 2016 House and Senate Bills All Purpose Table
(dollars in thousands)

Program	FY 2015 Enacted	FY 2016 Request		
		President	House	Senate
RURAL HEALTH				
Rural Health Policy Development	9,351	9,351	9,351	9,351
Rural Health Outreach Grants	59,000	59,000	59,000	63,500
Rural & Community AED	4,500	-	4,500	-
Rural Hospital Flex Grants	41,609	26,200	41,609	41,609

State Offices of Rural Health	9,511	9,511	9,511	9,511
Radiation Exposure Screening and Education	1,834	1,834	1,834	1,834
Black Lung	6,766	6,766	6,766	6,766
Telehealth	14,900	14,900	14,900	18,000
Subtotal, Office of Rural Health Policy	**147,471**	**127,562**	**147,471**	**150,571**
OTHER				
Nat. Health Service Corps Loan Repayment	1,190	1,190	1,190	1,190
Rural Physicians Training Grants	-	4,000	-	-
Nurse Corp Scholarship & Loan Repayment	81,785	81,785	81,785	79,785
Health Centers	5,000,533	5,091,522	5,091,522	5,091,522-

RURAL HOSPITAL ADVOCACY AND REPRESENTATION

The AHA continues to advocate for critical access hospitals and stands committed to maintaining a health care presence in rural communities.

AHA Advocacy Agenda for Rural Hospitals: The AHA supports policies and legislation that enable rural hospitals to care for their communities. Below are key areas of focus for our 2015 advocacy agenda.

- Outpatient therapy caps: Exempt CAHs from the cap on outpatient therapy services (H.R. 775/S. 539) and extend the outpatient therapy exception process and oppose the expansion of the cap to services provided in the outpatient departments of hospitals and CAHs.
- Direct supervision. The Protecting Access to Rural Therapy Services (PARTS) Act (S. 257/ H.R.1611) would ensure that CMS appropriately addresses the issue of direct supervision for outpatient therapeutic services for rural hospitals and CAHs. Recently introduced, S. 1461. and H.R. 2878 would extend through CY 2015 the enforcement delay on direct supervision requirements for outpatient therapeutic services provided in CAHs and rural PPS hospitals with 100 or fewer beds.
- 96-hour physician certification. The Critical Access Hospital Relief Act (S. 258/H.R. 169) would remove the 96-hour physician certification requirement as a condition of payment for CAHs. These hospitals would still be required to satisfy the condition of participation requiring a 96-hour annual average length of stay.
- MDH and low-volume adjustment. The Rural Hospital Access Act (S. 332/H.R. 663) would permanently extend the Medicare-dependent hospitals and enhanced low-volume adjustment programs.
- Ambulance add-on payment. The Medicare Ambulance Access, Fraud Prevention and Reform Act (S. 377/H.R. 745) would permanently extend the ambulance add-on payment adjustment.
- RCH demo. The Rural Community Hospital (RCH) Demonstration Extension Act (S. 607/H.R. 672) would extend the program for five years. The RCH program enables rural hospitals with fewer than 51 acute care beds to test the feasibility of cost-based reimbursement.

Other Legislation

Rural Emergency Acute Care Hospital: Sen. Charles Grassley (R-IA) on June 23 introduced the Rural Emergency Acute Care Hospital Act (S. 1648), which would allow CAHs and PPS hospitals with 50 or fewer beds to convert to Rural Emergency Hospitals (REH). REHs would provide emergency and outpatient services, but not inpatient care at enhanced reimbursement rates of 110% of reasonable costs. In a letter to the senator, AHA called the legislation "a good first step toward ensuring access to health care services in some rural communities."

Save Rural Hospitals Act: Reps. Sam Graves (R-MO) and Dave Loebsack (D-IA) introduced the Save Rural Hospitals Act (H.R. 3225), which would address beneficiary equity for outpatient services, regulatory relief, a new model for delivery of emergency care, and several Medicare extenders. AHA is supportive of several of the provisions included in this legislation, however we are concerned about others.

HEARINGS AND TESTIMONY

AHA is advocating for the interests of rural hospitals on Capitol Hill by providing testimony in hearings and panel discussions.

On July 28, in a statement, before the House Ways & Means Subcommittee on Health, the AHA urged Congress to take action on the 96-hour rule, direct supervision of outpatient therapeutic services, recovery audit contractors, the RCH demonstration program and the Medicare extenders. In addition, AHA encouraged Congress to lift the geographic and practice setting limitations and approve new technologies so CMS can expand telehealth by approving additional telehealth services for Medicare coverage.

On July 22, AHA submitted a statement to House Ways and Means Health Subcommittee on MedPAC's most recent hospital policy recommendations. AHA addressed several issues and reiterated its support for 340B drug pricing program and rural payment adjustments and necessary provider CAHs.

On June 24, the Senate Finance Committee approved AHA-backed bills – to support access to hospital services in rural communities.

On June 16, the AHA participated in a bipartisan Capitol Hill briefing hosted by the Senate Rural Health Caucus to educate congressional staff on the unique circumstances and needs impacting health care delivery in rural communities. The AHA highlighted the importance of continuing vital rural programs, such as the MDH and enhanced low-volume adjustment programs; and passing key rural legislation such as S. 607/H.R. 672 to extend the Rural Community Hospital Demonstration program.

To help educate Capitol Hill staffs about the unique circumstances and the vital role of rural hospitals, the AHA organized a June 9 briefing. Information is available on "AHA Stat" blog as well as a video replay of the briefing and discussions. Click on the links to hear the discussion.

- What is Rural?
- 96-hour Rule
- Direct Supervision of Outpatient Therapeutic Services
- State Profile in Innovation
- Interoperability / EHR
- Grants and Affiliations
- Questions & Answers Session

REGULATORY AND POLICY PRIORITIES

The AHA works to ensure vital funding and equitable treatment of hospitals that care for the 51 million Americans that live in rural areas. Public policy and rulemaking from various agencies influence the security of access and coverage. CAHs are implicated in a host of rules and public policy concerns, which are reviewed below.

CMS Transmittal 138, Appendix W, State Operations Manual (SOM) for CAHs: On April 7, through CMS Transmittal 138, Appendix W was revised to reflect recent regulation changes. CMS also uses this transmittal to make clarifications and updates to existing guidance. Revisions and updates address several sections of the rule such as:

- Bed counts
- Physician chart review of NPP
- Guidance for physician supervision
- Pharmacy operations in a CAH
- Infection control
- Nutritional requirements
- ALOS of 96 hours
- Services provided under agreement
- Nurse staffing and Rx administration
- Nursing care plan

Clarification of CAH Rural Status, Location and Distance Requirements: A CMS memorandum (S&C 15-45-CAH) from the Survey & Certification (S&C) Group to the State Survey Agency Directors dated June 26, 2015 reminds all parties that S&C-13-20, issued March 15, 2013, updated the interpretive guidelines to clarify that a CAH must meet the location and distance requirements not only at the time of its initial conversion to CAH status, but at all times thereafter. It also reviews the definition of primary roads and mountainous terrain referenced in S&C 13-26 sent to states on April 19, 2013.

CMS Transmittal 143, Revisions to SOM, The Certification Process and Interpretive Guidelines for CAHs: In Transmittal 143 published on July 31, CMS is informing State Survey Agencies (SAs) who survey and certify CAHs, that revisions are being made to portions of Chapter 2, section 2256 (the certification process) and Appendix W (survey protocol, regulations and interpretive guidance) concerning loss of rural status due to adoption of the latest Office of Management and Budget metropolitan statistical area delineations. In addition, CMS explains that additional revisions are needed to clarify existing guidance related to requirements concerning CAH location requirements relative to other CAHs or hospitals.

CMS Manual System	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Pub. 100-07 State Operations Provider Certification	
Transmittal 143	Date: July 31, 2015

According to CMS, a CAH that can document that it was designated by a State as a necessary provider CAH prior to Jan. 1, 2006, does not have to meet the "relative to other facilities" standard. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate. According to Transmittal 143, "*ROs and SAs should have the documentation related to a CAH's original designation as a necessary provider in the file on each CAH."* If they do not, SAs may ask the CAH to supply copies of the original necessary provider designation documents. An "Initial Certification Letter" from the fiscal intermediary or Medicare administrative contractor dated prior to Jan. 1, 2006 should suffice.

CMS is careful to explain that only the RO makes the determination whether a CAH applicant or existing CAH meets the rural location requirement. However, SAs may wish to make informal assessments prior to conducting a survey, following the guidance provided in Section 2256A of the SOM. If the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

CMS Manual System	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Pub. 100-07 State Operations Provider Certification	
Transmittal 145	Date: August 21, 2015

CMS Transmittal 145, Revisions to SOM: On Aug. 21 CMS released Transmittal 145 including a new exhibit for the State Operations Manual, Chapter 9: Critical Access Hospital (CAH) Recertification Checklist: Rural and Distance or Necessary Provider Verification. This document describes the process used by the RO to determine compliance with distance and location requirements for a CAH and the documentation requested from the SA to help them with this determination.

Hospital Outpatient PPS Proposed Rule: On July 1, CMS issued a proposed rule for CY 2016 for the hospital outpatient prospective payment system and ambulatory surgical center payment systems. Under the rule, CMS proposes to alter its two-midnight policy so that certain hospital inpatient services that do not cross two midnights may be appropriate for payment under Medicare Part A if a physician determines and documents in the patient's medical record that the patient requires reasonable and necessary admission to the hospital as an inpatient. CMS does not propose any changes for stays that are expected to last more than two midnights.

The agency also announces changes related to its medical review and enforcement strategy for patient status claims. Beginning no later than Oct. 1, CMS will use Quality Improvement Organizations to conduct first-line medical reviews of patient status claims rather than Medicare Administrative Contractors or Recovery Audit Contractors, which will focus only on those hospitals with consistently high denial rates. The rule is summarized in an AHA Regulatory Advisory. AHA has submitted comments on the OPPS proposed rule for CY 2016.

Medicare Physician Fee Schedule Proposed Rule: On July 8, CMS released its proposed rule for CY 2016 with changes to the Medicare physician fee schedule and other revisions under Medicare Part B. The rule is summarized in an AHA Regulatory Advisory. Among changes important to rural providers, the rule seeks to:

- Extend payment add-ons for ambulance transportation services in rural areas;
- Authorize Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to provide chronic care management services;
- Require RHCs to report all services using standardized coding systems, such as level I and level II of the HCPCS; and
- Create an exception to the Stark law that would permit payment from a hospital, FQHC, or RHC to a physician to assist the physician in employing a non-physician practitioner within the same geographic region.

Through this proposed rule, CMS is also seeking input on provisions included in the Medicare Access and CHIP Reauthorization Act of 2015 such as an appropriate low-volume threshold for excluding professionals from the Merit-based Incentive Payment System (MIPS). MIPS will assess professionals' performance in four specific performance areas: quality, resource use, clinical practice improvement activities and meaningful use of EHRs. It will then translate that performance into a payment adjustment. Qualifying Alternative Payment Mechanism participants are exempt from the MIPS, as well as most EHR meaningful use requirements.

Meaningful use of EHRs: We have transitioned from incentives to penalties for meaningful use of EHRs. Eligible hospitals and CAHs that can participate in either of the Medicare or Medicaid EHR Incentive Programs will be subject to *payment adjustments* unless they are meaningful users under one of the EHR Incentive Programs.

Stage 2 2015 modifications rule includes some important flexibility in two requirements. First, it proposes a 90-day reporting period for 2015. Second for the portal, a hospital would have to show that at least one patient used the portal, rather than having to reach the 5% mark. The rule also proposes to add flexibility to the requirements on sharing information during transitions of care. The final rule is past due from CMS and in a letter to HHS Secretary Burwell, the AHA has joined with other national hospital associations to urge the agency to release the rule as quickly as possible.

The Stage 3 rule continues to pursue aspirations without much thought to feasibility, and raises the bar yet again. There are some promising new directions in health IT such as patient-generated data or devices as part of an EHR. Vendors and others are making progress in allowing use of third-party apps to access and use data stored in an EHR. In Stage 3 CMS proposes to require these things even while they are still being developed and tested.

Given the track record of meaningful use, the AHA believes the wiser course of action is to hold off on finalizing Stage 3 so that we can learn from Stage 2 and test these promising new approaches. There is also a considerable amount of activity underway to improve interoperability, or the ability of EHRs to actually share data. We believe it is time to prioritize that work over new meaningful use requirements. More can be found in the AHA Regulatory Advisory.

340B Drug Pricing Program: On Aug. 28, HRSA Office of Pharmacy Affairs issued the proposed 340B Drug Pricing Program Omnibus Guidance in the Federal Register. The proposed guidance addresses key policy issues including eligibility and registration of hospitals and outpatient facilities, individuals eligible to receive 340B drugs (patient definition), drugs eligible for purchase under the program, prohibition of duplicate discounts, and manufacturer compliance, and others. The guidance proposes a change with regard to private non-profit 340B hospitals that have contracts with state or local government. See the AHA Special Bulletin for additional information. The proposed guidance will be open for public comment through Oct. 27.

A July 6 Government Accountability Office (GAO) report examining Medicare Part B spending at hospitals participating in the 340B Drug Pricing Program draws unsubstantiated conclusions about a program that has a proven track record of improving access to care for poor patients and vulnerable communities.In an “AHA Stat” blog the AHA, along with HHS, has expressed concerns about the methodology GAO used to conclude that financial incentives were driving 340B Medicare DSH to prescribe more drugs or more expensive drugs to treat Medicare Part B patients. AHA believes that the report does not appropriately account for certain differentiating factors and characteristics of 340B DSH hospitals. Find more facts on how the 340B program helps communities on the AHA website.

On June 16, HRSA released a proposed rule on drug ceiling prices and civil monetary penalties for manufacturers in the 340B Drug Pricing Program. Required by the ACA, the

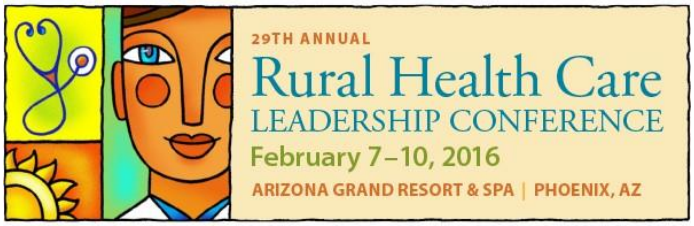
rule would amend Section 340B of the Public Health Service Act to impose monetary sanctions (not to exceed $5,000 per instance) on drug manufacturers who intentionally charge a 340B hospital or covered entity more than the ceiling price established under the procedures of the 340B program. The proposed rule also would require greater transparency in calculating the 340B ceiling drug prices to ensure that drug manufacturers are not overcharging 340B covered entities.

The House Energy and Commerce Committee is expected to engage on 340B this fall. The committee is seeking feedback on the legislative proposal that was circulated as part of its 21st Century Cures discussion.

Hospital Compare: CMS anticipates that the July update to the Hospital Compare website will include performance data reported voluntarily by CAHs, the agency told AHA. We expressed "deep disappointment" that the website's April update failed to include most of the CAH data. "The fact that so many CAHs are engaged in voluntary quality reporting demonstrates their commitment to sharing information with the communities they serve, and to identifying opportunities to improve care," wrote Nancy Foster, AHA vice president of quality and patient safety policy. "Moreover, many payers – including some Medicaid programs and private insurers – use Hospital Compare data reported by CAHs in their pay-for-performance programs. For these reasons, it is critical that CMS post voluntarily reported data in a timely fashion." CMS said it regrets that the data were not posted in April and is taking steps to help ensure future updates of the data are timely.

AHA RURAL HEALTH CARE LEADERSHIP CONFERENCE

The AHA Rural Health Care Leadership Conference provides a unique focus on innovative ideas, thoughtful insights, and tested strategies for improving rural health care and developing the thoughtful leadership that can produce results. Join top practitioners and thinkers to share strategies and resources for accelerating the shift to a more integrated, high performing, and sustainable rural health care system. Visit the Health Forum website for more information on registration.



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

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