

Regional Policy Board Spring 2016



BOARD OF TRUSTEES

AGENDA

Four Seasons Hotel Chicago
Ballrooms A-B, 8th Floor
November 19-20, 2015
Beginning at 8:00 a.m.

1 **Welcome and Overview**

- A. **Introductions**— Dr. Perlin
- B. **Reflections**—Mr. Hinton
- C. **Meeting Objectives**—Mr. Pollack

2 **[Approval of Minutes and Confirmation of Actions](#)**

Minutes were previously emailed to Board members. Three email votes require confirmation by the Board.

3 **Transition Update** — Mr. Pollack

Mr. Pollack will provide an update on transition developments and progress.

4 **Open Forum**—Dr. Perlin, Mr. Pollack

This forum is designed to provide an opportunity for Board members to raise issues of concern and interest.

PUBLIC POLICY

5 **Washington Update** — Mr. Nickels

Mr. Nickels will report on the political scene and AHA's key legislative and regulatory priorities.

6 **[Insurance Consolidation](#)** — Ms. Hatton and Mr. Nickels

Ms. Hatton and Mr. Nickels will discuss AHA's work on the major health insurance consolidation including some tools and resources. Resource materials are under **Insurance Consolidation**.



7 **Quality Improvement**

- A. **[The Joint Commission \(TJC\) Update](#)** — Craig Jones, chairman, TJC
Mr. Jones will report on the current work and priorities of TJC. The Board will be asked to discuss TJC’s efforts to be a more effective partner in health care quality and safety improvement and the differences between a TJC survey and surveys conducted by CMS or another accrediting agency. Resource materials are under **Quality Improvement**.
- B. **[HEN 2.0: Priorities and Strategies](#)** — Dr. Joshi
Dr. Joshi will share information with the Board about HEN 2.0 activities, progress and strategies to reduce preventable hospital-acquired conditions and readmissions. Resource materials are under **Quality Improvement**.

8 **Public Policy Issues** — Ms. A. Thompson
Resource materials are under **Public Policy Issues**.

- A. **[Drug Pricing Increases](#)**
Ms. Thompson will present for Board discussion and approval a proposed strategy to address drug pricing increases.
- B. **[Opioid Addiction Epidemic](#)**
Ms. Thompson will present a proposed strategy for Association leadership to address the opioid addiction crisis for Board discussion and action.
- C. **[Expanding Telehealth](#)**
The Board will be requested to discuss and approve proposed strategies in support of continued telehealth expansion.
- D. **Field Unity Report** — Mr. Pollack, Mr. Nickels, Ms. A. Thompson
Mr. Pollack, Mr. Nickels and Ms. Thompson will provide an update on key issues for the file.
 - 1. Area Wage Index—Mr. Nickels
 - 2. Bundled Payments Update — Ms. Thompson
 - 3. 340 B— Ms. Thompson



ASSOCIATION AFFAIRS

9 Executive Committee Report and Recommendations

10 Consent Calendar

The Consent Calendar will be distributed at the meeting.

11 Board and Association Affairs

A. [2017 Board Composition and Leadership Priorities](#) — Ms. Lovinger Goldblatt
The Board is requested to discuss and take action on proposed guidance to the Committee on Nominations on the Board's composition priorities for 2017. The Executive Committee is expected to recommend action. Resource materials are under **Board and Association Affairs**.

B. **Board Retreat Agenda** — Mr. Pollack, Dr. Joshi
Mr. Pollack and Dr. Joshi will update the Board about plans for the 2016 Board Retreat in Naples, Florida

12 Committee Reports

Resource materials are under **Committee Reports**.

A. [Equity of Care](#) — Mr. Woods

The Board will be updated about the goals and milestones of the #123forEquity Pledge to Act and provide further guidance about future strategic alignment.

B. [Operations Committee](#) — Mr. Gross

1. [Report on Current Activities](#) — Mr. Gross

Mr. Gross will present an update on the most recent work of the Operations Committee.

2. [Year-to-Date Financial Statements](#) — Mr. Evans

The Board will be requested to receive the most recent financial statements of the American Hospital Association.

3. [Health Forum Merger](#) — Mr. Jesuele

Mr. Jesuele will present a proposal for merging the Association's for-profit subsidiaries into one entity, Health Forum. Both the Operations Committee and the Executive Committee are expected to make recommendations for Board action.

Recess



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Reconvene 8:30 a.m.

C. [Committee on Performance Improvement/Committee on Research](#) —

Dr. Burke, Dr. Joshi, Dr. Combes

The 2015 report of the Committee on Performance Improvement and Committee on Research, *Care and Payment Models to Achieve the Triple Aim*, will be presented for Board action. In addition, the Board will be requested to discuss and approve the 2016-2018 AHA research agenda and proposed 2016 topics for the CPI and COR. Resource materials are under **Committee Reports**. The 2015 CPI/COR report is a separate document on the Board portal.

1. [2015 CPI/COR Report](#): *Care and Payment Models to Achieve the Triple Aim*
2. [2016 Topics](#): *Workforce and The Next Generation of Community Health*—Ms. P. Thompson, Ms. McNally, Mr. Woods, Dr. Combes
3. [2016-2018 AHA Research Agenda](#) — Dr. Joshi

13 [Strategic Plan](#) — **2016-2018 and 2016 Operating Budget** — Mr. Jesuele, Mr. Nickels,

Dr. Joshi, Mr. O'Dell, Mr. Evans

The Board will be requested to discuss and approve the Strategic Plan and 2016 Operating Budget. Resource materials are under **Strategic Plan**, and in a separate [Strategic Plan booklet](#) on the Board portal.

A. **Overview** — Mr. Jesuele, Mr. O'Dell

B. **2016 Operating Budget** — Mr. Evans

14 **Informational Reports**

The following reports are provided for information.

Informational Reports.

- A. [October and November Executive Committee Agendas](#)
- B. [Third Quarter Performance Report](#)
- C. [Institutional Membership Report](#)
- D. [RPB, Governing Council and Committee Reports](#)
- E. [AHAPAC](#)
- F. [July Board Meeting Evaluation/2015 Evaluation Summary](#)

- G. **Business Development and Services**
 1. [AHA Solutions](#)



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2. [Health Forum](#)
 3. [Personal Membership Groups](#)
- H. **Clinical Leadership and Health Improvement**
1. [American Organization of Nurse Executives](#)
 2. [Center for Healthcare Governance](#)
 3. [Health Research and Educational Trust and HPOE](#)
 4. [Institute for Diversity in Health Management](#)
 5. [Physician Leadership Forum](#)

15 **Next Meeting**

January 29-31, 2016, Naples, Florida

16 **Meeting Wrap Up** — Mr. Pollack

Break 10:10-10:20

17 **Executive Session**

A. **Transition Update**

B. **General Discussion** (with and without President)

18 **Adjournment**

###



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Ramanathan Raju, MD

By Invitation

Deborah Bowen

Incoming Board Class

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David Entwistle
Steven P. Johnson
Bruce Lawrence
Randall D. Oostra
Mary Beth Walsh, MD
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Agenda Item 14D—For Information

November 12, 2015

During the fall 2015 round of meetings, 17 governance and policy development groups met to provide input on key advocacy, public policy and field leadership issues. Agendas for the meeting included several issues that all the groups discussed, as well as unique topics of interest to specific constituency section governing councils and committees. Following is a summary of those agenda items in common across regional policy boards (RPBs), governing councils and committees. A more detailed summary of the discussions at *each* RPB, governing council and committee meeting is available on the American Hospital Association (AHA) Board of Trustees website.

Washington Report: Update and Discussion

Objective: To update participants on the political and regulatory environment in Washington and AHA's advocacy agenda.

What We Heard: The Washington Report was very well received. Participants heard that Congress is facing a “triple fiscal cliff” this fall, of passing a federal budget, raising the debt ceiling, and renewing an expiring highway bill. This leaves hospitals exposed to possible payment cuts. Key legislative issues include: halting any expansion of physician-owned hospital; influencing the development of “innovations” legislation; addressing RAC reforms; improving the readmissions penalty program; protecting graduate medical education funding; and addressing barriers to clinical integration. Hospital leaders expressed support for our advocacy agenda. They also expressed concerns about maintaining the 340b drug discount program, implementation of the Cadillac tax, and increases in Medicare Part B premiums, and thanked the AHA for continuing to work on behavioral health issues.

Hospital leaders appreciated detailed updates on the new bundled payment model from the Centers for Medicare & Medicaid Services (CMS), the new “mega guidance” on the 340b drug discount program, the transition to ICD-10, meaningful use and interoperability, and changes to the two midnight policy. Related to the two midnight policy, hospital leaders were pleased that CMS is proposing to keep the certainty of two-midnights for longer stays, but allow physician judgment to determine patient status when length of stay is less than two midnights.

In the first round of RPBs, members saw a video presentation of the Washington Report, followed by discussion with policy and federal relations staff at the individual meetings. The video was well received, although members also expressed appreciation for having experts in the room. Given the ever-changing political and policy landscape, the video was not used for the second round of RPBs or at the governing councils and committees. Additionally, hospital leaders at the council and committee meetings received a more targeted Washington Update with issues of interest to those constituency sections.

Next Steps: The Board will receive an update on these and other key political, legislative and regulatory issues at its November meeting.

National Call to Action to Eliminate Health Care Disparities Campaign

Objective: To update members on the progress of the National Call to Action (NCA) to Eliminate Health Care Disparities and to ask hospitals to sign on to AHA's Equity of Care Pledge campaign.

What We Heard: Hospital leaders shared very strong support for the goal of the campaign, and acknowledged that more could be done to eliminate disparities. Some members signed the pledge on site; others suggested they would take it back to their board or leadership for consideration. Some members expressed concern that the timing of the actions in the pledge is too short, making them a bit reluctant to commit. Some participants that were part of health systems were unaware that their health system made a commitment on behalf of all their hospitals.

A few participants suggested that their communities do have significant racial or ethnic diversity, while others highlighted different types of diversity (such as economic divisions, religious groups, or native populations) that they believe should be addressed. Operationally, data to assess disparities can be hard to collect, and may suffer from small sample sizes. Members agreed that it is important to have IT systems that support data collection.

When asked to share examples, members highlighted what they are doing to both address disparities across patient populations and increase diversity of suppliers. Trustee members noted that hospital boards play a key leadership role in building the commitment to act. Many hospital leaders have committed to creating more diverse boards, but note that it can take time to change board composition. Participants asked AHA to share best practices and promote "cultural dexterity." They also would like to learn about strategies to engage independent physician groups.

Next Steps: Institute for Diversity (IFD) will revise the preamble text to reflect that the timing of actions in the pledge are flexible. IFD and AHA will continue to push the hospital field to sign on to Equity of Care Campaign to eliminate health care disparities. The board will continue to be apprised of the Campaigns progress.

Expanding Telehealth

Objective: To summarize recent trends in telehealth, learn how members are innovating with telehealth, and get member feedback on barriers to and policy priorities for expanding telehealth.

What We Heard: Hospitals are using telehealth and remote monitoring in many different ways, with the goals of expanding access, increasing efficiency, improving care management, and meeting consumer demand. Members shared a rich array of case examples in their break-out groups. To expand access, they are engaged in teleneurology (including stroke care), telepsych, teledermatology and teleradiology, and virtual care for homeless shelters and prisons, among others. Telehealth also can be important in skilled nursing and other types of post-acute care (such as to facilitate transfers between the ICU and a LTACH). To increase efficiency, hospitals are deploying eICUs, remote assessment of inpatient monitors, and virtual urgent care for their employees. To improve care management, they are using remote monitoring and call centers to

track patients with serious chronic illnesses or those at high risk of readmission. To meet consumer demand, they are setting up remote exams and increasing the use of web portals to inform and engage patients.

Despite this rich array of current uses, all of the policy development and governance groups predicted even greater use of telehealth in the near future given changes in technology and growing consumer demand. The most commonly cited barrier that hampers expanded use of telehealth is lack of payment or return on investment. Other barriers include the investment costs for infrastructure (including adequate broadband in some rural and inner city areas), issues with licensing and credentialing, resistance from some clinicians, resistance from state medical societies, workforce and training needs, privacy and data security, and challenges integrating information from telehealth and remote monitoring into the EHR.

While members generally gave expanding telehealth a high priority ranking for the field, they were mixed on the priority that AHA should give to expanding Medicare payment for telehealth, given that it could come with a high price tag. Some members felt that payment is important, and Medicare often serves as a leader for other payers. Most urged AHA to advocate for greater inclusion of telehealth where we know it is helpful, and in alternative payment models and population health approaches. Members also emphasized the need for more studies that show the cost savings associated with telehealth. Participants recommended that AHA collect and disseminate best practices in using telehealth and overcoming barriers to educate both members and policymakers. Some members, and particularly rural hospitals, would like to see telehealth included in payment policy for rural health clinics and federally qualified health centers.

Next Steps: The AHA will use the feedback from our policy development and governance groups to shape and advocate for legislative proposals to expand telehealth. We will also continue to work with our allied associations on state-level activities and develop additional communication and member educational resources, such as webinars with case examples.

Bundled Payment

Objective: To obtain members' feedback on the expansion of Medicare bundled payment programs, including necessary tools for success and experiences with forming relationships with other providers.

What We Heard: Hospital leaders greatly appreciated the explanation of Medicare's bundled payment approach, as it is likely to be the first of many such initiatives. The most important tool they identified as necessary for success is accurate and timely data. In a related manner, they need IT systems that support analysis and care management, as well as interoperability to share data across care settings. From a policy point of view, success will require waivers from regulatory constraints that limit their ability to work with physicians, especially Stark and anti-kickback rules and limits on gainsharing. Given that most variation in cost occurs in the post-acute portion of an episode, they also need relief from current regulations that limit a hospital's ability to determine the best setting of care post-discharge. Specific to the newly proposed Comprehensive Care for Joint Replacement (CCJR) model, members need more time to implement it and better risk adjustment. They also would like the program to exclude non-elective procedures.

In general, managing bundled payment requires adequate volume to balance risk. Some CAHs expressed concern that they may be shut out of bundles, and worry about the impact bundling might have on use of swing beds. Similarly, post-acute providers expressed concerns about how they will fit into bundling arrangements.

Members could not share many specifics of their experiences bundling acute and post-acute services, as many are not yet engaged in bundling efforts and those that have experience are still in early days of implementation. In reality, fee-for-service is still the dominant payment method. However, many members shared good experiences working with physicians, who respond well to data. The Maternal and Child Health Governing Council noted that they have experience working with maternity payment bundles.

Next Steps: The AHA will use participant input in advocating with CMS on its bundled payment models. Additionally, AHA will provide CCJR additional data to guide their efforts.

Open Forum¹

Objective: To share via an open forum discussion the disruptors in health care today and how hospitals are engaging consumers in response.

What We Heard: Hospital leaders see many different kinds of disruptors, including new technologies, growing consumerism, and changes in policy and regulation. Growth in retail health options, use of mobile technologies, and new payment models were all identified, as were new consumer-oriented care delivery models, such as on-demand, self-pay house calls. Disruptors pose both opportunities and threats. Ideally, hospitals will watch the landscape, and try to “disrupt themselves” rather than reacting to outside pressures. Challenges in responding to disruptions include identifying and recruiting workforce with the right skill sets, and managing financial risk associated with new ventures.

Next Steps: Information and insights gleaned from the open forum discussion will help AHA develop tools and strategies to identify and respond to disruptors.

Opioid Epidemic

Objective: To discuss the roles and responsibilities of hospitals in helping to stop the U.S. opioid epidemic, and to identify policies or tools hospitals need to be effective in these roles.

What We Heard: Hospitals clearly have a role in leading efforts to address the opioid epidemic, but they must work with community partners to address the problem. One possibility is to play a convening role to ensure that health care providers, schools, and other community institutions are working together. Members, and particularly clinicians, noted that pain can be treated through use of opioids, but also through alternative treatments, such as nerve blocks, meditation, or other, non-addictive medications. The most frequently mentioned roles for hospitals included addressing prescribing practices, sharing/developing guidelines, reducing drug diversions, and using prescription drug management programs (PDMPs) to identify abusers. Participants identified many good examples of positive steps they are taking, most notably in the ED. These steps include limiting the number of pills prescribed, routine use of PDMPs, requiring adherence to guidelines, and even creating an “Opioid free Emergency Department (ED).”

¹ The open forum was discussed only at RPBs and the Committee on Governance.

Members noted that, in general, there is a need for greater focus on educating patients and giving physicians training and tools to support patients. Meeting participants noted positive outcomes from use of Narcan (naloxone) by trained first responders.

To support hospitals in their role, participants indicated that they would benefit from practice guidelines and improved PDMPs, particularly across borders. They support changing the focus of HCAHPS from being “pain free” to having “pain under control,” as they believe the current questions encourage excessive use of opioids. Other helpful policies include: increased use of naloxone and education of first responders on how to use it; addressing other prescribers (dentists, podiatrists, etc.); Good Samaritan laws; better drug disposal; and better reimbursement for medication-assisted treatment. A full solution will also require addressing capacity constraints and developing better treatment and recovery options for those who are addicted. The maternal and child health council expressed appreciation for the AHA’s support of legislation to address newborns born addicted to opioids.

Next Steps: At its November meeting, the Board will be asked to discuss and approve a set of action steps to increase AHA’s visibility, involvement and advocacy on this issue.

Physician Payment after SGR Reform

Objective: To summarize the new physician payment and quality reporting system created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and discuss the implications for hospitals and health systems.

What We Heard: Hospital leaders appreciated the detailed analysis of the new physician payment programs and clear explanation. Many fear that physicians are not yet paying attention to this issue because the programs start in 2019. Given the scope of changes, members identified three likely impacts on physicians: some may retire earlier than planned, some may leave Medicare altogether, and many will look to hospitals or larger physician groups for support. Members expressed considerable concerns with the administrative burden of the program, program complexity, and costs of compliance. However, many saw the coming emphasis on value-based payment and alternative payment models as an opportunity to better align with physicians in support of transformation. Concerns included how to keep physicians engaged, prevent physician burnout, and retain adequate workforce and access to care if physicians leave Medicare, particularly in rural and underserved areas.

As these programs are designed and implemented, participants encouraged AHA to advocate for administrative simplicity and clarity on how program will work. AHA should emphasize the need for CMS to make it possible for physicians to succeed. Members noted that the choice of quality measures will be key — they must be aligned across hospitals and physicians, be important for improving care, and focused on outcomes. In short, they must be measures that matter and include patient satisfaction, care management and population health. The program also should address personal accountability and wellness. Members expressed concern, however, that today’s IT systems will not support the level of metrics and data collection that will be needed, particularly without good interoperability.

AHA also should advocate for a fair and transparent payment methodology that includes risk adjustment and takes into account the impact on rural areas. Members expressed concern over

the fairness of an automatic penalty for those at the bottom 25 percent of performance. They suggested that the AHA also should reinforce that CMS will need to give access to timely and accurate data so that hospitals and physicians can manage new models, and ask CMS to clarify how the program will account for participation in Medicare Advantage. The administration will have to resolve clinical integration issues, such as gainsharing, and anti-kickback limitations if hospitals are going to support physicians. Looking forward, members urged the AHA to educate physicians and hospitals on the program, and consult with physicians on formulating comments. AHA also should work with other associations, particularly physician groups, and explore ways to model impacts.

Next Steps: The AHA will develop a strategy for member education on the new physician payment models and create mechanisms to gather feedback from clinical leaders on needed policies to shape further advocacy.

Health Insurance Consolidation

Objective: To share AHA's strategy in response to proposed health insurance acquisitions and discuss how hospital and health system engagement in value-based payment models might change with greater insurance consolidation.

What We Heard: Members generally felt AHA is on track with its activities on health insurance consolidation and appreciate the strong association role. They urged AHA to provide simple sound bites to ensure the public understands that hospital consolidation is different from insurance consolidation. For example, members pointed out that payers innovate on price, while providers innovate on care delivery, and the latter is more likely to create benefit for consumers. Members urged the AHA to educate the public on the negative impacts of insurer consolidation for consumers. They suggested working with consumer groups, and potentially with the business community, purchasers, other provider organizations and unions. Hospital leaders noted that it is important for AHA to work at both federal and state levels (esp. with state Attorneys General), as the impact of the insurance acquisitions will vary by market. Indeed, in some markets, the proposed mergers were not seen as a major issue, while other markets expect the mergers to have a significant, negative impact on competition.

When asked about their existing participation in value-based payment models, members noted that commercial payers are not very active in many markets, and fee-for-service continues to be the dominant payment model. However, direct to purchaser models are growing. Some states, such as Hawaii and Puerto Rico, have active managed care markets. In general, commercial payer value-based models are less common in rural areas. For those with active arrangements, members expressed concerns about receiving timely and accurate data to support new models. Members noted that it would be helpful to have more transparency on insurer activities.

Next Steps: The AHA continues to aggressively pursue communications, legislative, and administrative strategies to highlight the negative consequences of these mergers.

Drug Pricing

Objective: To discuss the increasing prices of patent protected, specialty, and generic drugs to hospitals and obtain feedback from members on the impact of these trends.

What We Heard: Hospital leaders are experiencing significant increases in drug prices and observe that hospitals are caught in the middle between pharmaceutical manufacturers and consumers, who face increased costs. Hospitals are devoting additional staff time to managing drug stocks and counseling patients on financing and charity options. They also report increased efforts working with drug companies to get patients access to less costly drugs.

Significant price increases are happening in all categories of drugs, with certain drugs, such as cancer drugs, biologics and Hepatitis C treatments being especially problematic. Generics have seen recent spikes, particularly if single-source. Even common drugs such as tetracycline, IV saline solutions and products like surgical cement have increased in price. Drug shortages often lead to price hikes, particularly if they must be purchased “off-contract” or in the gray market. In terms of settings, patients in the emergency department, observation and outpatient hospital department have been most affected and face significant costs even when insured. Inpatients are less affected due to more generous insurance coverage policies.

The policy development and governance groups discussed many different options for how to hold drug manufacturers accountable for their pricing decisions. Among them, the most commonly supported were bringing media and policymaker attention to the issue, requiring greater transparency on drug pricing and charity policies by drug companies, continuing and expanding the 340b drug discount program and allowing Medicare to negotiate prices. Members want the AHA to address this issue, but recognize that it is hard to overcome the influence of the pharmaceutical industry.

Participants urged the AHA to work with other organizations, such as the AARP, American Heart Association, American Cancer Society, to collect case examples and highlight the need for more rational pricing. Other ideas included limiting the length of patents, particularly if a drug company receives federal funding for research; limiting direct-to-consumer advertising; promoting comparative research; and ensuring adequate oversight of research by drug companies. Some members suggested that drug shortages be examined more closely to understand their causes and make sure that they are not manufactured to create price spikes. In addition, hospitals need to educate physicians on how to counsel patients on treatment alternatives, including cost and value in the discussion

Evaluations

The fall round of meetings was well received. Participants gave the meetings high ratings across all key meeting measures. On a five-point scale, the meetings received an overall rating of 4.84. Participants found the meeting to be a good opportunity to interact and discuss views with their peers (4.88), a good use of their time (4.86) and the issues on the agenda timely and important (4.85).

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

Eileen O’Keefe
Acting Senior Executive
Member Relations

BOARD OF TRUSTEES RETREAT MEETING

January 29 – 31, 2016
LaPlaya Beach & Golf Resort
Vanderbilt Room
Naples, Florida

DESTINATION CHECK

Retreat Objectives:

To discuss the state of the hospital field, identify innovations (sometimes referred to as “disruptors”) and reach an updated understanding of how we apply the Association’s vision and mission to ensure that every hospital and health system is given the opportunity to play a leadership role in serving their community.

Day One: Friday, January 29, 2016

Convening at 1:00 p.m. EST

1. **Call to Order and Welcome** — Mr. Skogsbergh (1:00-1:10)
2. **Reflections** — Ms. McNally (1:10-1:15)
3. **Retreat Objectives/Working Vision** — Mr. Pollack (1:15-2:10)
Mr. Pollack will discuss retreat objectives and the AHA’s working vision.
Resource Materials under Tab 3:
 - [Your Hospital’s Path to the Second Curve PowerPoint](#)
 - [Your Hospital’s Path to the Second Curve Executive Summary](#)
 - [Ensuring a Healthier Tomorrow](#)
 - [Your Hospital’s Path to the Second Curve \(link to full report\)](#)

Break (2:10-2:25)

4. **Plenary Session I: State of Key Disruptors**
Objective: *To learn more about the perspectives and opportunities that have shaped so-called disruptors in health care delivery and their implications for the state of the union. Innovators in physician practice, health insurance and consumer-focused care will present.*

- A. **Overview** — Mr. Skogsbergh (2:25-2:30)
- B. **Presenter Panel**
 - [Michael D. Snow](#), TeamHealth (2:30-3:15)
 - [Mario Schlosser](#), Oscar (3:15-4:00)
 - [Rod Hochman, MD](#) and [Aaron Martin](#), Providence Health Services (4:00-4:45)
[Resource materials](#) are under Tab 4, **Plenary Session I**.
- C. **Panel Discussion** — Mr. Skogsbergh (4:45-5:15)
- D. **Wrap Up** — Dr. Joshi (5:15-5:30)

Recess

Day Two, January 30, 2016

Convening at 8:00 a.m. EST

- 5. **Plenary Session II: State of the Hospital Field and Destination Check**

Objective: *To reach a fuller understanding of the consumer and public perception of hospitals as well as the state of hospital quality and finances and to reach consensus on significant areas of vulnerabilities for the field. With this information, to complete a destination check on the Association vision for the future and determine what refinements are needed and what tools the field will need to move forward.*

 - A. **State of Consumer/Public Perception of Hospitals (8:00-8:45)**
[Ryan Donohue](#), Corporate Director of Program Development, National Research Corporation
 - B. **[State of Hospital Quality](#)** — Dr. Joshi (8:45-9:05)
 - C. **[State of Hospital Finances](#)** — Ms. A. Thompson (9:05-9:25)

BREAK (9:25-9:40)

6 Plenary Session II (cont.): Destination Check

- A. **[Vulnerabilities of the Field](#) (9:40-10:40)**
 - **Overview/Bubble Chart** — Mr. Nickels, Ms. A. Thompson, Dr. Joshi, Ms. Mitchell



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- Voting Exercise

B. Breakout Session (10:40-12:00)

- Breakout Group Assignments and Instructions — Dr. Joshi (10:40-10:45)
- Travel to Breakouts (10:45-10:55)
BREAK AND MOVE TO BREAKOUT GROUPS
(BREAKOUT 1 –BAYVIEW B; BREAKOUT 2 – BAYVIEW C, BREAKOUT 3–BAYVIEW D)
- **Breakout Group Discussion Questions**
 - 1) Destination Check: Are we on track or off track?
 - A) How would you redraw this picture?
 - 2) What do members most need to get to the destination?

RECESS: NOON

Day Three, January 31, 2016

Convening at 8:00 a.m. EST

7 Destination Check/Vision/Bubble Chart — Dr. Joshi (8:00-9:00)

A. Breakout Group Conclusions

B. Voting Exercise

BUSINESS MEETING

8 2016 Advocacy Agenda—Mr. Nickels (9:00-9:30)

9 Next Generation of Trustee Engagement in AHA — Dr. Joshi and Dr. Combes (9:30-9:50)

10 Executive Committee Actions and Consent Calendar – Mr. Skogsbergh (9:50-9:55)

11 Audit and Financials — Mr. Evans (9:55-10:00)

12 Meeting Wrap Up—Mr. Pollack (10:00-10:10)

13 Informational Items

Informational items are under Tab 13, Informational Items

A. 2015 Fourth Quarter Strategic Plan Dashboard

B. Executive Committee Agenda



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C. Membership Report

BREAK (10:10-10:15)

14 Executive Session (10:15-11:00)

- A. Part I — Awards — Ms. Lovinger Goldblatt
- B. Part II — Compensation Committee Discussion — Mr. Skogsbergh
- C. Part III — Open Discussion (with and without President)

15 Adjournment (11:00)

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The AHA Vision is of a society of healthy communities, where all individuals reach their highest potential for health. The AHA Mission is to advance the health of individuals and communities. AHA leads, represents, and serves hospitals, health systems and other related organizations that are accountable to the community and committed to health improvement.

Federal Update and Discussion



Hospitals are transforming the way health care is delivered in their communities; working with other providers and community leaders to build a continuum of care to make sure every individual gets the right care at the right time in the right setting. In order to continue this transformation, and to provide patients with the access to care they need and expect, hospitals need a supportive and modernized public policy environment. In 2016, the American Hospital Association (AHA) will work with Congress, the administration, the courts, other agencies and our member organizations to:

1. Support health system transformation;
2. Protect patient access to care;
3. Sustain gains in health coverage;
4. Enhance quality and patient safety; and
5. Promote regulatory relief.

1. SUPPORT HEALTH SYSTEM TRANSFORMATION

- **Medicare physician payment.** The Medicare Access and CHIP Reauthorization Act of 2015 created a new physician payment and performance measurement system that includes incentives for participation in advanced payment models that lead to more integrated, better coordinated care. While the models may improve care, if properly designed, they also could lead to overly complex and burdensome rules. ***AHA continues to lobby the Centers for Medicare & Medicaid Services (CMS) on the new physician payment models and will gather additional input from hospital clinical leaders to help shape CMS's implementation of the new law. AHA also will educate members on the new payment system as implementation moves forward.***
- **Telehealth.** Recent years have seen significant growth in use of telehealth, to the point where more than half of U.S. hospitals connect with patients and consulting practitioners through the use of video and other technology. However, coverage, payment and other policy issues prevent full use of telehealth, remote patient monitoring and similar technologies. Medicare policy is particularly challenging, as it limits the geographic and practice settings where beneficiaries may receive services, as well as the types of services that may be provided via telehealth and the types of technology that may be used. Access to broadband services and state-level policy issues, such as licensure, also limit the ability to use broadband. ***AHA will urge Congress to expand Medicare coverage and payment for telehealth and provide resources for additional study of the cost-benefit of telehealth. AHA also will work with the administration to include telehealth waivers in all new care models and adopt a more flexible approach to adding new telehealth services to Medicare. AHA will continue to work with the allied associations to address state-level issues, including licensure and reimbursement for telehealth services.***
- **Sharing health information (interoperability).** Hospitals have collectively invested hundreds of billions of dollars implementing electronic health records (EHRs) and other health information technology (IT) tools that do not easily share data to support care, engage patients or provide the data and analytics to support new models of care. Failing to resolve the interoperability challenges

will lead to excess spending on inefficient work-arounds, inadequate data to support new models of care and continued accusations of “information blocking.” ***AHA will advocate for more consistent use of standards, better testing of health IT and more transparency about vendor products, while educating policymakers on how hospitals share information. AHA also will work with a range of public and private sector partners to identify the best approach to determine national priorities for advancing interoperability and mechanisms for accountability.***

- **Protecting health information (cybersecurity).** The Cybersecurity Information Security Act of 2015 established mechanisms and liability protections for sharing threat information among and between the public and private sectors. It also requires the Health and Human Services (HHS) secretary to report on and create a task force to improve cybersecurity in the health care field. These are welcome developments, as the health care field is experiencing escalating attacks on its information systems by bad actors seeking access to private information. ***AHA will continue to work with federal partners to identify and disseminate best practices for protecting critical infrastructure from cyberattack and increasing information sharing. AHA also will educate health care leaders on the importance of cybersecurity.***
- **Behavioral health.** AHA is concerned about persistent gaps in the availability of behavioral health care providers in many communities; the urgent need to address opioid addiction and its repercussions; and the need to truly establish parity in payment for mental health care. ***AHA will lobby to remove barriers to access to behavioral health services; promote and support field leadership to better integrated behavioral and physical health; and work to create greater public awareness and reduce stigma.***
- **Access to care in vulnerable communities.** The AHA Board of Trustees has commissioned a task force to confirm the characteristics of vulnerable communities and identify strategies and federal policies to help ensure access to care in these areas. The 30-member task force consists of two subcommittees that are examining the issue from the rural and urban perspective. ***AHA will work with the task force to identify appropriate policies to ensure access to care in vulnerable communities and advocate for those changes with Congress and the administration.***
- **CJR.** CMS recently finalized a new payment model that bundles payment to acute care hospitals for hip and knee replacement surgery – the Comprehensive Care for Joint Replacement (CJR) model. Under this model, the hospital in which the joint replacement takes place will be held financially accountable for quality and costs for the entire episode of care, from the date of surgery through 90 days post-discharge. The model will be implemented in 67 geographic areas across the country and mandatory for most hospitals in those areas. The final rule contains many AHA-recommended improvements to help hospitals achieve success, such as a delay in the start of the program and waivers of relevant fraud and abuse laws. CJR is the first mandatory model, but CMS continues voluntary models such as accountable care organizations (ACOs) and other bundling initiatives. ***AHA is actively monitoring the CJR and ACO models and continuously provides input to CMS on how to improve the success of its new delivery model demonstrations.***

2. PROTECT PATIENT ACCESS TO CARE

- **Site-neutral payments.** The recent budget agreement equalizes payment rates between new, off-campus provider-based hospital outpatient departments (HOPDs) and physician offices, despite evidence that these settings have different patient populations, regulatory requirements and

cost structures. Some, including the Medicare Payment Advisory Commission (MedPAC), have advocated for even greater use of such “site-neutral” payments. These proposals neglect the real difference between the care provided in each setting and the patients treated. ***AHA will continue to urge Congress to protect HOPDs under development and reject calls for any additional site-neutral payment policies. We also will urge CMS to implement the existing cut in the most favorable and flexible manner possible.***

- **340B Drug Pricing Program.** For more than 20 years, the 340B program has provided help to safety-net hospitals by allowing them to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services. However, some want to scale it back or significantly reduce the benefits of the program. Last August, the Health Resources and Services Administration (HRSA) proposed guidance that would reduce the volume of drugs eligible for 340B pricing. MedPAC also has put forth a draft recommendation that would cut Medicare payments to 340B hospitals. ***AHA will continue to urge Congress and MedPAC to oppose cuts to the 340B program and work with HRSA to protect patient access as it revises the rules for this program.***
- **Medical education and training.** Some are advocating for significant changes and reductions in Medicare Graduate Medical Education (GME) payments to teaching hospitals. In addition, Republican leaders of the House Committee on Ways and Means introduced legislation that would reimburse indirect medical education costs through lump-sum payments rather than for each discharge beginning with cost-reporting periods ending during or after fiscal year (FY) 2019. Furthermore, the Balanced Budget Act of 1997 imposed caps on the number of residents for which each teaching hospital is eligible to receive Medicare direct GME and indirect medical education reimbursement. These caps have remained in place and have generally been adjusted only as a result of certain limited and one-time adjustments. ***AHA will urge Congress to reject reductions in Medicare funding for indirect medical education and direct GME and pass the Resident Physician Shortage Reduction Act (S. 1148, H.R. 2124), which would increase the number of Medicare-funded residency positions.***
- **Physician-owned specialty hospitals.** Some members of Congress propose weakening significantly Medicare’s prohibition on physician self-referral to new physician-owned hospitals and loosening restrictions on the growth of grandfathered hospitals. The so-called Expanding Patient Access to Higher Quality Care Act (H.R. 976) and PACE Act (H.R. 2513) would allow many more physician-owned hospitals to open and permit unfettered growth in existing physician-owned hospitals. ***AHA will urge Congress to maintain current law; preserve the ban on physician self-referral to new physician-owned hospitals; and retain or increase restrictions on the growth of existing physician-owned hospitals.***
- **Drug prices.** Recent data show that prescription drug costs are rising rapidly – with the annual rate of increase in national spending on drugs accelerating from 2.5 percent in 2013 to 12.6 percent in 2014. Costs of specific drugs have increased even more dramatically. Even some common generic drugs have experienced dramatic price increases in recent years, leading to significant financial challenges for patients and their providers. ***AHA is evaluating options for addressing the escalation in drug prices, such as bringing media and policymaker attention to the issue, requiring greater transparency on drug pricing and charity policies by drug companies, continuing and expanding the 340B program, allowing Medicare to negotiate prices and engaging the presidential candidates on the issue in the 2016 campaign.***

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- **Tax-exempt status.** According to the Internal Revenue Service, hospitals provided \$62.4 billion in community benefit—or 9.67 percent of expenses – in 2011. A report from E&Y for the AHA found that hospitals spent an average 12.3% of total expenses on community benefits in tax year 2012. A study recently reported in *Health Affairs* estimates that the value of tax exemption (federal, state and local) in 2011 was \$24.6 billion. Nevertheless, some policymakers at the federal, state and local levels have begun to question whether community benefits provided by non-profit hospitals are commensurate with the tax benefits of tax-exempt status. ***AHA will continue to collect information from members, including Schedule Hs, to help make the case to policymakers that hospitals provide robust community benefits that more than justify their tax exemption. And we will work with state hospital associations to combat efforts to limit tax benefits available to non-profit hospitals.***

 - **CAH payment policies.** Some policymakers are calling for dramatic changes to the critical access hospital (CAH) program, including the elimination of CAH designation based on mileage between CAHs and other hospitals, and removal of CAH “necessary provider” exemptions from the distance requirement. In addition, CMS has indicated it will enforce a 96-hour condition of payment going forward. ***AHA will urge Congress to reject misguided proposals to change the CAH program. In addition, AHA will urge Congress to pass the Critical Access Hospital Relief Act (S. 258, H.R. 169), which would remove the 96-hour piece of the physician certification requirement as a condition of payment.***

 - **Medicaid provider assessments.** The Medicaid provider assessment program has allowed state governments to expand coverage, fill budget gaps and maintain patient access to health services to avoid additional provider payment cuts by helping states finance their portion of the joint federal/state program. Some have called for limiting states’ ability to use assessments as a financing tool. ***AHA will urge Congress to reject options that limit states’ ability to partially fund their Medicaid programs using provider assessments.***

 - **Payments for inpatient rehabilitation facilities (IRFs) and long-term care hospitals (LTCHs).** In recent years, IRFs have undergone multiple policy changes, including strict criteria for patients, multiple payment cuts and other policy restrictions. Collectively, these interventions have dramatically reduced the overall volume and steadily increased the medical complexity of IRF patients. Recent proposals to further reduce payments for IRF services, including through implementation of site-neutral payment policies, ignore these fundamental shifts and are unnecessary and detrimental to patients’ access to care provided by IRFs. Additionally, two years ago, Congress passed legislation implementing several reforms to more clearly distinguish the LTCH role. These include a new, two-tiered payment system that began in October, under which LTCHs will be paid an LTCH-level rate for patients with higher severity of illness levels, and a lower, “site-neutral” rate (comparable to general acute care hospitals) for patients with lower medical acuity. LTCHs serve a critical role by treating the sickest patients who need long hospital stays. In addition to these changes, post-acute care providers participating in alternative payment models still face many Medicare fee-for-service regulations that hamper innovation. ***AHA will urge Congress to reject further payment cuts to IRFs and LTCHs and help provide additional regulatory relief to those participating in episode-based demonstrations.***

 - **Medicare bad debt and DSH.** In recent years, Congress has reduced payments that recognize and partially offset the costs of treating low-income, uninsured and underinsured individuals, including Medicare bad debt and Medicare and Medicaid disproportionate share hospital (DSH) payments. MedPAC and others have suggested reducing these payments further. However, the full promise of increased coverage under the Affordable Care Act (ACA) has been limited by some states declining to expand Medicaid and uncertainties in the new insurance marketplaces. ***AHA will urge Congress to refrain from further cuts to Medicare bad debt and Medicare and Medicaid DSH.***

■ **Medicare rural payment extensions.** Medicare rules include a number of important payment policies that ensure financial stability for hospitals that primarily treat Medicare patients, account for low patient volumes, and address the high costs of providing ambulance services in rural areas. Without legislative action, these programs will expire in 2017:

- Medicare-dependent hospitals (MDH);
- Enhanced low-volume adjustment; and
- Add-on payments for ambulance services in rural areas.

In addition, the Rural Community Hospital (RCH) demonstration enables 23 small rural hospitals nationwide with fewer than 51 acute-care beds to test the feasibility of cost-based reimbursement. By extending the demonstration for an additional five years, participating hospitals can continue to seek opportunities to expand and improve access to care in their communities. Finally, small, rural hospitals need continued relief from onerous supervision requirements.

AHA will urge Congress to make these important programs permanent and extend regulatory relief by passing the:

- ***Rural Hospital Access Act (S. 332, H.R. 663), which would make the MDH program and low-volume adjustment programs permanent.***
- ***Medicare Ambulance Access, Fraud Prevention, and Reform Act (S. 377, H.R. 745), which would make the ambulance add-on payments permanent.***
- ***Rural Community Hospital Demonstration Extension Act (S. 607, H.R. 672), which would extend the RCH demonstration for five years.***
- ***Protecting Access to Rural Therapy Services Act (S.257, H.R. 1611), which would protect access to outpatient therapeutic services.***

3. SUSTAIN GAINS IN HEALTH COVERAGE

■ **Health plan consolidation.** The proposed acquisitions involving four of the five major U.S. health insurance companies (Anthem's proposed acquisition of Cigna and Aetna's proposed acquisition of Humana) are under review by the U.S. Department of Justice (DOJ), Congress and many state Departments of Insurance and Attorneys General. If approved, the increased market power of the merged companies would have harmful and far-reaching repercussions on both consumers and providers, including increased premiums for consumers; limited choice and reduced access to providers; and payments for hospitals and other providers that undermine innovation and access. ***AHA will continue to provide input to federal officials about the negative impacts that would result from these acquisitions. AHA also will support state hospital associations in impacted states with resources and technical assistance to assist with their communication with state officials.***

■ **Medicaid expansion and waivers.** The ACA led to significant increases in coverage in many parts of the country. However, the promise of coverage expansion has not been fully realized due to uncertainties in new insurance markets and the choice of some states not to expand Medicaid. States also are working with the administration to obtain waivers that allow coverage expansion and support new models of care. ***AHA will provide support and resources for state hospital associations as they examine options for maintaining and expanding coverage and negotiating Medicaid waivers with federal officials.***

■ **Insurance regulations.** The rules governing new insurance markets and Medicaid waivers must be fair to consumers and providers. ***AHA will monitor new insurance rules and advocate for fair treatment of consumers and providers, such as ensuring adequate benefits and access to provider networks.***

4. ENHANCE QUALITY AND PATIENT SAFETY

- **Quality measurement.** Hospitals, their clinicians and the post-acute care organizations with which they work are asked to provide data on a dizzying array of quality measures. While the field is committed to quality improvement and transparency, complying with these data requests is burdensome for providers, while consumers can be confused by the volume of information. Data collection and reporting activities would be more valuable if federal agencies and others asking for data agreed on a manageable list of high-priority aspects of care on which providers would be asked to make meaningful improvement, and then to use a small and critically important set of measures to track and report on progress toward improving the care delivered and the outcomes for patients. ***AHA will work with the administration to prioritize and simplify quality reporting and improve the transition to required reporting of electronic measures. The Institute of Medicine (now National Academy of Medicine) has proposed a list of high-priority topics from which this work would begin.***
- **Accreditation standards and Medicare Conditions of Participation.** Well-crafted quality standards and accreditation surveys help health care delivery systems ensure they are delivering safe, effective care. The existing standards and survey processes are constantly in need of updating to keep pace with changes in the science of care. Additionally, the standards used by Medicare and accrediting bodies were developed with a siloed approach to care delivery in mind that is no longer aligned with practice in the field. ***AHA will work with the administration and accreditation bodies to modify standards so that they support integrated and coordinated care.***
- **Health disparities.** Research has shown that individuals of color, of various ethnic backgrounds and with limited English proficiency have less access to care, get different care, and often have worse health than those who are white. There are many causes of the differences in health for individuals, but AHA's goal is to eliminate disparities in health by eliminating differences in access to care and differences in care delivery, and to promote better health in every community. ***AHA will continue to support the field in efforts to reduce health care disparities, including through the #123forEquity campaign to eliminate disparities.***
- **Patient safety.** Hospitals and other health care organizations recognize their responsibility to ensure patients are not harmed during the course of their care. The AHA and its member organizations have achieved important and meaningful improvements through rigorous adoption of evidence-based processes that have been shown to prevent errors in care. But more must be done. Further, the adoption of new technologies, procedures and drugs can advance outcomes for patients, but also may result in additional challenges. ***AHA will advocate continuously for the development of knowledge and adoption of practices to make care safer.***
- **Adjusting outcome measures to account for socioeconomic factors.** A body of research demonstrates that readmissions are higher in communities that are economically disadvantaged. It is likely that other outcome measures, such as 30-day mortality rates and measures of efficiency, are similarly affected. MedPAC has recommended changes to the Hospital Readmissions Reduction Program to alter the calculation of the payment penalties to recognize that sociodemographic factors affect the likelihood that a patient will be readmitted. ***AHA will urge Congress to pass the Establishing Beneficiary Equity in the Hospital Readmission Program Act (S. 688, H.R. 1343), which would address the need for a sociodemographic adjustment. AHA also will evaluate the need to similarly adjust other outcome measures. AHA will press the administration to appropriately adjust outcome measures for sociodemographic factors.***

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- **Quality measurement for new payment systems.** As CMS and other entities develop and experiment with new payment strategies that link quality performance or value to payment, it is increasingly important that a common set of scientifically valid measures are used to assess the quality and safety of the providers involved in care and their impact on patient outcomes. ***AHA will continue to work with CMS, other payers, the National Academy of Medicine, the National Quality Forum and the Measure Applications Partnership to identify meaningful and valid measures for use in payment programs, and will collaborate with other organizations to assess whether the measures are contributing toward intended improvements and/or having unintended consequences.***

5. PROMOTE REGULATORY RELIEF

- **Recovery audit contractors (RACs).** In 2015, CMS announced several changes that will help reduce the significant burden hospitals bear as a result of RAC audits. For example, Quality Improvement Organizations, rather than RACs, will bear primary responsibility for auditing the appropriateness of inpatient admissions under the two-midnight inpatient admissions criteria. In addition, hospitals with a low error rate may see a reduction in audits. Despite these incremental improvements, more reform is needed to address the contingency fee payment structure that continues to reward RACs for inappropriate denials. ***AHA will urge Congress to pass the Medicare Audit Improvement Act (H.R. 2156), which would, among other measures, eliminate the RAC contingency fee structure and instead direct CMS to pay RACs a flat fee, as every other Medicare contractor is paid, and rationalize payments to RACs by lowering payments for poor RAC performance due to high rates of incorrect denials.***
- **Two-Midnight 0.2% withhold.** As part of the two-midnight policy, CMS unlawfully imposed a permanent 0.2 percent reduction to the operating prospective payment system (PPS) standardized amount to offset what the agency claimed would be an increase of \$220 million in inpatient PPS expenditures as a result of the two-midnight policy. While CMS has made changes to the two-midnight policy, which took effect Jan. 1, to allow certain hospital inpatient services that do not cross two midnights to be appropriate for payment under Medicare Part A, it did not rescind the payment cut. Thus, AHA's lawsuit challenging the payment reduction continues. A federal judge has ruled in favor of AHA, finding that CMS failed to meet the legal requirements for rulemaking when implementing this payment cut. CMS was provided the opportunity to further explain its rationale within a specified period of time. ***AHA will evaluate the 0.2 percent rule the court required CMS to promulgate in the first quarter of 2016. If the cut is not restored prospectively and retrospectively, AHA will continue to press the courts for full payment.***
- **EHR Incentive Program.** America's hospitals are strongly committed to the adoption of EHRs and the transition to an EHR-enabled health system is well underway. CMS recently finalized rules making some needed changes to the program to increase flexibility in the short term. Unfortunately, at the same time it also finalized rules raising the bar on meaningful use requirements yet again with Stage 3 requirements that are required in 2018. These rules contain provisions that are challenging, if not impossible, to meet and require use of immature technology standards. ***AHA will urge CMS to modify the Stage 3 rules to be more flexible and feasible. CMS also should delay implementation to no sooner than 2019. AHA will urge Congress to monitor CMS action and step in, where appropriate.***

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- **Hospital realignment.** Hospitals are reshaping the health care landscape by striving to become even more integrated, aligned, efficient and accessible to the community. To support these changes, it is important to standardize the merger review process between the two federal antitrust agencies. The Federal Trade Commission (FTC) has frequently used its own internal administrative process to challenge a hospital transaction, an option not available to Department of Justice, which increases the time and expense of defending a transaction and the likelihood of an outcome that favors the agency. ***AHA will urge Congress to pass the Standard Merger and Acquisition Reviews Through Equal Rules (SMARTER) Act (H.R. 2745), which would help rebalance the merger review process.***

 - **ICD-10.** The new ICD-10 coding system was implemented on Oct. 1, 2015. CMS will likely analyze claims data with the new codes for possible recalibration and refinement of payments and may propose payment cuts to offset increases CMS deems to be the result of the move to a new coding system. ***AHA will monitor CMS rules to ensure proper handling of the transition to new ICD-10 codes. AHA also will continue to educate and inform members about the importance of proper documentation and ICD-10 code assignment.***

 - **Administrative simplification.** By law, health care providers, health plans and clearinghouses use specific transaction standards in the course of billing and paying for health care services (HIPAA transactions). HHS will likely introduce new versions of these standards in 2016. ***AHA will safeguard against excessive burden in reporting requirements and will continue to inform members about changes in HIPAA standards and help them prepare for a successful transition.***

Hospital and Health System Challenges



**American Hospital
Association**

DATE: March 2016
TO: Regional Policy Boards
SUBJECT: Hospital and Health System Challenges

Objective

To identify and prioritize the key challenges facing hospitals and health systems.

Background

The hospital and health system field is undergoing unprecedented change. AHA members are becoming more integrated with physicians and other providers of care, more accountable to their communities, and more at risk financially for the services they deliver. The changing policy, technology, consumer and health care landscapes are presenting the hospital and health system field with new challenges.

As a means of identifying specific challenges – and perhaps opportunities – to be addressed in the coming years, the AHA Board of Trustees considered the attached “bubble chart” and explanatory document during its January retreat. The chart identifies top issues relative to the magnitude of their financial impact, the probability that they will occur and the estimated share of members they will affect.

For example, large bubbles in the top right quadrant (such as public payer funding) represent issues that have a high probability of happening, could have a major financial impact, and would affect most members. However, regardless of the size of the bubble or its location on the chart, every issue identified requires ongoing attention. We are looking for your feedback to ensure that the appropriate hospital and health system challenges are identified and prioritized for action. This agenda item will be discussed in break-out groups.

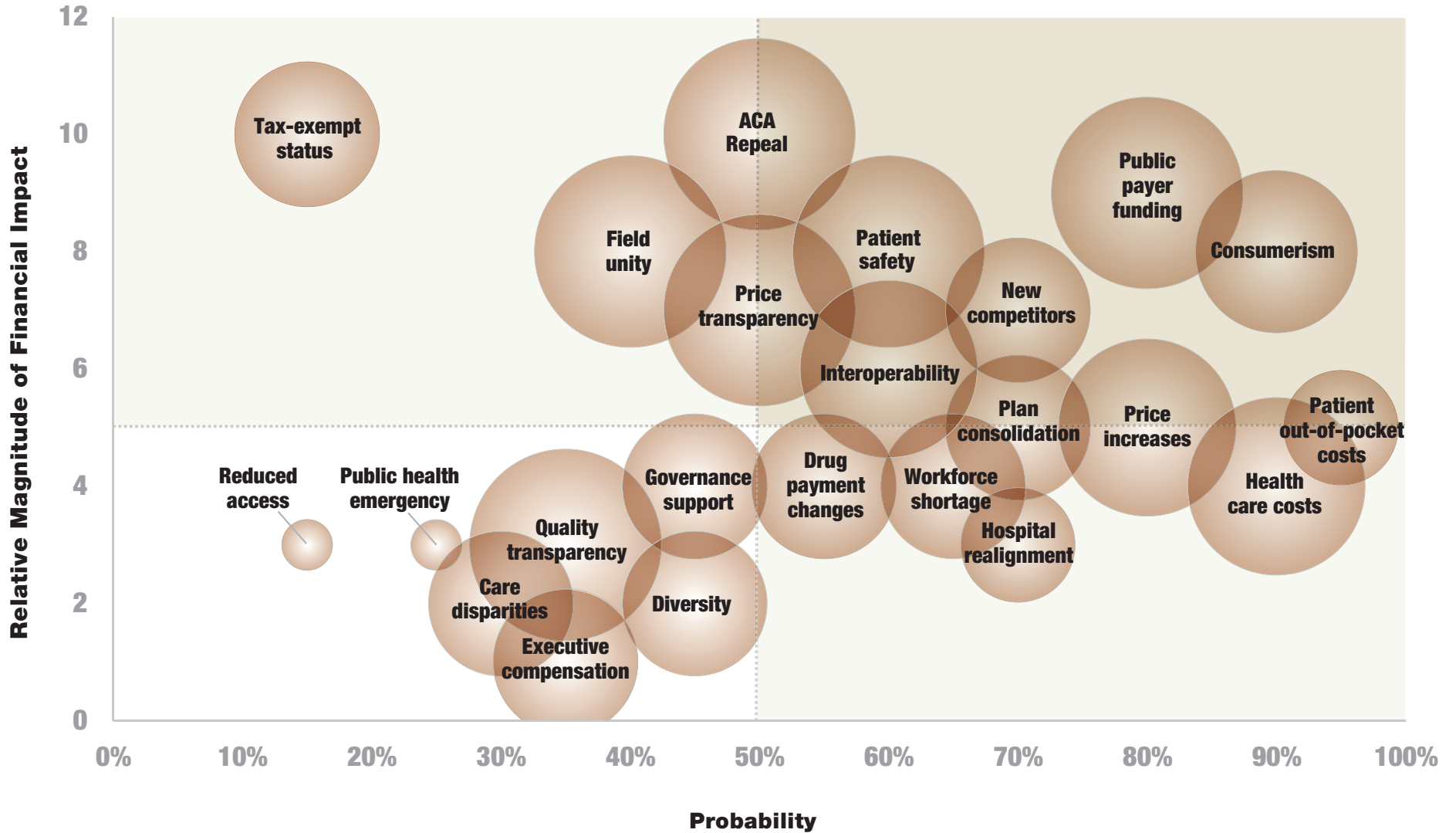
Discussion Questions

Please review the chart and explanatory document and come to the meeting prepared to discuss the following:

1. What do you see as the key challenges for the hospital and health system field?
2. Are there any challenges that you would modify, take off or add to the chart?

Attachments: “Bubble chart”
Explanatory document

Hospital and Health System Challenges



*Relative size of bubble indicates estimate share of hospitals and health systems affected.

Hospital and Health System Field Challenges

Hospitals and health systems face the following major policy, market, and system challenges in the coming years. Links to the AHA Advocacy Agenda are noted after the descriptions (the AHA Advocacy Agenda can be found in the Washington Update tab).

ACA Repeal. If significant policies under the Affordable Care Act are repealed (Medicaid expansion, subsidies for premiums, insurance reforms, etc.), many individuals could lose health care coverage, leading to worse health outcomes and greater financial liabilities for individuals and increased bad debt for hospitals and other health care providers. (*Advocacy Agenda: Sustain Gains in Health Coverage*)

Care disparities. Research has documented differences in care across subsectors of the population, such as socioeconomic variables, race, and ethnicity. Failure to improve care for diverse populations timely risks imposition of punitive policies. (*Advocacy Agenda: Enhance Quality and Patient Safety*)

Consumerism. People increasingly expect the health care sector to adapt the consumer-friendly attributes of other sectors of the economy, such as greater convenience, the ability to comparison shop, and widespread use of mobile and other technologies to arrange, access, and pay for services. Hospitals and health systems are challenged to meet these expectations given existing investments in physical infrastructure and sophisticated clinical technology (*Advocacy Agenda: Support Health System Transformation*)

Diversity. Hospitals and health systems are on a journey to establish services, leadership and governance structures that are responsive to, and reflective of, the needs of their diverse communities. Failure to meet expectations in this area timely risks eroding public support for health care institutions. (*Advocacy Agenda: Enhance Quality and Patient Safety*)

Drug payment changes. Congress, MedPAC, and the Administration are seeking to reduce payments for drugs through the 340b program and Medicare Part B. (*Advocacy Agenda: Protect Patient Access to Care*)

Executive compensation. Some policymakers and the media continue to raise questions about the level of executive compensation in the hospital and health system field.

Field Unity. Given the diverse circumstances and services provided by America's hospitals and health systems, it can be challenging to maintain field unity on key advocacy issues. However, the strength of the AHA depends on finding policy solutions for difficult, and potentially divisive topics like the area wage index.

Governance Support. In addition to executive leadership, hospitals and health systems will need significant support from their governance bodies to successfully navigate health system transformation and minimize the impact of various challenges. Trustee education will be

essential to ensure that key decisions are well informed and position hospitals and health systems for success.

Health care costs. As health spending grows as a share of the total economy and individual financial responsibility grows, individuals and policymakers are paying more attention to health care costs, including issues such as “surprise bills.” Hospitals and health systems are challenged to reduce health care costs while facing price increases, workforce shortages, and regulatory compliance burdens. (*Advocacy Agenda: Support Health System Transformation*)

Hospital consolidation. Hospitals are responding to the consumer and payer – public and some private – pressures to become more integrated, efficient, and convenient at a lower cost by merging, employing physicians and developing new products and capabilities. Federal and state antitrust officials are impeding these efforts by clinging to outdated regulatory restrictions on integration and/or challenging the mergers employing procedural advantages that deny hospitals the ability to have the benefits of integration judged impartially. (*Advocacy Agenda: Promote Regulatory Relief*)

Interoperability. Hospitals have collectively invested hundreds of billions of dollars implementing electronic health records and other health IT tools that do not easily share data to support care, engage patients, or provide the data and analytics to support new models of care. Failing to resolve the interoperability challenges will lead to excess spending on inefficient work-arounds, inadequate data to support new models of care, and continued accusations of “information blocking.” (*Advocacy Agenda: Support Health System Transformation*)

New competitors. The health care field increasingly faces new competitors, such as retail providers, single-service providers such as imaging centers, and technology-enabled competitors, such as on-line doctor visits and technology-enabled house calls. Hospitals and health systems are challenged to both harness innovations and maintain a full set of services in the face of new competitors. (*Advocacy Agenda: Support Health System Transformation*)

Patient out-of-pocket costs. While the number of insured individuals is increasing, the scope of coverage has declined on average, leaving consumers paying more out of pocket for their health care. Growing cost-sharing requirements can discourage patients from receiving needed preventive care, leading to negative health outcomes. This trend also can create significant financial burdens for individuals, negatively impacting their lives and possibly leading to increased bad debt for the health care field. (*Advocacy Agenda: Sustain Gains in Health Coverage*)

Patient safety. Hospitals have made significant progress in improving many patient safety indicators in the recent past. However, policymakers and the media continue to shine a spotlight on safety indicators, creating significant pressure to continue making progress. Hospitals and health systems face financial penalties and negative media attention if sufficient progress is not made. (*Advocacy Agenda: Enhance Quality and Patient Safety*)

Plan Consolidation. The proposed health plan acquisitions under consideration by the Department of Justice for antitrust considerations (Anthem’s proposed Acquisition of Cigna and Aetna’s proposed Acquisition of Humana) would, if approved, increase the market power of the merged companies. That, in turn, could lead to create increased premiums for consumers and lower payments for hospitals and other providers. (*Advocacy Agenda: Sustain Gains in Health Coverage*)

Price increases. Hospitals and health systems face significant price increases for the professionals and supplies used in caring for patients. Notably, drug prices have increased significantly in recent years, as have the costs of technology. (*Advocacy Agenda: Protect Patient Access to Care*)

Price transparency. Policymakers, media, and entrepreneurs continue to call for and create greater transparency into the cost of health care. Report cards and online tools foster greater ability to compare prices at hospitals and health systems with each other and other entities, such as retail health care providers. Hospitals and health systems are caught between complex charge masters that are the result of historical health plan negotiations and the demand for greater transparency fueled by growing consumerism in health care.

Public health emergency. Recent years have seen significant public health emergencies, such as Ebola, natural disasters, terrorist attacks, and active shooters. A widespread cyber attack targeting critical infrastructure could also lead to a public health emergency. Hospitals and health systems face significant costs to respond to public health emergencies, and face criticism if they are believed to be inadequately prepared to respond.

Public payer funding. For budgetary reasons, Congress and CMS are considering many different payment cuts that could impact hospitals and other health care providers. Key among them are reductions associated with site-neutral payment policies (ambulatory services, post-acute care), cuts related to reporting programs (hospital-acquired conditions, readmissions, meaningful use, etc.), reduced payments for DSH/bad debt, cuts to payment for teaching hospitals, and a possible coding offset due to the move to ICD-10. Furthermore, some in Congress would like to convert the Medicaid program into a block grant, while others in Congress and the Administration are interested in curtailing the use of provider taxes, and reducing DSH and supplemental payments. (*Advocacy Agenda: Protect Patient Access to Care*)

Quality transparency. Policymakers, media, and entrepreneurs continue to generate report cards and other quality measurement tools of varying quality. Hospitals and health systems must both respond to these efforts and manage the growing burden of reporting on a multitude of measures. (*Advocacy Agenda: Enhance Quality and Patient Safety*)

Reduced access. Changes in the availability and scope of services provided by hospitals and health systems in vulnerable communities (rural and inner-city) threaten to reduce access to care. (*Advocacy Agenda: Support Health System Transformation*)

Tax-exempt status. Some policymakers at the state and federal level have begun to question whether community benefits provided by non-profit hospitals are commensurate with the tax benefits of non-profit status. Losing tax-exempt status would threaten hospital and health systems' financial sustainability and limit their ability to provide community benefit. (*Advocacy Agenda: Protect Patient Access to Care*)

Workforce shortages. Hospitals and health systems are struggling to address shortages in primary care physicians, certain specialties, nursing, and allied professions, leading to significant added costs for temporary personnel and limits on services that can be provided. (*Advocacy Agenda: Protect Patient Access to Care*)

Entitlement Reform

DATE: March 2016

TO: Regional Policy Boards

SUBJECT: Getting Ready for 2017: Entitlement Reform

Objective

To obtain input on whether AHA's existing principles for a defined contribution Medicare program remain relevant today and consider issues transitioning to such a model might raise.

Background

In response to continued growth in Medicare spending, some policymakers favor moving Medicare from a defined benefit program to a defined contribution program. Under such a model, the federal government would provide Medicare beneficiaries with a set amount of money to purchase private health insurance coverage, similar to Medicare Advantage and the Medicare Part D prescription drug programs.

Given the outcome of the Presidential election, Congress may revisit a defined contribution Medicare program with rigorous debate. Proponents suggest that such a model would save federal dollars by restricting the growth in Medicare costs, provide more budget stability for the Medicare program, and encourage improvements in quality and health outcomes through competition among plans. Opponents raise concerns with potentially insufficient coverage of benefits, increased cost-sharing for beneficiaries, and limitations on access to providers. Versions of defined contribution models have been offered by the Bowles-Simpson and Rivlin-Domenici commissions (both in 2010) as well as by Speaker of the House, Paul Ryan (R-WI). Appendix A provides more details on what a defined contribution approach could entail.

In 2011 and 2012, the AHA's policy development bodies discussed what such a defined contribution approach might look like and how it might affect Medicare beneficiaries and providers. Participants considered, among other issues:

- Whether or not a minimum standard benefit package should be required;
- Whether or not the traditional fee-for-service (FFS) Medicare program should remain eligible to compete for beneficiaries or should be discontinued altogether;
- The level of subsidy and how it may vary by beneficiary characteristics, including income;
- The factors that would be used to calculate yearly changes in the subsidy amount;
- What consumer protections should be implemented, such as maximum annual cost-sharing caps;

- Whether or not non-benefit related costs should be included, such as graduate medical education and payments for bad debt, among others; and
- How beneficiaries in communities without private plan options should receive coverage.

Those discussions led to the following principles, to be used internally by the AHA staff in evaluating such proposals. Details on each principle and corresponding design features can be found in Appendix B.

Principles for a Medicare Defined Contribution Program

1. Protect the future availability of Medicare.
2. Ensure that effective dates protect current beneficiaries and those near the eligibility age at the time of enactment.
3. Guarantee a standard core benefit and catastrophic protection.
4. Simplify beneficiary selection of plans and avoid increasing administrative costs.
5. Maintain a future role for traditional Medicare and Medicare Advantage.
6. Protect beneficiary access to adequate coverage and high quality care.
7. Ensure that the basis for setting and updating the defined contribution is adequate.
8. Maintain beneficiary responsibility for income-related premiums.
9. Protect against risk selection by adjusting plan payments.
10. Ensure continued funding of public benefit activities.

Discussion

The U.S. healthcare system has changed significantly since the above policy principles were developed: tens of millions of additional Americans are insured; a higher percentage of consumers are choosing high-deductible health plans that give them more “skin in the game;” and the Health Insurance Marketplaces are now mechanisms for the purchase of private insurance.

Given these changes and our expectation that Congress will explore a defined contribution model in the near future, the AHA seeks to review these principles to identify what, if any, modifications should be made and what parameters we should put in place around operationalizing such a model.

Discussion Questions:

Please come prepared to discuss the following:

1. What modifications, if any, should be made to the above principles to better align with today's healthcare system?
2. What are the more important issues or elements to include in a premium support proposal?
3. Should AHA support the concept of premium support?

Attachments: FAQs on defined contribution

Principles for a Medicare defined contribution program

Appendix A: “Defined Contribution” Medicare Model: Frequently Asked Questions

What is a “defined contribution model?”

In defined contribution models, beneficiaries receive a set amount of money to put towards the purchase of benefits. In a Medicare context, the federal government would give Medicare beneficiaries a certain dollar amount to purchase private coverage. Beneficiaries would select among private plans, which could offer different benefits and cost sharing. This differs from today’s “defined benefit” Medicare program where the government ensures coverage of a set of services regardless of cost.

Is defined contribution the same thing as “premium support” or “vouchers?” The concept of “premium support” and Medicare “vouchers” is the same as defined contribution models. The amount of premium support or the value of the voucher would be the defined contribution amount. Often, these terms are used interchangeably although some defined contribution programs may not actually issue vouchers and therefore would not technically be “voucher” programs.

What are some examples of a “defined contribution” model?

In many ways, the existing Medicare Advantage and Part D programs are defined contribution models. The government covers up to a certain amount of the cost for a private plan, and beneficiaries can spend their own money to upgrade their coverage, such as through the purchase of a Medigap policy. Another common example is 401(k) retirement plans. Employers pay a defined amount into an employee’s 401(k) account. This is in contrast to the previous defined benefit model in which employers provided a set of benefits, such as a monthly pension payment and health insurance benefits.

What would a defined contribution model look like in the Medicare program?

A defined contribution model could be structured a number of different ways. Today, no specific proposals are on the table for consideration. In developing such a model, policymakers would need to consider a number of design features, including whether or not to require a minimum standard benefit package; whether to make the program voluntary or required (thus ending the traditional Medicare program); how much of a subsidy would be paid and how it would vary based on beneficiary characteristics, such as income; and how the government would update the subsidy amount each year, among other considerations.

What are some of the considerations when evaluating a defined contribution model?

Proponents suggest that such a model would save federal dollars by restricting the growth in Medicare costs, provide more budget stability for the Medicare program, and encourage improvements in quality and health outcomes through competition among plans. Opponents raise concerns with potentially insufficient coverage of benefits, increased cost-sharing for

beneficiaries as the cost of healthcare services outpaces the subsidy amount, and limitations on access to providers due to cost-saving measures.

Where can I learn more?

- [“Premium Support in Medicare, a Health Policy Brief,” Health Affairs, March 2012.](#)
- [Fuchs, B. and Potetz, L. “The Nuts and Bolts of Medicare Premium Support Proposals,” The Henry J. Kaiser Family Foundation, June 2011.](#)

Appendix B: Principles for a Medicare Defined Contribution Program

1. **Protect the future availability of Medicare.** The Medicare program must remain viable and available for the elderly and disabled populations.
2. **Ensure that effective dates protect current beneficiaries and those near the eligibility age at the time of enactment.** Any Medicare defined contribution program should be implemented prospectively only and with sufficient advance notice so that future eligible beneficiaries can prepare financially. Those individuals at or above a specific age (for example, 55) in the year of enactment should have a choice of shifting to the defined contribution program or staying with the traditional Medicare program.
3. **Guarantee a standard core benefit and catastrophic protection.** All Medicare beneficiaries must be guaranteed a standard set of core benefits, whether they remain under the traditional program or select a private plan. Standard core benefits initially should be equal to the existing Medicare benefits package. A catastrophic benefit should be added to the traditional Medicare program to protect beneficiaries from the costs of serious illness, and catastrophic coverage should be required of all current and future private plans participating in Medicare. Consideration also should be given to ways in which the benefit package and Medicare supplemental plans can be modernized to encourage healthy behaviors, promote advanced care planning, avoid unnecessary utilization, ensure parity for mental health services, and accommodate the need for post-acute care services for this population.
4. **Simplify beneficiary selection of plans and avoid increasing administrative costs.** The benefits, premiums, and cost sharing (but not the source of funding or the Trust Funds) for Medicare parts A, B, and D should be integrated to simplify beneficiary plan selection and reduce administrative costs. A federal Medicare Exchange should be maintained to provide one-stop shopping for Medicare beneficiaries for Medicare benefits, as well as supplemental insurance options (such as Medicare supplemental and long term care policies). This Medicare exchange should build on the current Medicare.gov web-based program to aid Medicare beneficiaries and their surrogates in comparing and selecting among private Medicare plans. It also should identify variations in delivery arrangements, such as medical homes, that help beneficiaries receive better coordinated care. Health plans offered through the Medicare exchange must provide reliable information to consumers in a clear and timely way. Plan-specific additional benefits and their cost must be distinguished from the standard core benefits and their costs to aid beneficiaries in comparing private plan offerings for core benefits. Federal resources should be made available to help beneficiaries and others understand the changes that a defined contribution approach would entail.
5. **Maintain a future role for traditional Medicare and Medicare Advantage.** The traditional Medicare program should be retained as a public option for Medicare beneficiaries. While initially a FFS program, there should be no impediment for the traditional program to continue experimenting with and moving toward delivery and payment alternatives to FFS systems. Current Medicare Advantage plans may be offered

to Medicare beneficiaries through the Medicare exchange or through employer arrangements for retirees. By a specified date, the traditional public Medicare option should be offered to all beneficiaries through the federal Medicare exchange in competition with private plan choices.

6. **Protect beneficiary access to adequate coverage and high quality care.** Health plans in the Medicare exchange should be required to offer insurance to all beneficiaries regardless of age or health status, including guaranteed issue (the inability to deny coverage based on pre-existing conditions) and community rating (the inability to impose prohibitively disparate costs on subsets of beneficiaries). Plans must be subject to government oversight with respect to benefit and network adequacy; quality standards and monitoring; solvency and reserves; medical loss ratios; marketing practices; and sufficient access to a variety of plans. Access to coverage and care in rural areas must be ensured.
7. **Ensure that the basis for setting and updating the defined contribution is adequate.** The initial government defined contribution should be adequate to cover the cost of the existing Medicare benefit package in the first year of the new program. The level of the defined contribution should be transitioned to, and subsequently increased annually by, an explicit measure of economic growth or price inflation per capita. There should be a periodic assessment of the continued adequacy of the defined contribution amount to ensure the ability of beneficiaries to purchase standardized core benefits.
8. **Maintain beneficiary responsibility for income-related premiums.** If a private plan costs less than the defined contribution amount, the difference should be made available to the beneficiary in the form of a non-cash credit for the purchase of supplemental benefits or to fund a health savings account to help with cost sharing. If a beneficiary chooses a plan that costs more than the defined contribution amount, he/she must pay the difference. The defined contribution amount available to the beneficiary to purchase a plan should be income-related so that lower-income beneficiaries can afford to purchase coverage and higher-income beneficiaries are responsible for paying a larger share of the premium. While it is important to consider changes that incentivize prudent care decisions by beneficiaries, it is equally important to recognize that beneficiaries already bear substantial premium and cost sharing under all elements of the Medicare program.
9. **Protect against risk selection by adjusting plan payments.** After the beneficiary selects a plan, the premium paid to the plan on behalf of the beneficiary by the Medicare exchange should be risk-adjusted to mitigate the effect of adverse or favorable selection in a plan's total Medicare enrollee population, as is currently the case under the Medicare Advantage program. The premium should be adjusted for age, gender, the portion of utilization that results from differences in beneficiary health status, and local/regional variations in input costs (e.g., labor, supplies, and utilities).
10. **Ensure continued funding of public benefit activities.** Current Medicare support for clinical education, including direct graduate medical education and indirect medical education costs, and for the cost of serving disadvantaged populations (disproportionate

share) must be continued and paid directly to providers, and consideration should be given to requiring that all other health plans and payers contribute to these costs as well.

Addressing Rising Drug Prices



DATE: March 2016
TO: Regional Policy Boards
SUBJECT: Addressing Rising Drug Prices

Objective

To obtain feedback on possible policy approaches to mitigate rising drug prices.

Background

The high cost of prescription drugs is putting a strain on Medicare, Medicaid and the entire health care system. Sudden and excessive price increases are threatening access to and the affordability of critical drug therapies for patients. Some hospitals have reported that their physicians have begun to change their prescription ordering practices and courses of treatment because of the high cost to patients.

The AHA has been working with a number of stakeholders to raise awareness of and develop policy solutions to combat the problems caused by drug price increases. Since our first discussions on excessive drug pricing last fall, we have worked collaboratively with other stakeholders to obtain data on the magnitude of the problem, increase consumer and policymaker awareness, and explore policy options. Indeed, broad stakeholder awareness of the problems caused by drug price increases is up dramatically, with the issue becoming a prominent topic in the Presidential primary campaigns for both parties and the subject of a scathing Congressional hearing in February. In this session, we will discuss AHA's activities to-date and seek your input on potential policy options to mitigate the increase in drug prices.

Update on AHA Activities

Campaign for Sustainable Rx Pricing: The AHA is a steering committee member of the Campaign for Sustainable Rx Pricing (CSRxP). The CSRxP is a multi-stakeholder coalition that works to raise consumer and other stakeholder awareness of the rising cost of drugs and engage in a dialogue with drug companies on the impact of drug price increases on the healthcare system. The group is developing a set of policy solutions that seek to minimize the negative impact of high drug costs on patient access to care, healthcare premiums, and taxes while still enabling drug companies to innovate and develop new therapies. The AHA is actively participating in the development of the CSRxP's policy agenda along with organizations such as America's Health Insurance Plans, AARP and the BlueCross Blue Shield Association. Many of the solutions being explored by CSRxP are included in the policy positions described below.

Media Advertisements: Earlier this year, the AHA launched a series of advertisements in the “early presidential primary states” to highlight the impact of the rising cost of pharmaceutical drugs on patients and hospitals. These advertisements were published in newspapers, billboards, and on airport digital displays and encouraged consumers to ask Presidential candidates what they would do to reduce prescription drug prices. The state hospital associations in Iowa, New Hampshire, and South Carolina joined us in these campaigns and co-logged the advertisements. The AHA is evaluating next steps for a future campaign on drug pricing.

Drug Pricing Survey: The AHA, in conjunction with the Federation of American Hospitals (FAH), has developed a survey to quantify the impact of rising drug prices on hospitals. The survey seeks data on older drugs for which pricing has dramatically increased without reasonable cause, the top drugs that are impacting hospital budgets, and the drugs that have had the largest year-over-year price increase. The survey was developed with the assistance of a workgroup of member hospitals. The AHA anticipates the survey will be sent to the field in the first quarter of 2016 and results will be available in spring 2016. We plan to use the data collected to illustrate how drug prices are adversely impacting hospitals.

Policy Positions under Consideration

The AHA is exploring policy positions to help rationalize drug prices while still supporting innovation. These policy positions were drawn from the work of the CSRxP, our prior discussions with our governance groups, and healthcare industry thought leadership. Below, are five policy positions for further discussion.

- Strengthen Medicare’s negotiating power;
- Reduce backlog of generic applications;
- Increase transparency through the collection of information on drug pricing, comparative effectiveness, and investment in research and development;
- Increase competition by shortening the exclusivity period for biologics and prohibiting anti-competitive practices such as “ever-greening” and “pay for delay;” and
- Strengthen requirements around direct-to-consumer drug advertising.

1. Strengthen Medicare’s negotiating power. Some policymakers and health policy leaders recommend that Medicare leverage its negotiating power to reduce the cost of drugs covered by the Medicare Part D program. Currently, Medicare Part D plan sponsors negotiate prices with drug manufacturers and evidence shows that plans are unable to obtain the same low prices achieved by other payers, most notably state Medicaid programs. In this policy option, Medicare would negotiate prices with drug manufacturers on behalf of the Medicare Part D plan sponsors for either the full suite of drugs available through Medicare Part D plans or a subset of these drugs, e.g., the most expensive drugs or the most commonly used drugs. Part D sponsors would continue to design plans based on different formularies and cost sharing but would have access to Medicare-negotiated rates. As part of those negotiations, Medicare

could also mandate that drug manufacturers provide the lowest price available for the drug (“best price”) for low income Medicare beneficiaries.

As part of its negotiating authority, Medicare could also pursue new value-based reimbursement models. While several models are being developed in the private sector, including indication-based payments and outcomes-based contracts, government programs have lagged behind. These models can provide enhanced financial incentives for manufacturers of new drugs and medical technologies that are contingent upon agreed-upon standards for quality care and outcomes.

- 2. Reduce backlog of generic applications.** The FDA continues to face a significant backlog of generic drug applications, with nearly 4,000 applications pending and average approval times reaching three or more years. This option would provide the FDA with the resources necessary to clear this backlog and prioritize approval of generic drug applications, particularly for classes of drugs with no or limited generic competition. An abbreviated pathway could be developed for instances where there is a shortage of generic drugs or when a single source generic manufacturer raises its price irresponsibly.
- 3. Increase transparency through the collection of information on drug pricing, comparative effectiveness, and investment in research and development.** As part of the drug approval process, manufacturers could be required to disclose as part of their applications to the Food and Drug Administration (FDA) information such as:
 - Drug pricing, including the estimated unit price for the product, the estimated cost of a course of treatment, and a projection of federal spending on the product;
 - Clinical effectiveness and cost as compared to existing therapies; and
 - Investment in research and development for the drug, including by source of research and development funding (e.g., National Institutes of Health (NIH), academic centers, the drug manufacturer, or other drug manufacturers).

This information would be reported to the Department of Health and Human Services (HHS), with protections in place to exclude sensitive, proprietary information. To ensure robust reporting, manufacturers could be required to submit this information both as part of the product’s application process with the FDA and as a condition of having their products covered by government programs.¹

Subsequent to drug approval by the FDA, manufacturers could be required to report annually on any increase in the list price of that drug over a threshold, how many times a year the price of a drug has been increased, and any new data that supports comparative effectiveness studies. HHS would be able to use this information to develop public reports on issues such as the top 50 price increases over the last year by a branded drug; the top 50 price increases

¹ There is precedent for these kind of requirements. For example, in order to have their drugs covered under Medicare Part D manufacturers must sign an agreement with HHS that they will provide a discount to Medicare beneficiaries on drugs they use while in the Part D coverage gap.

over the last year by a generic drug; the top 50 drugs by annual spending; and historical price increases for common drugs over the most recent 10 year period.

This approach is consistent with reporting requirements on other entities in the healthcare sector. Health plan issuers are required to provide premium information to state insurance commissioners. In addition, issuers with rate increases above 10 percent are required to submit a justification to the government for review and must make summary information accessible to the public in an understandable format. Hospitals, skilled nursing facilities, and certain other providers are also required to submit cost data to HHS annually. This includes information on facility characteristics, utilization data, costs and charges, and financial data. This policy would simply extend transparency to the pharmaceutical sector as well. This policy would also align U.S. requirements with those of other countries, such as Germany which requires submission of comparative effectiveness data as part of its drug approval process.

- 4. Increase competition by shortening the exclusivity period for biologics and prohibiting anti-competitive practices such as “ever-greening” and “pay for delay.”** Currently, biologics enjoy a 12-year market exclusivity period, the purpose of which is to provide the manufacturer with an opportunity to recoup their investment in the research and development of the drug. However, significant doubts exist about whether such a length of time corresponds with manufacturers’ actual research and development costs. For example, the research and development for the hepatitis C drug Sovaldi was largely conducted by a small bio-tech company that received the majority of its funding from the NIH. The drug’s manufacturer, Gilead, purchased this bio-tech and recouped the cost of the acquisition in one year of sales of the \$1,000 a pill drug.

Despite concerns that the current duration of market exclusivity is too long, some drug manufacturers attempt to extend these periods, including tactics such as “evergreening” and “pay for delay.” A manufacturer attempts to “evergreen” a product when it applies for patent and market exclusivity protections by seeking approval for a “new” product that is essentially the same as the original product, such as extended release formulations or combination therapies that simply combine two existing drugs into one pill. A branded drug manufacturer “pays to delay” when it offers financial incentives to a generic drug manufacturer to delay entry into the market.

The FDA could increase competition by shortening the exclusivity period from 12 to 7 years and prohibiting anti-competitive practices like evergreening and pay for delay. To quickly identify and take action against evergreening, the FDA could be prohibited from providing branded drug manufacturers with preferential treatment or an exception from participating in the U.S. Patent and Trademark Office’s Inter Parties Review (IPR) process, which quickly and efficiently clears the system of patents that do not deserve patent protection.

- 5. Strengthen requirements around direct-to-consumer drug advertising.** The U.S. is one of two countries world-wide that allows direct-to-consumer (DTC) broadcast advertising of drugs. These ads are aimed at a general audience, not healthcare professionals, and drive up

spending on drugs by increasing the underlying cost of the drug (marketing costs) and potentially leading to over utilization of high-cost drugs, even when highly effective, when lower cost drugs are available. In 2013, drug manufacturers spent considerably more money on marketing than on research and development. Nine of the largest drug manufacturers spent between 12.8 and 23.8 percent of revenue on research and development. Those same manufacturers spent between 17.9 and 28.4 percent of revenue on marketing.² Despite the potential negative impact of marketing, drug manufacturers are permitted under the tax code to write off these promotional expenses.

The federal government could move to tighten regulations regarding DTC advertising and remove tax breaks for drug promotion activities. As part of enhanced regulatory oversight, the FDA could require that information on historical price increases and the effectiveness of the drug as compared to other therapies be prominently displayed in any DTC advertising.

In addition to the options presented above, we recognize that there may be other policy proposals worth considering and have provided an additional list of options in Appendix A.

Discussion Questions

Please come prepared to discuss the questions below:

1. What is your reaction each to these five policy positions? Which should AHA advocate in its efforts to combat increased drug pricing?
2. Given the list of proposals in Appendix A, are there other policies that the AHA should explore further?
3. Which of the policy proposals could have the greatest impact on drug costs for your organization and the patients you serve?

Attachment: Additional policy proposals

² Center for American Progress, "Enough is Enough: The Time Has Come to Address Sky-High Drug Prices," September 2015.

APPENDIX A
ADDITIONAL POLICY PROPOSALS TO ADDRESS RISING DRUG COSTS

- **Leveraging Existing Laws that Protect Taxpayers.** Existing law provides federal agencies with authority to license drugs to third-parties where the benefits of the product are not available to the public on reasonable terms (otherwise known as federal “march in” rights). When products are funded (fully or partially) with NIH dollars, federal agencies could consider whether this authority could be used in cases where high prices or price increases threaten access to important medications, and they could inform Congress where they lack authority necessary to protect taxpayers.
- **Foster Competition for Branded Drugs.** Delays in the FDA approval process often prevent competitors from coming to market in a timely manner. In such situations, adjustments could be made to bring potential market competitors to the market more quickly. The tools to do so already exist. For example, several FDA programs are intended to facilitate and expedite review of new drugs that address unmet medical need in the treatment of a serious or life threatening condition. These include: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. These incentives also could be utilized to encourage additional market entrants and drive competition for expensive classes of treatments where there are no competitors and to encourage a second or third market entrant. Such a strategy could not only increase competition but will serve as an important protection to consumers if the first market entrant has to be withdrawn due to safety concerns.
- **Consider Updating the Medicaid Rebate Program for Maximum Benefit.** For over 25 years, the Medicaid rebate program and associated programs have benefitted from favorable prescription drug pricing for programs and providers serving low-income populations. The program has improved the affordability and sustainability of drug benefits for beneficiaries and public programs. However, one concern raised about the rebate program is whether the existing formula for calculating rebate levels is inadvertently slowing the availability of value-based pricing contracts and preventing private purchasers from fully utilizing their negotiating power, resulting in higher drug prices than necessary. Research is needed to determine whether alternative approaches could protect or even improve the savings from the current Medicaid rebate program while at the same time supporting market-based negotiating efforts to lower drug prices.
- **Strengthen Post-Market Surveillance.** Today, manufacturers may be required to conduct additional clinical trials post approval of a particular product. This is often the case when expedited approval pathways are used, which typically involve smaller clinical trials with a narrower patient population. In such cases a given drug may show significant promise and because of high unmet need, the FDA wants to get the product to market despite an incomplete understanding of long-term efficacy or side effects. However, once a drug is approved, many of these studies are never conducted. A related concern is that for the clinical trials that are completed, much of this information is never reported publically.

Specific timelines could be put in place to ensure that post-market trials are conducted. If manufacturers do not follow through with their commitment to launch a required trial, they could be subject to fines or other penalties unless an exception has been granted by the FDA. In addition, manufacturers could be required to report summary data for all trials (whether a product is approved or not) that summarizes demographics and baseline characteristics of participants, primary and secondary outcome results, and information on any adverse events.

- **Targeted Orphan Drug Incentives.** The Orphan Drug Act introduced a range of incentives to encourage the development of medications to treat rare diseases – diseases which affect fewer than 200,000 individuals. These incentives include waived FDA fees, tax credits, and seven years of marketing exclusivity. Since passage of the Orphan Drug Act, hundreds of orphan drugs have been approved. Many of these medications are helping patients who previously had no options. However, an increasing number of orphan drugs have achieved blockbuster status, with billions of dollars in sales annually. One driving factor of this trend is a strategy used by pharmaceutical companies to create new subcategories of diseases underneath a more common disease category to qualify for orphan drug status. Subsequently, the pharmaceutical company will seek additional approvals for non-orphan indications which substantially expands use of the drug. Utilization can also grow significantly through off-label use. These dynamics, combined with the high prices orphan drugs command, can lead to blockbuster levels of sales. HHS could take steps to assess such trends and ensure that the Act’s incentives are being utilized to develop medicines to treat true rare diseases. For example, the FDA could require additional information when companies seek orphan drug status, such as providing information about additional indications for which a company intends to seek approval. HHS could also analyze and report on orphan drug utilization and pricing trends, including trends by indication for orphan and non-orphan uses.
- **Expand Research on Treatment Effectiveness and Value.** Consumers and providers should be empowered to know which treatments and drug regimens work and which are less effective. Policymakers could increase funding for private and public efforts aimed at providing information on the comparative effectiveness of different treatments to physicians and their patients which can help them make appropriate assessments about the value of different treatment approaches, particularly those with very high costs. A prime example is the Institute for Clinical and Economic Review (ICER). ICER is a non-profit organization that evaluates the evidence on the value of medical tests and treatments with an aim toward improving patient care and controlling costs. Recently, ICER released an important draft report on PCSK9 inhibitors for treatment of high cholesterol. In their draft assessment, ICER concluded that the price that best represents the overall benefits of these new drugs would be between \$3,600 and \$4,800 – a 67% discount off the manufacturers' list price of about \$14,000 per year of treatment. Investments in the development of information such as this are critical for physicians, patients, and payers as more high cost drugs are introduced into the health care system.
- **Reduce Out-of-Pocket Costs for Patients.** Today, pharmacy benefit managers (PBMs) negotiate drug prices on behalf of insurers. More than 200 million Americans are covered by

plans that used PBMs to negotiate prices. However, consumers' out of pocket costs do not necessarily reflect the discounts obtained by PBMs because consumer cost sharing is based on the negotiated retail price, not the actual price paid. Federal law could require that consumer cost sharing be based on prices actually paid.

- **Require Review and Approval of Price Increases.** As previously discussed, insurers in the U.S. are subject to annual rate reviews and approvals by state insurance commissioners. The government could require that drug companies similarly submit requests for price increases if they intend to increase the price of a drug above a specified threshold, e.g., general inflation, similar to the process used for insurance companies.
- **Allow beneficiaries to purchase drugs in other countries (re-importation).** Under drug re-importation, patients purchase drugs that were originally manufactured in the U.S. and then exported to another country, where drug prices are often significantly lower. In most cases, this occurs when Americans fill prescriptions in Canadian or Mexican pharmacies (in person, through mail order, or online). This practice is currently illegal in the U.S. due to concerns about drug safety. While re-importation is unlikely to have a major impact on drug pricing on its own, it could be an important tool for some consumers who are making a choice between not filling a prescription due to cost and re-importing drugs.

Task Force on Ensuring Access



DATE: March 2016

TO: Regional Policy Boards

SUBJECT: Task Force on Ensuring Access in Vulnerable Communities

Objective: To provide an update on the progress of the AHA Task Force on Ensuring Access in Vulnerable Communities (roster attached) and obtain input on the characteristics of vulnerable communities, essential health care services, and emerging strategies, delivery models, and payment models to ensure access.

Background

The millions of Americans living in rural and inner city urban areas depend upon the hospital serving their community as an important, and often only, source of care. The nation's nearly 2,000 rural community hospitals and more than 2,000 urban community hospitals frequently serve as the anchor for their area's health-related services, often providing prevention and wellness services, community outreach, and employment opportunities.

While every community faces challenges, these hospitals face unique pressure points. Rural hospitals struggle with their remote location, limited workforce, and constrained resources, while inner city urban hospitals often struggle financially while pursuing their charitable mission. Certain special payment programs attempt to account for these special circumstances; however, none represents an integrated, comprehensive strategy to reforming health care delivery and payment within which vulnerable communities could make individual choices based on their needs, support structures and preferences.

To that end, in 2015, the AHA Board of Trustees approved the creation of a task force to examine ways in which hospitals can help ensure access to health care services in vulnerable rural and urban communities. They charged the task force with the following:

- Confirming the characteristics and parameters of vulnerable rural and urban communities by analyzing hospital financial and operational data and other information from qualitative sources, where possible;
- Identifying emerging strategies, delivery models and payment models for health care services in rural and urban areas;
- Identifying policies and issues at the federal level that impede, or could create, an appropriate climate for transitioning to a different payment model or model of care delivery, as well as identifying policies that should be maintained.

The task force work is ongoing – it began in September 2015 and is anticipated to conclude in fall 2016. Below is an update on the task force work thus far.

Characteristics and Parameters of Vulnerable Communities

As its first step, the task force identified the characteristics and parameters of vulnerable rural and urban communities. Task force members both relied upon their own experience and analyzed financial data and other information from qualitative sources about vulnerable rural and urban communities.

The task force has identified a number of characteristics and parameters that could be used to identify both vulnerable rural and urban communities, including a lack of access to primary care services, high rates of uninsurance or underinsurance, a poor economy, limited economic resources, high unemployment rates, low education levels or cultural challenges (e.g. language barriers, immigration, literacy, religion).

The task force also identified characteristics that varied across rural and urban communities. Those that were unique to vulnerable rural communities included a declining population, an aging population, difficulty attracting new businesses or business closures. For vulnerable urban communities, the task force identified a lack of access to basic “life needs” (e.g. food, shelter and clothing), a high disease burden and unhealthy environments (such as pollution, poor infrastructure, overly high population density) as additional characteristics and parameters.

Essential Health Care Services

While acknowledging that the range of health care services offered and the ability of individuals to obtain access to health care services is not the same in every community, the task force determined it was necessary to identify a set of essential health care services that should be provided in a high quality, safe, and effective manner in every community. These essential health care services include: primary care, emergency department and observation care, behavioral health, dentistry, transportation, diagnostic and prenatal services, as well as a robust referral structure to provide access to other services as needed.

Emerging Strategies, Delivery Models and Payment Models

The task force has started to identify and explore models that may help ensure access to health care services in vulnerable communities. During discussions, task force members have made clear that there will be no ‘one size fits all’ solution that will work for all communities. Therefore, it is their intent to present a variety of models so that each community may choose the model(s) that best sustains and ensures access to essential health care services for them. Some models that are being considered by the task force include:

- **Addressing the Social Determinants of Health.** The task force has had robust discussion around the social determinants of health. Social challenges often prevent community members from being able to access health care or achieve their health goals, even when quality care is available. For example, lack of access to transportation may prevent patients from being able to obtain necessary care, or food insecurity may prevent individuals from adhering to specific diets dictated by certain conditions. The task force plans to explore a model that would bridge the gap between clinical care and community services. Such a model could focus on screening patients to identify unmet social needs; providing navigation services to assist patients in accessing community services; and encouraging alignment between clinical and community services to ensure that community services are available and responsive to patient needs. The task force also plans to explore the extent to which it may be appropriate for the hospital itself to provide patients with assistance such as hospital-funded transportation or housing assistance.

- **Global Budgets.** This model would establish global budgets to cover all inpatient and outpatient services provided at a hospital. Doing so would provide financial certainty and potentially fair payments for hospitals in vulnerable communities, as well as incentives to contain health care cost growth and improve quality. While the task force continues to consider the details, it believes that such a model could function as an ‘umbrella’ option that would provide a community with flexibility to provide care in the manner that best fits its circumstances. This could include the adoption of one of the models described below, as well as any number of other options they deemed appropriate, to function within the global budget.
- **Emergency Medical Center (EMC) Model.** This model would allow existing facilities in rural and urban communities to meet the needs of the community for emergency room and outpatient services, without having to maintain inpatient beds or provide inpatient acute care services. EMCs would only be able to arise from a hospital conversion – that is, they could occur only where a hospital already exists. They would be required to provide emergency services (24 hours a day, 365 days a year) and transportation services (either directly or through arrangements with transportation providers) to allow for the timely transfer of patients who require inpatient acute care services. However, they would also have the ability to provide outpatient services and a variety of post-acute care services. In order for these facilities to remain financially viable, a new reimbursement methodology would need to be developed to account for low volume and other challenges these facilities would face in vulnerable rural and urban communities.
- **Virtual Care Model.** The task force also has been exploring telehealth and virtual care models that may be used to maintain or supplement access to health care services in vulnerable rural and urban communities. Task force members have explored a range of health care services that may be offered remotely – including intensive care unit monitoring, pharmacy services that include real-time pharmacist review of all new hospital medication orders, and emergency services that allow for immediate access to board certified emergency physicians and nurses. In addition to providing immediate, 24/7 access to physicians and other health care providers that otherwise would not be located in these communities, telehealth and virtual medicine models have the potential to result in better access to care, better care and outcomes, lower costs and workforce stability. The task force will continue to evaluate the full scope and potential of telemedicine opportunities available to vulnerable communities, as well as the reimbursement challenges such models face.

Discussion Questions

Please come prepared to discuss the following questions:

1. Based on your experience, what is your reaction to the characteristics and parameters of vulnerable communities that the Task Force has identified?
2. Regarding the Task Force’s set of essential health care services, are there missing services or changes you would recommend?
3. Beyond those described above, are there additional delivery or payment models the task force should explore?



**American Hospital
Association**

Task Force on Ensuring Access in Vulnerable Communities

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Medicare Hospital Payment Reform



**American Hospital
Association**

DATE: March 2016

TO: Regional Policy Boards

SUBJECT: Medicare Hospital Payment Reform

Objective

To advise the AHA on whether we should advocate for policy changes that would consolidate separate Medicare hospital pay-for-performance programs into a single program, potentially to include a bonus for participation in alternative payment models.

Background

Most hospitals currently participate in at least five separate, legislatively-mandated quality reporting and pay-for-performance programs from the Centers for Medicare & Medicaid Services (CMS), as well as the Medicare Electronic Health Record (EHR) Incentive Program.¹ The attached table summarizes the key aspects of these six programs. While there is some overlap in measures and requirements among the programs, each one uses different payment incentive structures and methodologies for determining good and bad performance.

To date, the AHA's advocacy efforts have focused on urging critically important, but incremental, changes to the individual programs. CMS's existing programs and their key policy issues are briefly summarized below.

Pay-for-Reporting. The hospital inpatient quality reporting (IQR) and outpatient quality reporting (OQR) programs are CMS's "pay-for-reporting" programs. That is, hospitals must report quality measure data to receive a full annual market basket update under the inpatient and outpatient prospective payment systems (PPS), but payment is not tied to how well they perform. Nevertheless, hospitals have raised concerns about the significant growth in the number of measures required in the IQR and OQR programs. In addition, some of the measures do not accurately portray hospital performance. And many measures appear to be unrelated to each other or to any specific goals for system-wide improvement. The proliferation of measures makes it difficult to ensure the value of reporting quality measures is greater than the significant resources required to collect and analyze data, as well as to improve performance.

Pay-for-Performance. The Affordable Care Act (ACA) significantly raised the financial stakes of quality measurement by introducing three "pay-for-performance" programs tying payment to the level

¹ By statute, CMS's quality reporting and pay-for-performance programs generally apply to hospitals participating in the inpatient and outpatient prospective payment systems (PPS). Critical Access Hospitals (CAHs) do not participate in most CMS quality measurement programs, except for the Medicare Electronic Health Record Incentive Program. However, many CAHs do voluntarily report data from the inpatient and outpatient quality reporting programs.

of quality performance. The Hospital Value-Based Purchasing Program (VBP) and Hospital Readmissions Reduction Program (HRRP) began affecting hospital inpatient PPS payments in FY 2013, while the Hospital Acquired Conditions Reduction Program (HACRP) began in FY 2015. In addition, the American Recovery and Reinvestment Act (ARRA) of 2009 established the Medicare EHR Incentive Program for hospitals. This program initially awarded hospitals bonus payments for implementing EHRs and meeting the requirements for the “meaningful use” of EHRs. However, beginning in FY 2015, the program began to penalize hospitals that failed to meet the CMS-established level of performance.

The AHA has generally supported the Hospital VBP program because it is designed in a budget neutral manner, and it rewards hospitals for both performance achievement and performance improvement over time. However, we have significant concerns about the HRRP, HACRP and Medicare EHR Incentive Programs. The AHA has strongly advocated for sociodemographic adjustment in the HRRP and supports legislation in the current Congress that would mandate such adjustment. We also have advocated that the HACRP program be folded into VBP, because it is unfair that one-quarter of hospitals receive the HAC penalty each year regardless of improved performance. Lastly, we have urged CMS and Congress to make a number of changes to the Medicare EHR Incentive program to make the requirements more realistic and fair.

Interest in a More Aligned Approach

In general, policymakers and hospitals continue to believe that quality measurement and pay-for-performance aligns with the health care field’s movement from volume to value. However, some stakeholders are beginning to question whether having separate hospital programs is the most effective policy strategy to advance this goal. Hospitals have reported frustration that they are spending time interpreting each program’s requirements and methodology that could otherwise be spent on improving care. In addition, the inconsistencies across the programs can lead to mixed signals on quality performance, making it harder for hospitals to prioritize limited resources. In fact, even when using the same measures, hospitals may score well on one CMS program but poorly on another. For example, the HACRP’s measures overlap with the measures in the VBP program, yet each program uses different performance periods and scoring approaches.

Some observers also assert that the existing programs are not aligned with those for other sectors of the health care delivery system and fail to encourage hospital participation in innovative delivery and payment models. They view the new physician quality measurement system required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 as a potential template for reforming hospital pay-for-performance programs.

The MACRA provides two “tracks:” (1) the default Merit-based Incentive Program (MIPS), and (2) payments to professionals who demonstrate significant participation in alternative payment models (APMs), such as bundled payments or ACOs. Starting in 2019, MIPS will consolidate three separate² pay-for-performance programs for physicians into a single program. Physicians will be measured across their performance on quality, resource use, clinical practice improvement activities and meaningful use of EHR technology. They will earn rewards or penalties of up to ± 4 percent of Physician Fee Schedule payments in 2019, rising to ± 9 percent by 2022 and beyond. In contrast, the APM track allows physicians receiving a significant portion of their payments through eligible APMs to be exempt from most MIPS provisions. In addition, through 2024, they can receive a 5 percent

² The programs are the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM) and the Medicare EHR Incentive Program for Eligible Professionals (EPs).

bonus payment. Eligible APMs must meet a number of criteria, including quality measurement, use of certified EHR technology, and responsibility for more than a nominal amount of financial loss.

Reforming Hospital Programs

Given that the current hospital pay-for-performance programs are mandated by law, making major reforms to them would require legislation. At this time, no legislation has been introduced that would consolidate CMS hospital pay-for-performance programs but there is policymaker interest in the idea. In addition, President Obama's FY 2017 budget includes a proposal to award hospitals participating in APMs bonuses. The bonuses would be funded by reducing inpatient and outpatient PPS payments to all hospitals. The Administration's proposal does not include details on either the amount of bonus or payment reduction, or on which particular APMs would qualify for the bonus. It also appears the existing CMS programs would remain in place. We are looking for your guidance on whether AHA should advocate to combine the existing hospital performance-based payment programs, and whether there is interest in exploring a bonus for hospitals participating in APMs.

The Tradeoffs of Reforming Hospital Pay-for-Performance. As hospitals consider potential paths forward, the AHA staff have identified a number of benefits and risks to consolidating the separate programs into one program:

Benefits

- **Administrative simplicity.** The use of a single program should lead to the use of a consistent set of measures, and a consistent way of determining performance. Hospitals would only have to track one program instead of six separate programs.
- **Alignment with other CMS pay-for-performance approaches.** In particular, a single pay-for-performance program that includes quality measurement and the Medicare EHR Incentive program aligns with the new structure of the MIPS.
- **Potential flexibility on Meaningful Use criteria.** Reforming hospital pay-for-performance may provide an opportunity to create more flexibility in meeting Meaningful Use criteria.
- **The potential for innovation:** A MACRA-like policy approach that provides an alternative pathway for hospitals who receive a significant amount of payment from APMs could encourage participation in innovative payment models.

Risks

- **Expectation of savings to Medicare.** The Congressional Budget Office (CBO) scored the HACRP and HRRP as saving CMS \$8.5 billion over 10 years. In the current political environment, any changes to hospital pay-for-performance programs would likely need to be budget neutral with respect to existing spending. As a result, it is possible that some hospitals would incur payment penalties that will simply be retained as savings to Medicare. The likely need for budget neutrality also might make it difficult to provide the same type of bonuses for hospital participation in APMs that physicians will receive under MACRA.
- **A potential avenue for future payment cuts.** A consolidated pay-for-performance program likely would place a certain percentage of payment at risk for performance. This amount could be changed over time in order to generate additional savings to Medicare, especially if the program is designed in a non-budget neutral fashion.

- **The scope of pay-for-performance programs could be broadened.** To date, Medicare pay-for-performance has not affected outpatient PPS payments. With the exception of the Medicare EHR Incentive Program, the programs also have not been applied to critical access hospitals (CAHs). A combined program could result in more hospitals having significantly more of their overall payments tied to pay-for-performance programs

Design Goals for Revised Hospital Pay-for-Performance. As the AHA evaluates emerging proposals, we believe any program should achieve the following design goals:

- **Promote focus on what is important** by using a limited number of measures aligned with national goals for quality improvement across the delivery system.
- **Use rigorous performance measures** that are well-tested and appropriately risk adjusted. This includes sociodemographic adjustment for outcome measures like readmissions where there is evidence that performance is affected by community factors beyond hospitals' control.
- **Reward improvement** by scoring hospitals on both their achievement versus benchmarks and improvement over time, as is done in the existing hospital VBP program.
- **Promote innovation and alignment across the healthcare delivery system** by creating alternative pathways for members participating in emerging care delivery and payment models.

Discussion Questions

Members may find it helpful to consult with their quality, clinical and health IT leadership to help explore to the following questions:

1. What is your assessment of the benefits and risks of consolidating the separate hospital pay-for-performance programs into a single program?
2. What is your reaction to the hospital pay-for-performance program design goals? Are there any goals that are missing or that should be prioritized?
3. Would you support a (possibly budget-neutral) bonus payment for hospital participation in alternative payment models?

Attachment: Overview of Medicare hospital pay-for-performance programs

Overview of Medicare Hospital Pay-for-Performance Programs¹

Program	Measures / Performance Assessment	Incentive Structure	Maximum Payment At Risk (FY 2017 onward)	Cumulative Hospital Payment Cuts, FY 2013 – FY 2016
Hospital Inpatient Quality Reporting (IQR) Program	Various clinical process, outcome, complication and patient experience measures	<ul style="list-style-type: none"> • Pay-for-reporting – Hospitals must submit required data to receive a portion of the annual market basket update 	25 percent of the inpatient PPS annual market basket update	Negligible – nearly all eligible hospitals meet IQR requirements
Outpatient Quality Reporting (OQR) program	Various process and outcome measures focused on hospital outpatient services	<ul style="list-style-type: none"> • Pay-for-reporting – Hospitals must submit required measure data to receive full annual market basket update 	2.0 percent of the outpatient PPS annual market basket update	Negligible – nearly all eligible hospital meet OQR requirements
Hospital Readmission Reduction Program (HRRP)	30-day readmission measures for selected clinical conditions (e.g., heart attack) and procedures (e.g., hip / knee replacement)	<ul style="list-style-type: none"> • Payment penalty to hospitals with excess readmissions • Applied as a percentage of base inpatient PPS payments on a sliding scale 	3.0 percent of base inpatient PPS payments	\$1.3 billion
Hospital Value-Based Purchasing (VBP) Program	Hospitals scored on: <ul style="list-style-type: none"> • Healthcare associated infections • Mortality • Complications • Patient experience (HCAHPS) • Medicare spending per beneficiary 	<ul style="list-style-type: none"> • Bonus or penalty on a sliding scale • Budget neutral – a percentage of each hospital’s payments is withheld each year to create a pool • Hospitals earn back some, all, or more than withhold 	2.0 percent of base inpatient PPS payments	No net payment impact – the program is budget neutral. However, the program has created funding pools of approximately \$5 billion between FY 2013 and FY 2016

¹ Depending on its mix of services and participation in particular CMS payment systems, a hospital also may participate in CMS’s other quality measurement programs. For example, hospitals with separately licensed inpatient psychiatric facilities (IPFs) receiving payment under the IPF prospective payment system (PPS) may participate in the IQF Quality Reporting Program.

Program	Measures / Performance Assessment	Incentive Structure	Maximum Payment At Risk (FY 2017 onward)	Cumulative Hospital Payment Cuts, FY 2013 – FY 2016
Hospital-Acquired Condition Reduction Program (HACRP)	Measures focused on patient safety issues, including: <ul style="list-style-type: none"> • Healthcare associated infections • Claims-based patient safety indicator 	<ul style="list-style-type: none"> • Payment penalty applied to worst-performing 25 percent of hospitals each year • Penalty is the same percentage for all penalized hospitals 	1.0 percent of total inpatient PPS payments	\$737 million
Medicare Electronic Health Record (EHR) Incentive Program	Objectives and measures of “Meaningful Use” of EHRs	<ul style="list-style-type: none"> • Payment penalty -- Hospitals that do not meet required level of performance receive lower annual market basket update 	75 percent of the inpatient PPS annual market basket update	More than 200 hospitals penalized in FY 2015. Expected to grow over time.

Eliminating Fraud and Abuse Barriers



**American Hospital
Association**

DATE: March 2016
TO: Regional Policy Boards
SUBJECT: Eliminating Fraud and Abuse Barriers to Care Transformation

Objective

To provide the AHA with examples of how fraud and abuse laws inhibit efforts to improve care for Medicare beneficiaries through better care coordination and participation in alternative payment models.

Background

For hospitals working to transform care delivery, a key strategy is to improve care coordination by building relationships with physicians and other health care providers. These relationships also are necessary for success in new payment and delivery models, such as accountable care organizations and bundled payments. However, certain fraud and abuse laws – namely, portions of the Anti-kickback Statute and the Ethics in Patient Referral Act (known as the Stark Law) – are impeding efforts by hospitals and other providers to collaborate more closely.

The Anti-kickback Statute and Stark Law both regulate financial incentives that could impact referrals for health care services. Specifically, the Anti-kickback Statute states that anyone who knowingly and willfully receives or pays anything of value as an incentive to influence the referral of federal health program business (including Medicare and Medicaid) can be held accountable for a felony. The Stark Law prohibits physicians from making referrals for designated health care services paid for by Medicare to an entity in which the physician has a financial relationship (including ownership interests and compensation), subject to civil monetary penalties. Although these laws include exceptions and safe harbors that may protect certain financial arrangements between providers, navigating these exceptions and safe harbors can be costly and time-consuming for hospitals, and may not provide absolute protection. The Anti-kickback and Stark Laws were designed to address fraud and abuse concerns in a fee-for-service payment system, and changes to the laws have not kept pace with the health care field's movement toward payment based on value.

Success in Reducing Barriers and Further Opportunities for Reform

The AHA has long advocated for changes to the fraud and abuse laws in order to better allow hospitals to coordinate and transform care (fact sheet attached). Increasingly, Congress and the Department of Health and Human Services (HHS) are recognizing that the current fraud and abuse framework inhibits movement toward new payment models. Congress expressly authorized waivers of these laws for the Medicare Shared Savings Program (MSSP) and models being tested by the Center for Medicare and Medicaid Innovation (CMMI). The Secretary of HHS waived provisions of the Anti-kickback, Stark, and Civil Monetary Penalty (CMP) Laws for MSSP participants, and has provided similar waivers for participants in certain CMMI models.

The AHA achieved a significant victory in reducing fraud and abuse barriers in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), when Congress modified a provision in the CMP law that had prevented hospitals from offering physicians gainsharing, or incentives to follow evidence-based care guidelines, if those incentives could be seen as inducing physicians to reduce or limit care. Now, a hospital is subject to CMPs only for making payments to reduce or limit *medically necessary* care. In addition, the AHA successfully advocated for waivers to the Anti-kickback and Stark Laws for participants in the new Comprehensive Care for Joint Replacement bundled payment model that is mandatory for hospitals in selected markets beginning April 1; the model as originally proposed by CMMI did not include such waivers.

Congress and HHS have both indicated interest in additional reforms that could reduce barriers the fraud and abuse laws pose to transforming care and moving to new payment models. The MACRA included a requirement that HHS, in consultation with the Office of Inspector General, submit a report to Congress with options for amending fraud and abuse laws to permit gainsharing or similar arrangements between hospitals and physicians “that improve care while reducing waste and increasing efficiency.” The government’s report is due in April 2016. In the calendar year 2016 physician fee schedule proposed rule, the Centers for Medicare and Medicaid Services solicited feedback on barriers the Stark regulations pose to delivery system reform efforts. Additionally, in January the Senate Finance Committee requested feedback on needed changes to the Stark Law (AHA letter attached). The AHA has used these opportunities to advocate for needed reforms to the fraud and abuse laws. Specifically, AHA has urged Congress to adopt a single, broad exception that cuts across the Stark law, the anti-kickback statute and relevant CMPs for financial relationships designed to foster collaboration in the delivery of health care, as well as incentivize and reward efficiencies and improvements in care.

Gathering Examples of Barriers to Care Transformation

The AHA seeks to capitalize on the opportunity provided by the MACRA-mandated report on reducing fraud and abuse barriers to gainsharing by submitting a “hospital report” with recommendations on reforming the fraud and abuse laws. Over the past several months, we have conducted one-on-one interviews with counsel and staff engaged in care redesign efforts from member hospitals and health systems. From these conversations, we have identified several key areas in which hospitals’ efforts to transform care are being impeded by the Stark and Anti-kickback Laws:

- **Financial incentives** that reward providers for implementing specific clinical protocols or achieving desired outcomes
- **Implementation of multi-disciplinary teams** that include physicians and non-physician practitioners
- **Coordination across the care continuum**, including the ability to develop closer relationships with post-acute care providers
- **Infrastructure building**, such as standardizing electronic medical records across providers

We are developing concrete, persuasive examples of how the fraud and abuse laws hinder care transformation in each of these areas. These examples will demonstrate what hospitals can achieve for beneficiaries and the Medicare program in the absence of fraud and abuse barriers and provide an effective way to get Congress’s attention on this issue.

Discussion Questions

Members may find it helpful to consult with their counsel and clinical leadership to help prepare answers to the following questions:

1. How have the fraud and abuse laws impacted your organization's strategy to change care delivery or pursue alternative payment models? Do you have any specific examples you can share?
2. How can we best illustrate the benefit of reforms for Medicare beneficiaries while also addressing policymakers' significant concerns regarding health care fraud and abuse?

Attachments: AHA letter to Senate Finance Committee

AHA fact sheet on the fraud and abuse barriers to care transformation

January 29, 2016

The Honorable Orrin Hatch
Chairman
Committee on Finance
219 Dirksen SOB
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
219 Dirksen SOB
Washington, DC 20510

Dear Chairman Hatch and Senator Wyden:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide input on how to improve the physician self-referral (Stark) law. We welcome the Committees' focus on the law's challenges to implementing new payment models and the changes that experience shows would be essential to realizing their full benefit for improving quality, outcomes and efficiency in the delivery of patient care.

As the reimbursement landscape changes for hospitals, physicians and other health care providers, moving to a value-based paradigm from a volume-based approach, enforcement mechanisms and perspectives tethered to a by-gone era must be revisited, revised and, in some cases, abandoned to make way for innovation and improvement. Today, health care services are delivered through collaboration by multidisciplinary teams of professionals and providers in a growing variety of settings. Public and private payers increasingly are using incentives to drive behavior to achieve efficiencies and outcomes. To achieve those goals, the financial interests of members of the team need to be aligned. In this changing environment, it is imperative that laws affecting the ability of hospitals, physicians and others to work together should facilitate, rather than limit, those efforts.

As Congress recognized last year in the Medicare Access and CHIP Reauthorization Act (MACRA), the Stark law is not the only one that has created impediments to implementation of these new payment models. We applaud Congress's elimination of a barrier created by the "gainsharing" Civil Monetary Penalty (CMP). As interpreted by the Office of Inspector General (OIG), it prevented hospitals from sharing financial incentives with physicians for developing and implementing evidence-based care guidelines. In the MACRA, Congress made clear that a penalty was intended only if a hospital made payments to a physician to reduce or limit *medically necessary* care. As a result, hospitals and physicians can share the rewards for improving quality of care without risk of sanction under that law.



Below, we begin by addressing the two items identified as of primary interest in the Committees' request for input:

- What changes in the Stark law are needed to implement the MACRA in its current form, as well as accountable care organization (ACO)/shared savings programs; and
- Where to draw the line between technical and more serious violations of the law.

LEGAL IMPEDIMENTS TO IMPLEMENTATION OF NEW PAYMENT MODELS

We understand and echo the importance of focusing on the Stark law and removing the barriers it creates. The Stark law, however, is not the only legal barrier that needs to be addressed. Hospitals, physicians and other health care providers must break out of the silos of the past and work as teams to achieve the efficiencies and care improvement goals of the new payment models. To do that, a legal safe zone for those efforts is needed that cuts across the fraud and abuse laws (Stark, anti-kickback and certain CMPs).

In our view, the Stark law is not suited to the new models and should not be the locus of oversight for these new arrangements. The statute and its complex regulatory framework are designed to keep hospitals and physicians apart – the antithesis of the new models. Its core provisions micro-manage compensation arrangements on a strict liability basis that has proved unworkable. **To us the answer seems clear: Congress should adopt a single, broad exception that cuts across the Stark law, the anti-kickback statute and relevant CMPs for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care. We recommend that the exception be created under the anti-kickback statute and arrangements protected under the exception be deemed compliant with the Stark law and relevant CMPs.**

The need to reset oversight of these arrangements is reinforced by Congress's repeated grant of authority to the Secretary of Health and Human Services (HHS) to waive their application in the various demonstrations, pilots and other innovation programs. For example, when crafting the Medicare Shared Savings Program (MSSP), Congress granted the Secretary authority to waive provisions of the anti-kickback, Stark and CMP laws to remove these impediments to the successful creation and operation of Medicare ACOs. It did the same to enable new models to be tested under the Innovation Center. The Secretary has made full use of that authority with the new models. We urge adoption of a new framework for oversight of these efforts so the benefits of the quality and efficiency improvements are available to all Medicare beneficiaries, not only those affected by a discrete programmatic initiative.

THE PROBLEM

The Stark law's oversight of compensation arrangements is anchored in a fee-for-service world where physicians were self-employed, hospitals were separate entities, and both billed for

services on a piecemeal basis. It presumes that compensation arrangements are suspect and attempts to micromanage the circumstances in which a compensation arrangement is permitted and the amount paid. Increasingly, public and private payers are holding hospitals accountable for reducing costs and improving quality, and using financial incentives to drive behavior. Payment models for physicians also are using financial incentives to drive behavior. Achieving Congress's goals for the government health care program and beneficiaries can be accomplished only through teamwork among hospitals, physicians and other health care providers across sites of care. An essential component for the success of their efforts is also the use of financial incentives – specifically, arrangements that align incentives.

Yet the ability to share the rewards of collaboration is different for hospital-physician relationships than when a physician practices alone or as part of a group. As interpreted today, the two “hallmarks” of acceptability under the Stark law – fair market value and commercial reasonableness – are not suited to the collaborative models that reward value and outcomes. Fair market value has become a rigid measure of hourly wage equivalents. Commercial reasonableness has been contorted to cap a physician’s compensation at levels that he or she could generate if he or she remained an independent seller of physician services, even if part of that compensation is paid for supervising non-physician members of a multidisciplinary team in the efficient delivery of quality care. And the statutory and regulatory caveat that compensation may not take into account or vary with the volume or value of referrals, as interpreted by law enforcement officials today, has become a “gotcha,” since compensation tied to successful outcomes almost necessarily includes some nexus to the number of patients whose treatment a physician oversees.

For example:

- A hospital and a primary care physician want to work together to expand access to primary care by adding a nurse practitioner and social worker to the practice. Each beneficiary would have a team for his or her care, and the practice would be able to serve additional beneficiaries. An individual newly released from the hospital would get assistance from the social worker in implementing and arranging for the follow-up care prescribed by the physician in the discharge plan. The nurse practitioner would follow-up to monitor the effect of medications. The physician, social worker and nurse practitioner would each be available to the beneficiary and collectively coordinate his care. Each beneficiary would have the benefit of the same coordinated care. The result: A beneficiary would have someone to call or an office to visit instead of a trip to the emergency department and avoidable readmissions would be reduced.
 - The problem: Compensation of the physician cannot recognize the quality of the services provided by the other team members and the clinical outcomes, nor increase to recognize the expansion of services he or she oversees.
- A hospital wants to engage physicians to improve clinical outcomes and the recovery time for certain hospitalized patients (e.g., those with an acute diabetic condition). The work would involve consensus building, research and study to select appropriate, evidence-based

clinical protocols. The hospital would like to use financial incentives to encourage and reward consistent implementation of those clinical protocols.

- The problem: Compensation of the physicians cannot recognize adherence to the protocol for individual patients or the achievement of clinical outcomes.
- A hospital wants to establish the electronic infrastructure for sharing medical record information among physicians and other providers and professionals who are part of the care team for a patient after discharge. Having real-time and complete information across the patient's care team will facilitate the care coordination to optimize the individual's recovery and health status.
 - The problem: A hospital may not bear the cost of the investment.

At the same time, Medicare is conditioning a portion of payment to hospitals on achieving goals that require the collaboration of hospitals and physicians across the care continuum (e.g., specific metrics regarding readmissions and hospital-acquired conditions, bundled payment for the Comprehensive Care for Joint Replacement model). Physician payment is undergoing a similar change. The MACRA ties a portion of most physicians' Medicare payments to performance on specified metrics, beginning in 2019. It also includes financial incentives to encourage physician participation in alternative payment models. While these changes in hospital and physician payments have been made on separate, but parallel, tracks, all are making shared performance objectives and financial incentives important among providers across the care continuum.

A SOLUTION: NEW EXCEPTION FOR TEAM-BASED CARE

We urge the creation of an exception under the anti-kickback statute for hospital-physician clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. There should be protection for shared savings and incentive programs, as well as any arrangement start-up or support contribution. Any arrangement covered by the exception would be deemed compliant with the Stark law and applicable CMPs.

The exception should establish the basic accountabilities for an arrangement: The shared savings or incentive payments should be part of a documented program; performance practices under each program must be supported by credible medical evidence; the program must have ongoing monitoring to protect against reductions or limitation of medically necessary care; and payments must reflect the achievements of the physician, the practice or the program. The exception should recognize existing quality improvement processes and the reporting and other quality and safety oversight within the Medicare program.

A new exception also would address the impediments created by the anti-kickback statute on implementation of new payment models. The enforcement landscape has effectively made any financial relationship between hospitals and physicians questionable. If a hospital rewards a physician for following evidence-based clinical protocols, the reward could be construed as violating the law, since technically such a reward could influence a physician's order for treatment or services. In acknowledgement that there are cases where the anti-kickback statute

thwarts good medical practices, Congress has periodically created “safe harbors” to protect those practices.

This is another occasion where the same is needed. Hospitals and physicians should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient work-arounds to try to ensure that their efforts to achieve the goals of the new payment models are achieved and do not run afoul of such laws and regulations. The exception also should apply when an arrangement includes other providers and professionals.

DISTINGUISHING BETWEEN TECHNICAL AND SUBSTANTIVE VIOLATIONS AND OTHER STARK LAW CHALLENGES

While originally intended to provide a “bright line” standard to assure hospitals and others clear guidance, the self-referral law has evolved into a series of increasingly complex, confusing and continually changing rules. Many involve form and audit-type requirements that carry the same weight as the core requirements of a legitimate arrangement for compliance purposes. As a result, the Stark law places hospitals at risk for draconian compliance penalties that have no relationship to the harm, if any, to the Medicare program. As a strict liability statute, any violation is subject to the same penalty – return of any amount paid by the Medicare program for services provided to a beneficiary and billed to the program based on a physician’s “self-referral,” without regard to whether the services were medically necessary.

Congress recognized the difficulties created when all requirements in the law are given the same weight when it granted the Secretary authority to develop a self-referral disclosure protocol (SRDP) to enable providers to disclose actual or potential violations. Importantly, the Secretary also was granted authority to determine what, if any, repayment is due by a provider based on the individual facts and circumstances of the situation after consideration of certain factors: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.

The AHA supported creation of an SRDP throughout the legislative process as a means to address the unintended consequences of a strict liability approach and restore fairness to a law that makes compliance a virtual impossibility. We urged, and continue to urge, that the amount of any repayment should be calibrated to the harm, if any, to the program. Distinguishing “technical” from “substantive” violations has become shorthand for identifying the types of violations for which there should be no repayment or only a nominal amount.

In principle, we believe that any requirement governing the form rather than the substance of an arrangement is a technical rather than substantive requirement. This would include: a requirement that an arrangement be set forth in writing; a requirement that the writing setting forth the arrangement be signed by one or more parties to the arrangement; and/or a requirement that an arrangement that expires according to the terms of the writing be extended under the

terms of a written amendment or new agreement. For example, arrangements involving missing signatures, or where a course of dealing demonstrates that parties had agreed to an economically compliant but undocumented, or improperly documented, arrangement would be covered.

We believe the statute should require that enforcement take into account mitigating factors when a violation does occur. These factors should include: whether the violation is “technical” or “substantive;” whether the parties’ failure to meet all the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; the corrective action taken by the parties; whether the services provided were reasonable and medically necessary; whether access to a physician’s services was required in an emergency situation; or whether the Medicare program suffered any harm beyond the statutory disallowance.

Regarding other Stark law challenges, the most consequential are the unpredictable and potentially catastrophic developments occurring in litigation. Punitive fines and penalties are threatened that bear no relation to the value or volume of the harm novel relationships may cause the federal health care programs. And even worse, the guidance issued by the Centers for Medicare & Medicaid Services to implement the law is being disregarded and has now been shown to be irrelevant as a defense to hospitals who relied on it. As described earlier in this letter, fair market value, commercial reasonableness and the volume/value prohibition are imbedded in the exceptions for compensation arrangements. The specter of relators and the relator’s bar taking control of how to interpret the Stark law in service of achieving the financial bounties available under the False Claims Act, will no doubt chill, and could extinguish, the development of new relationships essential to the success of the new reimbursement models.

Thank you for the opportunity to provide input on this important issue. We stand ready to provide additional detail on our recommendations. If you have any questions or would like additional information, please contact Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org or Robyn Bash, vice president of government relations and public policy operations, at (202) 626-2672 or rbash@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

CC:

The Honorable Kevin Brady
The Honorable Sander Levin
The Honorable Peter Roskam
The Honorable John Lewis
The Honorable Patrick Tiberi
The Honorable James McDermott

Moving Health Care Forward:

Barriers that Prevent Hospitals and Physicians from Working Together to Improve Care

(And what to do about them)

The health care landscape is rapidly changing, driven by advances in technology, a rise in consumerism and the continued switch from payment models dictated by volume to ones focused on value. Hospitals across the nation are adapting by eliminating silos and replacing them with a continuum of care to improve the quality of care delivered, the health of their communities and overall affordability. Standing in the way of their success is an outdated regulatory apparatus predicated on enforcing laws no longer compatible with the new realities of health care delivery. Chief among these outdated barriers are portions of the Anti-kickback Statute and the Ethics in Patient Referral Act (also known as the “Stark Law”).

Hospitals are taking significant steps to create a continuum of care, also known as clinical integration. At its heart, clinical integration is about better care for patients through teamwork: It emphasizes developing relationships – between hospitals and physicians, and with other health care professionals – across different sites of care.

Clinical integration can take many forms. In some, different providers may collaborate to tackle a single condition, like diabetes. In others, the hospital, doctors and other caregivers may function as a single entity, working together to provide seamless care to all patients. Regardless of its form, clinical integration relies on teamwork – with the aim of getting individuals the right care at the right time, in the right setting.

At the same time, advances in medical practice, technology and quality are influencing the way care is delivered and how decisions are made about what care is most appropriate for an individual patient. In fact, clinical knowledge doubles as fast as every two years. Clinical integration is important to ensure all patients benefit from these advances. It also helps to drive down costs by improving efficiency and making the health care system easier to navigate for patients and providers alike.

Public and private payers are increasingly holding hospitals accountable for delivering care that can only be accomplished through teamwork with physicians, including the alignment of financial incentives. In contrast, the Anti-kickback and Stark laws were designed to keep hospitals and physicians at arm's length.

These laws are no longer keeping up with the practice of medicine and must be updated or replaced to enable providers to continue to transform care delivery and usher in a new era of value.

Congress has recognized there are legal barriers currently in place and authorized waivers of the laws to enable implementation of new payment models. Waivers for the Medicare Shared Savings Program and other accountable care arrangements were expressly authorized. The Secretary of Health and Human Services (HHS) has consistently waived provisions of the Anti-kickback, Stark and Civil Monetary Penalty (CMP) Laws to achieve the goals of new payment models, most recently to enable implementation of the Comprehensive Care for Joint Replacement (CCJR) model.

Recently, Congress acknowledged the need for a permanent fix to the CMP law. The Medicare Access and CHIP Reauthorization Act of 2015 limited the scope of this prohibition, which had prevented hospitals from offering physicians incentives to follow evidence-based care guidelines, so that a hospital or critical access hospital is only subject to CMPs for making payments to reduce or limit medically necessary care. All federal health program beneficiaries should have the opportunity to benefit from the quality and care coordination improvements that clinically integrated organizations can provide.

Read on for more on each barrier and how it can be overcome.

Continued

The Ethics in Patient Referrals Act (The ‘Stark’ Law)

What is this law and why is it a barrier?

Usually called the Stark law, the Ethics in Patient Referrals Act was originally enacted to ban doctors from referring patients to facilities in which they had a financial interest (known as self-referral). However, a tight web of regulations and other prohibitions that have grown up around the law can now prohibit arrangements designed to encourage hospitals and doctors to work together to improve patient care in a clinical integration program.

The Stark law requires that compensation for physicians be fixed in advance and paid only for hours worked. As a result, payments that are tied to achievements in quality and efficiency instead of hours worked do not meet the law’s strict standards.

That means a hospital and primary care physician who want to improve care for patients post-discharge by adding a social worker and nurse practitioner to the care team could be found in violation if the physician is rewarded for the quality of care provided by the other team members and clinical outcomes of the patients. The hospital and physician can face penalties under the Stark

and Anti-kickback laws even though the nurse practitioner’s monitoring of medications, and the social worker’s follow-up to make sure all of the care in the discharge plan is in place, would minimize trips to the emergency department and avoidable readmissions would be reduced.

The law is so strict that, in order to launch the Medicare Shared Savings Program and other demonstration projects supporting clinical integration, the Secretary had to waive this and other laws. Without these waivers, a government-led program, in which hospitals were able to share cost savings with non-employed physicians who participated in a well-designed effort to enhance quality and efficiency, would have been in violation of the law.

Those found in violation face severe consequences: In addition to civil penalties, providers can be barred from serving patients covered by Medicare, Medicaid and other federal programs for years, effectively shutting down the hospital and ending the doctors’ careers.

What’s a solution?

Refocus the Stark law on its original intent of regulating self-referral to physician-owned entities.

This could be done by removing compensation arrangements from the definition of “financial relationships” that are subject to the Stark law. These same compensation arrangements would still be regulated, but by other federal laws already on the books, such as the anti-kickback and civil money penalty law, that are better equipped to do so.

The Anti-Kickback Law

What is this law and why is it a barrier?

The anti-kickback law was intended to protect patients and federal health programs from fraud and abuse. The law states that anyone who knowingly and willfully receives or pays anything of value as an incentive to influence the referral of federal health program business, including Medicare and Medicaid, can be held accountable for a felony. Today, the law has been stretched to cover any financial relationship between hospitals and doctors.

For example, if, as part of a clinical integration program, a hospital rewards a doctor for following evidence-based clinical protocols, the reward could be construed as violating the anti-kickback law. This is because, technically, such a reward could influence a doctor's order for treatment or services.

For example, a hospital that wanted to improve care for patients experiencing a heart attack by working with emergency department (ED) physicians to implement guidelines for administering a specific medication within a specific period of time (e.g., a blood thinner medication within 30 minutes of arrival in the ED) could run afoul of the anti-kickback law,

even though the intervention is a best practice to minimize damage to the heart. The law carries both civil and criminal penalties and can result in both the hospital and the doctor being barred from Medicare, Medicaid and other federal programs, effectively shutting down the hospital and ending the doctor's career.

Although the Department of Health and Human Services' Office of Inspector General can protect good medical practices, such as the one above, by issuing an advisory opinion, the process is costly and of very limited value. Advisory opinions are strictly limited to the facts in the letter delivering the opinion, and to the person making the official request for that opinion. They do not protect other clinical integration programs that seek to engage in the very same activity.

Congress, recognizing that the anti-kickback statute sometimes thwarts good medical practices, has periodically created "safe harbors" to protect those practices. However, there is no safe harbor for clinical integration programs that reward physicians for improving quality.

What's a solution?

Congress should create a safe harbor for clinical integration programs.

The safe harbor should allow all types of hospitals to participate in such programs, establish core requirements to ensure a program's protection from anti-kickback charges, and allow flexibility in meeting those requirements so the programs can achieve their health care goals.

Workplace Safety



**American Hospital
Association**

DATE: March 2016
TO: Regional Policy Boards
SUBJECT: Workplace Safety

Objective

To discuss violence in hospitals and learn from members what they are seeing, how they are reacting, and the policies they have in place.

This agenda item has a homework assignment that was distributed in advance of the meeting. It is attached again for your reference (Attachment A).

Background

Workplace violence is an increasingly recognized safety issue in the health care community. Workplace violence is generally defined as any act or threat of physical assault, harassment, intimidation and other coercive behavior. It also includes lateral violence, or bullying, between colleagues (e.g. nurse/nurse, doctor/nurse, etc.). The Bureau of Labor Statistics (BLS) reports that workers in health care and social assistance settings are five times more likely to be victims of nonfatal assaults or violent acts than the average worker in all other occupations, estimating 11,370 assaults in 2010. While workplace violence against health care professionals can and does happen everywhere, the hospital emergency department is among the most vulnerable settings.

According to a 2011 study by the Emergency Nurses Association (ENA), 54.5 percent of 6,504 emergency nurses surveyed experienced physical violence and/or verbal abuse from a patient and/or visitor during the past week. The actual rate of incidences of violence is likely much higher as many incidents go unreported, due in part to the perception that assaults are “part of the job.”

An article recently published by *The New York Times*, “When the Hospital Fires the Bullet,” gives an account of how an incident involving one patient exhibiting erratic behavior escalated into a major safety episode (article and AHA letter to the Editor in Attachment B). This incident, among many others that are not as well-documented, illustrates the importance of safety across health care facilities for all – patients, families, and staff.

A *Hospitals & Health Networks Daily* article published in July, 2015, “Addressing Violence in the Health Care Workplace” highlights many of the critical issues around this topic (Attachment C). Of note, the implications and costs of workplace violence are critical to this conversation because of the lasting emotional effects on providers and financial effects on facilities.

Risk Factors for Violence in Health Care Settings

Hospitals have become a de facto safety net for the acute and chronically mentally ill who lack adequate treatment options. Furthermore, societal issues, especially the opioid epidemic, are increasing the potential for violence in hospitals. The Occupational Health and Safety Administration's (OSHA) Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers enumerate additional risk factors that are associated uniquely with health care settings.

- Lack of staff training in recognizing and managing escalating hostile and assaultive behavior.
- The prevalence of weapons (handguns, etc.) among patients, their families or friends.
- The increasing use of hospitals by police and the criminal justice system for criminal holds and the care of acutely disturbed, violent individuals.
- Unrestricted movement of the public in health care facilities and long waits in the emergency or clinic areas.
- Increasing presence of gang members, drug or alcohol abusers, trauma patients, or distraught family members.

States Take Action

According to national nursing and state hospital associations, there are 21 states that have laws designating penalties for assault of nurses. Seven states require employers to offer workplace violence prevention programs to staff, although the requirements, in some cases, are limited to only public employees (New York); to only emergency room personnel (Louisiana); or only to public health personnel (Mississippi). In 2015, the Minnesota state legislature passed a law requiring hospitals to develop and maintain a violence prevention response program. California also passed legislation in 1993 requiring staff training and development of a security plan, and it has been updated since then to include a variety of perspectives and interests from the regulatory and labor community.

Discussion Questions:

Please complete the homework assignment as preparation to discuss the following:

1. Do you think that the incidence or severity of inappropriate behavior and threats of harm/violence in health care facilities is increasing, decreasing, or about the same?
2. Is this an issue that you believe AHA should assist members in addressing at the federal level?
3. What policy initiatives, tools and resources would help you deal with violence in hospitals?

Attachments:

Homework Assignment

New York Times article and AHA letter to the Editor, February 2016

H&HN article, July 2, 2015



**American Hospital
Association**

DATE: February 26,2016
TO: Regional Policy Boards
SUBJECT: Homework Assignment on Workplace Safety

We are looking forward to seeing you at the upcoming Spring Regional Policy Board meetings. You will receive your full packet of meeting materials shortly.

To prepare for the discussion on Workplace Safety, we are asking RPB members to complete a brief homework assignment.

The objective of the agenda item is to discuss ways that societal issues lead to violence in hospitals and learn from members what they are seeing, how they are reacting, and the policies they have in place.

Workplace violence is an increasingly recognized safety issue in the health care community. An article recently published by *The New York Times*, "[When the Hospital Fires the Bullet](#)," gives an account of how an incident involving one patient exhibiting erratic behavior escalated into a major safety episode. The full article will be in your meeting materials, together with a letter to the editor by Pam Thompson, chief nursing officer and senior vice president of the AHA, and chief executive of the American Organization of Nurse Executives.

Homework Assignment:

To best prepare for the meeting, we ask you to talk to your Chief Nursing Officer, Director of Security or Director of Risk Management to explore the following questions:

1. Does your facility have a written policy to address incidents on the part of staff, patients, and/or families that threaten harm to others?
2. Do you formally train personnel to recognize and intervene in incidents that potentially or actually threaten others?
3. Do you track and monitor incidents that occur in your facility that have resulted in physical harm or threatened violence against staff, patients, or families?
4. Do you think that the occurrence of these events is increasing? Decreasing? About the same?

If you have any questions about the homework assignment, please contact Chantal Worzala (cworzala@aha.org).

Thomas P. Nickels
Executive Vice President

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The New York Times <http://nyti.ms/1LkEjW>
U.S.

When the Hospital Fires the Bullet

More and more hospital guards across the country carry weapons. For Alan Pean, seeking help for mental distress, that resulted in a gunshot to the chest.

By ELISABETH ROSENTHAL FEB. 12, 2016

When doctors and nurses arrived at Room 834 just after 11 a.m., a college student admitted to the hospital hours earlier lay motionless on the floor, breathing shallowly, a sheet draped over his body. A Houston police officer with a cut on his head was being helped onto a stretcher, while another hovered over the student.

Blood smeared the floor and walls. "What happened?" asked Dr. Daniel Arango, a surgical resident at the hospital, St. Joseph Medical Center.

The student, 26-year-old Alan Pean, had come to the hospital for treatment of possible bipolar disorder, accidentally striking several cars while pulling into the parking lot. Kept overnight for monitoring of minor injuries, he never saw a psychiatrist and became increasingly delusional. He sang and danced naked in his room, occasionally drifting into the hall. When two nurses coaxed him into a gown, he refused to have it fastened. Following protocol, a nurse summoned security, even though he was not aggressive or threatening.

Soon, from inside the room, there was shouting, sounds of a scuffle and a loud pop. During an altercation, two off-duty Houston police officers, moonlighting as security guards, had shocked Mr. Pean with a Taser, fired a bullet into his chest, then handcuffed him.

"I thought of the hospital as a beacon, a safe haven," said Mr. Pean, who survived the wound just millimeters from his heart last Aug. 27. "I can't quite believe that I ended up shot."

Like Mr. Pean, patients seeking help at hospitals across the country have instead been injured or killed by those guarding the institutions. Medical centers are not required to report such encounters, so little data is available and health experts suspect that some cases go unnoticed. Police blotters, court documents and government health reports have identified more than a dozen in recent years.

They have occurred as more and more American hospitals are arming guards with guns and Tasers, setting off a fierce debate among health care officials about whether such steps -along with greater reliance on law enforcement or military veterans -improve safety or endanger patients.

The same day Mr. Pean was shot, a patient with mental health problems was shot by an off-duty police officer working security at a hospital in Garfield Heights, Ohio. Last month, a hospital security officer shot a patient with bipolar illness in Lynchburg, Va. Two psychiatric patients died, one in Utah, another in Ohio, after guards repeatedly shocked them with Tasers. In Pennsylvania and Indiana, hospitals

have been disciplined by government health officials or opened inquiries after guards used stun guns against patients, including a woman bound with restraints in bed.

Hospitals can be dangerous places. From 2012 to 2014, health care institutions reported a 40 percent increase in violent crime, with more than 10,000 incidents mostly directed at employees, according to a survey by the International Association for Healthcare Security and Safety. Assaults linked to gangs, drug dealing and homelessness spill in from the streets, domestic disputes involving hospital personnel play out at work, and disruptive patients lash out. In recent years, dissatisfied relatives even shot two prominent surgeons in Baltimore and near Boston.

To protect their corridors, 52 percent of medical centers reported that their security personnel carried handguns and 47 percent said they used Tasers, according to a 2014 national survey. That was more than double estimates from studies just three years before. Institutions that prohibit them argue that such weapons -and security guards not adequately trained to work in medical settings -add a dangerous element in an already tense environment. They say many other steps can be taken to address problems, particularly with people who have a mental illness.

Massachusetts General Hospital in Boston, for example, sends some of its security officers through the state police academy, but the strongest weapon they carry is pepper spray, which has been used only 11 times in 10 years. In New York City's public hospital system, which runs several of the 20 busiest emergency rooms in the country, security personnel carry nothing more than plastic wrist restraints. (Like many other hospitals, the system coordinates with the local police for crises its staff cannot handle.)

"Tasers and guns send a bad message in a health care facility," said Antonio D. Martin, the system's executive vice president for security. "I have some concerns about even having uniforms because I think that could agitate some patients."

But many hospitals say that with proper safeguards -some restrict armed officers to high-risk areas like emergency rooms and parking areas -and supervision, weapons save lives and defuse threatening situations. The Cleveland Clinic, which has placed metal detectors in its emergency room, has its own fully

armed police force and hires off-duty officers as well. The University of California medical centers at Irvine and San Diego and small community hospitals are among the more than 200 facilities that use stun guns produced by Taser International, which has courted hospitals as a lucrative new market.

"I've worked in systems where everyone has a firearm and an intermediate weapon, and I've worked in systems where a call to security meant the plumber and every able-bodied man would respond," said David LaRose, past president of the health care security association. "How much has your system thought about safety and security? In some places that's a 2 or 3; in some places it's a 10."

After Mr. Pean's shooting, St. Joseph's chief executive, Mark Bernard, said the officers were "justified." The hospital said it was reviewing its practices but declined to respond to questions. The Houston Police Department, citing an internal investigation, declined to comment or to make the officers available for interviews, and released only a heavily redacted version of its report on the shooting. This account is drawn from a review by federal health investigators, medical records, criminal complaints and interviews with medical personnel and family members.

Mr. Pean had expected an apology after the shooting. Instead, during four days in intensive care, prosecutors charged him with two counts of felony assault on a police officer. They accused him of attacking with four "deadly weapons" - an unspecified piece of furniture, a wall fixture, a tray table and his hands.

James Kennedy, a lawyer representing Mr. Pean, says his client disputes that he was the aggressor and other allegations by the police, but cannot discuss specifics until the charges are resolved. His family has filed complaints with the Justice Department and health care regulators, including the Centers for Medicare and Medicaid Services, which provides funding to most American hospitals.

After an emergency investigation, the Medicare agency faulted St. Joseph for the shooting, saying it had created "immediate jeopardy to the health and safety of its patients." Threatening to withdraw federal money, the agency demanded restrictions on the use of weapons.

A family with Haitian and Mexican roots who settled in McAllen, Tex., the Peans

were shocked that Mr. Pean's effort to get medical aid ended so badly. Though his father, Harold Pean, and a half-dozen other relatives are physicians, they said they had no idea that guns could be used against patients. After watching the nation roiled by the shootings of unarmed black men by police officers over the last year or so, the family now wonders whether race contributed to Alan's near-fatal encounter.

"We never thought that would happen to us," Dr. Pean said.

'I'm Manic!'

In his family of high-achievers, Alan Pean (pronounced PAY-on) is the soft-spoken and mellow middle sibling, into yoga, video games and pickup football. Christian, 28, now a medical student at Mount Sinai in New York, is the Type A leader; Dominique, 24, is following his path, applying to medical school while pursuing a master's degree. Alan, who had never been in any sort of trouble, is "probably the nicest of us three," Dominique said.

Like many people with mental health issues, he did not get a clear-cut diagnosis. After a brief delusional episode in 2008, he was hospitalized for a more severe recurrence the next year, at the end of his second year at the University of Texas. He was kept for a week and told that he had possible bipolar disorder, though his symptoms did not reappear for years even after he tapered off medication.

He was prone to bouts of sadness and anxiety, he recalled in an interview, but had attended college, taking breaks from time to time, and worked for a while as a medical assistant back home in McAllen, near the Mexican border. Though he had smoked marijuana regularly to help tame his symptoms, he said in an interview, he quit last summer when he enrolled at the University of Houston to complete his bachelor's degree.

Just days into the semester, though, he barely slept and found himself increasingly agitated and delusional.

On Aug. 26, he talked repeatedly on the phone with his parents and brothers, who tried to calm him but worried that he sounded disoriented. Christian had been concerned enough that he called the Houston police to do a "welfare check" on his

brother at his apartment, though no one answered the door when officers arrived.

When Mr. Pean sounded worse in the evening, his family summoned a fraternity brother in Houston to take him to an emergency room; his parents would fly in the next morning. But Mr. Pean did not wait. His mind vacillating between the knowledge that he needed psychiatric medication and encroaching delusions that he was a Barack Obama impersonator or a "Cyborg robot agent" who was being pursued by assassins, he said, he got into his white Lexus and drove at high speed to St. Joseph Medical Center, the only major hospital in downtown Houston.

Turning into the parking lot just before midnight, he crashed, nearly totaling his vehicle. As Mr. Pean was helped into the emergency room and onto a stretcher by paramedics and nurses, he recalled, he yelled: "I'm manic! I'm manic!"

He was seen immediately by a doctor from the trauma team to assess his injuries (scans and exams showed none). The physician's initial note, minutes after arrival, lists the young man's history of bipolar disorder. His father and brother, in separate phone calls to the emergency room, and a family friend who came to the hospital, alerted the staff about his psychiatric issues, they recalled.

Nonetheless, Mr. Pean was admitted for observation to Room 834 on a surgical floor. The diagnoses: hand abrasion, substance abuse, motor vehicle accident. His toxicology tests were negative for alcohol, opiates, PCP or cocaine, records show. (They did disclose some THC, the active ingredient of marijuana, but the chemical remains in the body for many weeks.)

While St. Joseph does have a psychiatric ward, Mr. Pean was never seen by a psychiatrist or prescribed any psychiatric medicines before the shooting. Because he had complained of back pain, he was given Flexeril, a muscle relaxant, which can exacerbate psychotic symptoms.

In interviews with the Medicare investigators and notations in medical records, the nurses who cared for Mr. Pean describe a man who had flashes of lucidity, but was increasingly restless and bizarre.

He pulled out the IV in his arm. He thought it was 1989. He could not remember the car crash or why he was in a hospital. But even in the throes of his illness, he was

polite. When a nurse told him to return to his room after he repeatedly emerged naked into the hall, he complied, she told investigators, with a "Yes ma'am, righty-o, O.K. ma'am."

'No Clear Guidance'

Though the trauma team had planned to discharge Mr. Pean that morning, his parents were so alarmed when they arrived about 10 a.m. that they insisted a psychiatrist see him. As they waited for doctors to discuss their concerns, the Peans went to their nearby hotel to try to rent a car and drive their son to a psychiatric facility. In their 30-minute absence, a nurse made the call to security.

At St. Joseph Medical Center, the security force included armed off-duty police officers as well as unarmed civilian officers. Who responded to a call depended only on availability, according to the investigators' interview with the chief nursing officer.

The two men who arrived were Houston police officers. Roggie V. Law, 53, who is white, and Oscar Ortega, 44, who is Latino, each had decades on the force. They supplemented their base salaries of about \$64,000 by moonlighting at the hospital. Their records were unremarkable. Both had some commendations, and Officer Ortega had one distant four-day suspension for failing to submit an accident report.

Houston police officers get 40 hours of crisis intervention training, according to the department. The N.A.A.C.P. and the Greater Houston Coalition for Justice, a civil rights group, have complained that local officers too often use their weapons, and repeatedly requested the appointment of an independent police review board. From 2008 to 2012, there were 121 police shootings, in which a quarter of the victims were unarmed, according to an investigation by The Houston Chronicle.

The two off-duty officers had signed on with Criterion Healthcare Security, a four-year-old staffing agency based in Tennessee whose executives had previously managed prisons and owned gyms. Their training at St. Joseph consisted of an orientation and online instruction, which investigators found inadequate. "The facility had no clear guidance for the role, duties and responsibilities of the police officers they employ to provide security services," the Medicare investigators' report said.

Like many other security firms, Criterion encourages applications from those with law enforcement or military backgrounds, who are trained to use weapons and to deal with volatile situations. But working in health care settings requires a different mind-set, security experts emphasize.

"If they come from law enforcement or the military, I ask them directly, 'How would you respond differently here than if you encountered a criminal on a street in L.A. or when you are kicking down a door in Iraq?'" said Scott Martin, the security director at the University of California, Irvine, Medical Center. "You have to send the message that these are patients, they're sick, the mental health population has rights -and you need to be sensitive to that."

Many mental health professionals strongly object to weapons in hospitals, saying they have numerous other means -from talk therapy to cloth restraints and seclusion rooms to quick-acting shots of sedatives -to subdue patients if they pose a danger. State mental health facilities typically do not allow guns or Tasers on their premises; even police officers are asked to check weapons at the door. (Twenty-three percent of shootings in emergency rooms involved someone grabbing a gun from a security officer, according to a study by Dr. Gabor Kelen, director of emergency medicine at Johns Hopkins Medical School.)

Uniforms and weapons may, in fact, exacerbate delusions, since many psychotic patients are paranoid and, like Alan Pean, believe they are being pursued. Anthony O'Brien, a researcher at the University of Auckland, in New Zealand, said, "That's not a good thing, pointing something that looks like a gun at a patient with mental health issues."

When the two Houston officers arrived on St. Joseph's eighth floor, they headed for Room 834. Unannounced, and unaccompanied by doctors, nurses or social workers, they went in, the door closing behind them.

Anxious Patient to Felony Suspect

Racing upstairs to a Code Blue in Room 834, Dr. Arango found a cluster of about 20 Houston police officers in the hall, according to his interview with investigators.

When he pulled back the sheet covering Mr. Pean, he saw that the patient was in handcuffs, his torso dotted with Taser probes and a bloody wound on his upper chest. It was only after the doctor noted the blood pooling around the young man, who began shouting that he was Superman as the physician tried to examine the wound, that someone mentioned he had not only been hit with the Taser, but also shot.

"Take the damn handcuffs off!" Dr. Arango yelled, according to an employee.

Initially combative and flailing, Mr. Pean allowed a staff member to start an IV as she told him: "It's O.K., Alan, I'm a nurse. We're here to help." Within minutes, doctors placed him on a ventilator, inserted a tube into his chest and whisked him away for a scan, which showed that the bullet had fractured his fifth and sixth ribs, scattering metal fragments and causing extensive bleeding as it ripped through his chest.

According to a statement on the Police Department's website, Alan struck one officer in the head, causing a laceration, when they arrived in the room. Officer Law shocked the patient with a Taser, to no apparent effect, and then Officer Ortega, fearing for their safety, shot Mr. Pean.

After the shooting, his father said officers asked over and over if Alan had a criminal record. The next day, Christian Pean asked Sgt. Steve Murdock, a Houston police investigator, why the officers had to shoot his brother. In a phone conversation, Christian recalled, the sergeant replied, "Let's just say the term 'Tasmanian devil' comes to mind."

"It was like a big whirlwind," he went on. "Everything was fair game. Objects, chairs, eating trays, everything was being thrown."

An ambiguity in Medicare rules allowed Alan Pean's conversion from delusional patient to felony suspect. If a patient throws a tray at a nurse and the staff responds with restraints, it can be considered a health care incident. If the same patient throws the same tray at a police officer, even one off-duty, who shoots in response, the encounter is subject to a criminal investigation.

While Mr. Pean was in the intensive care unit, he was handcuffed to his bed, even though he was heavily sedated, with a Houston police officer standing guard.

His family had to post \$60,000 bail days later so he could be discharged from the hospital.

Mr. Pean's felony case is likely to go before a grand jury in the coming months. Under the care of a psychiatrist and on medication, Mr. Pean left Texas behind. Living with his brother in New York, he is finishing his degree at Hunter College and planning to go to graduate school in public health.

But the day before Christmas, Mr. Pean learned that prosecutors had brought a new charge -reckless driving -against him, referring to his race to the hospital.

Accompanied by his father, he flew to Houston. In five hours of processing at the Harris County Detention Center, Mr. Pean was interviewed by a detention officer, photographed for a mug shot and fingerprinted. "Being paraded around was really stressful," he said. "Did they not understand what I'd gone through? I'd been shot in a hospital room by an officer."

Paul DeBenedetto contributed reporting from Houston.

A version of this article appears in print on February 14, 2016, on page A1 of the New York edition with the headline: When the Hospital Fires the Bullet.

New York Times
Letter to the Editor
Published online: February 23, 2016
Published in the paper: February 24, 2016

[“When the Hospital Fires the Bullet”](#) (front page, Feb. 14) reports on the changing nature of health care facility security. The article on rare incidents of violence highlights the challenge that hospitals face daily both to serve our patients and protect the dedicated men and women who care for them 24/7.

Hospital doors, especially emergency rooms, are open to everyone, and many of society’s ills — domestic abuse, gang violence, family disputes and more — find their way to the hospital doorstep. Hospital patients, their loved ones and members of the community must have a safe environment where caring and healing can occur. And hospital workers need a safe environment while caring for patients.

The complex issues of assuring that patients are safe and protecting hospital workers are best addressed on a hospital-by-hospital basis, and specific training and education are essential. But it doesn’t stop there.

As a society, we must also do more to better address our country’s growing mental health care challenges. America’s hospitals are already working to do both and welcome the support of the communities and patients we serve.

PAM THOMPSON
Washington

The writer is chief nursing officer and senior vice president of the American Hospital Association, and chief executive of the American Organization of Nurse Executives.

Addressing Violence in the Health Care Workplace

 www.hhnmag.com/articles/3365-addressing-violence-in-the-health-care-workplace

Emergency nurses are frequently victims of violence, but often fail to report it. Encouraging them to report acts of physical and verbal violence helps to ensure their safety.

July 2, 2015

[Pamela Thompson, R.N.](#)

Workers in health care and social assistance settings are five times more likely to be victims of nonfatal assaults or violent acts than the average worker in all other occupations, according to the Bureau of Labor Statistics.

Nurses in the emergency department are disproportionately victims of workplace violence according to the Emergency Department Violence Surveillance Study, conducted by the Emergency Nurses Association, which found that 55.6 percent of nurses reported they had experienced physical violence, verbal violence or both. Furthermore, the study found that 57.6 percent of nurses surveyed rated the safety of their ED as a 5 out of 10 or lower (ENA, 2010).

Guidance Toward a Solution

The growing number of reported incidents of violence in the workplace is a clear indicator that hospitals need to make a concerted effort to raise their commitment toward eliminating workplace violence. The ENA, whose journal cover sports the phrase "Safe Practice, Safe Care," and the American Organization of Nurse Executives, whose goal is to "establish healthy work environments for all care providers," held a day of dialogue about workplace violence.

The day of dialogue was a forum for AONE and ENA representatives to talk about workplace violence. Participants, ED nurses and nurse leaders in the acute care setting discussed how incidents of violence are currently addressed in hospitals; the necessity of partnership between hospital leaders, especially nurse leaders and nursing staff; and the need to create an environment in which health care professionals, patients and families feel safe. Participants developed guiding principles and prioritized action items to assist all hospital leaders in systematically reducing lateral, or colleague-to-colleague, violence as well as violence perpetrated by patients and family members.

Fighting a Culture of Acceptance

There is an underlying cultural problem within the health care setting regarding workplace violence: Workers tend not to report incidents, specifically in the ED. Recent research indicates that many health care workers underreport violence because it is inconvenient and they accept such conditions as "part of the job," according to a Medscape Multispecialty report (quoted in Bird, 2015). The Emergency Department Violence Surveillance Study found that 65.6 percent of physical violence victims and 86.1 percent of verbal abuse victims did not file a formal report (ENA, 2010). This culture of acceptance among health care workers may contribute to the incidence and prevalence of workplace violence; it also may also contribute to the difficulty in enacting and enforcing felony laws related to the assault of health care workers.

Implications and Costs

The most devastating impact of violence to health care professionals is their inability to feel safe at work. One-third of emergency nurses surveyed considered leaving their ED or emergency nursing because of ED violence (ENA, 2010).

Costs to nursing in terms of physical injury and financial loss are significant. Staff turnover associated with bullying and sickness can cost between \$60,000 and \$100,000 for RN replacement, according to an AORN Journal editorial. Furthermore, this disruptive behavior can lead to increased lengths of hospital stay for patients, reduced patient satisfaction and facility reputation, and malpractice/negligence liability costs that can amount to more than \$500,000. (Seifert, 2011.)

Involving Law Enforcement

Some states have sought legislative solutions including mandatory establishment of a comprehensive prevention program for health care employers, as well as increased penalties for those convicted of assaults of a nurse or other health care personnel. It is a felony to assault health care workers in 32 states.

"Anyone who has worked in a hospital setting recognizes that you never know who is going to walk through the doors and in what state of mind," said Sen. Alex Padilla in response to recent attacks in California hospitals (quoted in Simmons, 2014). Sen. Padilla authored California Senate Bill 1299, which requires additional safety training and greater employee security.

One incident of violence is one too many. Stressing a zero-tolerance policy supported and observed by every person in the organization is the first step toward enacting change and shifting away from a culture that accepts violence as a part of the job.

Pamela A. Thompson, M.S., R.N., C.E.N.P., F.A.A.N., is senior vice president of nursing and chief nursing officer at the American Hospital Association, and the CEO of the American Organization of Nurse Executives.

Visit aone.org/workplaceviolence to view the complete "Guiding Principles on Mitigating Violence in the Workplace" and the accompanying toolkit.

Guiding Principles on Mitigating Violence in the Workplace

The guiding principles and priorities listed below are steps to systematically reduce bullying as well as patient and family violence in the workplace. The guiding principles and accompanying toolkit are available at aone.org/workplaceviolence.

1. Recognize that violence can and does happen anywhere.
2. Understand that healthy work environments promote positive patient outcomes.
3. All aspects of violence (from patients and family members as well as coworkers) must be addressed.
4. A multidisciplinary team, including patients and families, is required to address workplace violence.
5. Everyone in the organization is accountable for upholding foundational behavior standards, regardless of position or discipline.
6. When members of the health care team identify an issue that contributes to violence in the workplace, they have an obligation to address it.
7. Intention, commitment and collaboration of nurses with other health care professionals at all levels are needed to create a culture shift.
8. Addressing workplace violence may increase the effectiveness of nursing practice and patient care.

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FIG. 2. Getting Started
Five strategies are critical to a successful workplace violence prevention program.

1. **Necessary foundational behaviors.** What is the social environment of the institution or unit?
2. **Essential elements of a zero-tolerance policy.** How should environmental hazards be addressed?
3. **Ensuring ownership and accountability.** Does the institution embrace the Just Culture concept?
4. **Proper training and education.** What are evidence-based training techniques?
5. **Outcome metrics.** How can hospitals measure success?