Prescription for Change: Congressional Actions Impacting Healthcare Providers

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Today’s Presentation

- A View from Capitol Hill
  - The 114th Congress & The Senate Finance Committee
  - Legislative Process Overview
- Recent Legislative & Policy Changes Affecting Physician Practices
  - Audits and Appeals
  - Physician Transparency Requirements
  - Physician Payment – SGR Legislation
  - Fraud and Abuse
Disclaimer & Fine Print

The comments expressed by Kimberly Brandt are her own opinions and ideas, and do not reflect the opinions of the Senate Finance Committee or Senator Orrin G. Hatch.

A View from Capitol Hill
Standing Committees
Agriculture, Nutrition, and Forestry
Appropriations
Armed Services
Banking, Housing, and Urban Affairs
Budget
Commerce, Science, and Transportation
Energy and Natural Resources
Environment and Public Works
Finance
Foreign Relations
Health, Education, Labor, and Pensions
Homeland Security and Governmental Affairs
Judiciary
Rules and Administration
Small Business and Entrepreneurship
Veterans' Affairs
Special, Select, and Other
Indian Affairs
Select Committee on Ethics
Select Committee on Intelligence
Special Committee on Aging
Joint
Joint Committee on Printing
Joint Committee on Taxation
Joint Committee on the Library
Joint Economic Committee

What is it and What does it do?

Finance Committee Jurisdiction:
- Tax matters
- Social Security
- Medicare & Medicaid
- Supplemental security income
- Family welfare programs
- Social services
- Unemployment compensation
- Maternal and child health
- Revenue sharing
- Tariff and trade legislation
- Oversees 50% of Federal Budget

History
- During the 14th Congress (1815–1817), the Senate created the Select Committee on Finance to handle some of the proposals set forth in President James Madison's message to Congress
- On December 10, 1816, the Senate established the Committee on Finance as a standing committee of the Senate
Committee Leadership

Chairman Orrin Hatch

Ranking Member Ron Wyden

Democrats
- Chuck Schumer
- Debbie Stabenow
- Maria Cantwell
- Bill Nelson
- Robert Menendez
- Tom Carper
- Ben Cardin
- Sherrod Brown
- Michael Bennett
- Bob Casey
- Mark Warner

Republicans
- Chuck Grassley
- Mike Crapo
- Pat Roberts
- Mike Enzi
- John Cornyn
- John Thune
- Richard Burr
- Johnny Isakson
- Rob Portman
- Pat Toomey
- Dan Coats
- Dean Heller
- Tim Scott

How a Bill Becomes a Law - Simplified
Political Outlooks 2016

Presidential Election Year = Big Changes

- **House of Representatives**
  - Currently solidly Republican with Republican speaker
  - Slim potential for shift to Democrat control

- **Senate**
  - Currently Republican control (shift from 113th Congress)
  - Potential for shift to Democrat control

- **White House**
  - Party conventions in July and then candidates will be official
  - Election on November 8th
Senate Balance of Power in Question

Control of Senate May Seesaw Back to Democrats in 2016
Projected Control of the Senate, 2016 and Beyond

Recent Legislative & Policy Changes Impacting Physician Practices
Audits and Appeals

Recovery Audit Contractors (RACs)

Who are they?
• Four private companies that run Medicare’s Recovery Audit Program

What do they do?
• Identify improper payments from Medicare Part A and B claims.
• Analyze claims and review those most likely to contain improper payments, which may include:
  • (1) payment for items or services that do not meet Medicare’s coverage and medical necessity criteria;
  • (2) payment for items that are incorrectly coded; and
  • (3) payment for services where the documentation submitted did not support the ordered service.
• Request and analyze provider claim documentation to ensure services provided were reasonable and necessary.
Controversy

What’s the big deal?

- RACs are paid on a contingency-fee basis.
- CMS coding standards are complex and constantly changing.
- RACs can audit healthcare providers for up to three years.

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Understanding the RACs Appeals Process

The five-levels of appeal include:

- Redetermination by the Medicare Administrative Contractor;
- Reconsideration by a Qualified Independent Contractor;
- Administrative Law Judge Hearing;
- Medicare Appeals Council Review; and
- Judicial Review in U.S. District Court.

Problems with the process:

- Overloaded system, causing at least a two-year delay at the ALJ level
- High cost of RAC appeals
Updates on RACs

- On June 4, 2015, CMS withdrew the Requests for Quotes for the next round of Recovery Auditor contracts.
- RACs were legislatively prohibited from auditing short stay observation services until September 30, 2015.
- CMS announced that RACs would no longer audit short stays; beginning on October 1, 2015, Quality Improvement Organizations (QIOs) took responsibility for inpatient status reviews. Beginning on January 1, 2016, QIOs and Recovery Auditors began conduct patient status reviews in accordance with policy changes finalized in the OPPS rule and effective in calendar year 2016.
- At the end of December, CMS proposed to expand the risk adjustment audit program to cover all Medicare Advantage (MA) plans, every year.

Audit & Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015 (AFIRM)

June 4, 2015 – Senate Finance Committee passed AFIRM.

Purpose:
- Seeks to increase coordination and oversight of government audit contractors while implementing new strategies to address growing number of audit determination appeals that delay taxpayer dollars from reaching the correct source.

December 8, 2015 – Chairman Hatch introduced AFIRM, S. 2368, and it was placed on the Senate Legislative Calendar.
AFIRM of 2015

Proposed Changes

1. Improve oversight capabilities for HHS/CMS that increase the integrity of the Medicare auditors and claims appeals process.

2. Coordinate efforts between auditors and CMS to ensure that all parties receive transparent data regarding audit practices, improved methodologies, and new incentives/disincentives to improve auditor accuracy.

3. Establish voluntary alternate dispute resolution process to allow for multiple pending claims with similar issues of law or fact to be settled as a unit, rather than as individual appeals.

AFIRM of 2015

4. Ensure timely and high quality reviews, raise amount in controversy for review by an ALJ to match amount for review by District Court.

5. Allow for use of sampling and extrapolation, with the appellant’s consent, to expedite the appeals process.
Physician Payment: SGR

SGR = Sustainable Growth Rate

- The Medicare Sustainable Growth Rate (SGR) is a method intended to be used by the Centers for Medicare & Medicaid Services (CMS) to control spending by Medicare on physician services.
- Since 2002, the SGR would have resulted in decreases in physician payment under the Medicare Physician Fee Schedule (PFS), but Congress has delayed these reductions.
Physician Payment: SGR

**What’s the big deal?**

- The SGR formula has been criticized for incentivizing volume over value.
- Congress’s annual “doc fix” measures from 2003 through 2014 have delayed the impact of cumulative cuts, which grew each year.
- By 2015, the magnitude of cuts to physician payments would have totaled over 20%.

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Physician Payment: SGR

**Latest Developments: Repeal of SGR**

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
- Signed into law April 16, 2015
- In a nutshell:
  - Repeals SGR formula
  - Consolidates and integrates existing payment incentive programs
  - Calls for phased long-term implementation
Physician Payment: SGR

Latest Developments: Repeal of SGR

Physician Payment: SGR Repealed

What happens next?

- 2015-2019
  - Annual increases in the PFS of 0.5%
  - Continued application of Physician Quality Reporting System (PQRS), Meaningful Use of Electronic Health Records (EHR), and Value-Based Payment Modifier measures
    - Sunset in 2018
  - Development of criteria for Physician-Focused Payment Models (PFPMs) by November 2016
Physician Payment: SGR Repealed

What happens next?

• Starting in 2019
  ◦ PFS rates generally frozen at 2019 levels
  ◦ Payment adjustments under the Merit-Based Incentive Payment System (MIPS)
  ◦ MIPS will incorporate elements of the sunsetting PQRS, Meaningful Use, and VBPM measures

• 2019-2024
  ◦ Alternative Payment Models (APMs): 5% payment bonus

Physician Payment: SGR Repealed

What happens next?

• Starting in 2026
  ◦ 2 separate conversion factors:
    • Qualifying Alternative Payment Models (APMs) – 0.75%
    • Nonqualifying APMs – 0.25% + MIPS adjustments
Physician Payment: SGR Repealed

Latest Developments: CMS Request for Information

- Responses and comments due to CMS by November 2, 2015.
- Generally, CMS seeks feedback on MIPS, APMs, and technical assistance to small practices.

Physician Payment: SGR Repealed

Latest Developments: CMS Request for Information

- CMS seeks comments on various aspects of MIPS, including how to identify eligible professionals, establishment of processes for “virtual groups” of small practices, and measurement of MIPS evaluation factors.
- On APMs, CMS expressed particular interest in defining eligible alternative payment entity, the relationship between APMs and MIPS, and criteria for the PFPM Technical Advisory Committee.
Physician Transparency Requirements

The Sunshine Act

- **Section 6002 of the Affordable Care Act**
  - Requires certain drug, device, and supply manufacturers to report payments – direct and indirect – and other transfers of value provided either to physicians or teaching hospitals.
  - Requires manufacturers and group purchasing organizations (GPOs) to report ownership or investment interests held by physicians or immediate family members of physicians.
  - Regulations released in February 2013 and November 2014.
The Sunshine Act: Open Payments Data

- CMS has published data for 2013 and 2014.
- Data includes over 15 million records.
- Payments amount to nearly $10 billion of total undisputed payments in 2013 and 2014.
  - From over 1,600 companies to 683,000 physicians and over 1,100 teaching hospitals
  - Captured payments include research payments of $4.78 billion, ownership or investment interest payments of $1.61 billion, and general payments of $3.53 billion.
- CMS website provides searchable and downloadable data at openpaymentsdata.cms.gov.

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<td>Total value published on 12/19/2014</td>
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<tr>
<td>Total number of records published on 12/19/2014</td>
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<td>Total number of physicians published on 12/19/2014</td>
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<td>Total number of teaching hospitals published on 12/19/2014</td>
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<td>Total number of applicable manufacturers and applicable group purchasing organizations (GPOs) represented in the published data on 9/30/2014</td>
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<tr>
<td>Total number of applicable manufacturers and applicable GPOs represented in the published data on 12/19/2014</td>
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* rounded
+ up to 546,000 (rounded) based on possible physician identifier inconsistencies within de-identified data
** up to 1,360 (rounded) based on possible teaching hospital identifier inconsistencies within de-identified data

Summary of 2014 Data: [https://www.cms.gov/OpenPayments/Downloads/Fact-Sheet-Published-Data.pdf](https://www.cms.gov/OpenPayments/Downloads/Fact-Sheet-Published-Data.pdf)
Fraud and Abuse

MACRA’s Fraud and Abuse Provisions

§ 504 – DME Face-to-Face Encounter Documentation
- Allows documentation by physicians, physician assistants, nurse practitioners, or specialists.

§ 505 – Medicare Administrative Contractor Improper Payment Outreach and Education Program
- Amends § 1874A of the Social Security Act to give providers and suppliers information from Recovery Audit Contractor program data regarding:
  - Most frequent and expensive payment errors (quarterly);
  - Instructions on correcting and avoiding such errors;
  - Notice of new topics for RAC audits; and
  - Instructions on preventing issues related to such audits.
- Imposes restrictions on the use of recovered funds (no capital investments or IT infrastructure)
MACRA’s Fraud and Abuse Provisions

§ 512 – Eliminating Certain CMPs; Gainsharing Study & Report

- Amends Gainsharing CMP at § 1128A(b)(1) of the Social Security Act to limit prohibition on gainsharing to medically unnecessary services.
- Requires the HHS Office of Inspector General to submit a report to Congress with options for amending laws to allow for more gainsharing arrangements by April 16, 2016.

Physician Self-Referral Law ("Stark Law")

"[If a physician (or an immediate family member of such physician) has a financial relationship with an entity ... then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made]" under Medicare and to some extent Medicaid.

Social Security Act § 1877; 42 U.S.C. § 1395nn
Identifying a Financial Relationship

- “Financial relationship” is defined as any direct or indirect (a) ownership or investment interest or (b) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the designated health service (DHS).

- DHS refer to 13 types of services.

Stark Law Problems & Potential Solutions

**PROBLEMS**
- Complex and rigid law with difficult exceptions
- Diverged from original intent
- Not aligned with health care delivery reform
- Complicating efforts to implement alternative payment models like ACOs and bundled payments

**SOLUTIONS**
- **H.R. 2914 (2013)** – limiting scope of DHS and narrowing in-office ancillary services exception
- **H.R. 3776 (2013)** – reducing penalties for technical violations
- Expanding Medicare Shared Savings Program Waivers
Recent CMS Changes to Stark Regulations

  - New Exceptions
    - “Assistance to compensate a nonphysician practitioner (NPP)” exception
  - Clarifications
    - Writing requirement.
    - One-year term requirement for office space rental, equipment rental, and personal service arrangements exceptions.
    - “Split bill” arrangements
  - Revision to “temporary noncompliance with signature” requirement
  - Indefinite holdover provisions

Other Stark Law Proposals

**Legislation:**

  - Amends Social Security Act Title XIX to clearly apply Stark-like prohibitions.
  - Creates direct False Claims Act liability for Stark Law violations.

**Other Changes:**

- **Obama Administration Proposed FY 2016 Budget**
  - Excludes radiation therapy, therapy services, advanced imaging, and anatomic pathology services from the in-office ancillary services Stark Law exception unless a practice is “clinically integrated” and demonstrates cost containment.
Committee Work on Stark Law

- **December 2015** – Senate Finance Committee and House Ways and Means Committee host roundtable to hear from Stark Law experts.
  - Invited key stakeholders to submit suggestions for improving the Stark Law.
- **February 2015** – Reviewing submissions and preparing a white paper on proposed legislative fixes for the law.

Physician-Owned Distributorships (PODs)
What are PODs?


• “Physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).”

POD Developments

• **June 2011** – Senate Finance Committee Report on Physician-Owned Entities

• **March 26, 2013** – OIG Special Fraud Alert on PODs released

• **October 23, 2013** – OIG’s Report on PODs (per Congressional request)
POD Developments

- **November 2014** – U.S. DOJ filed two False Claims Act complaints against a Michigan neurosurgeon, a spinal implant company, two of its distributorships, and the companies’ owners.

- **May 2015** – A Michigan neurosurgeon, previously involved in a FCA complaint, pleaded guilty to $111 million in fraud for unneeded surgeries and patient harm.

- **May 2016** – Finance Committee issues updated report on marketplace impact of PODs post OIG fraud alert.

Bipartisan Chronic Care Working Group
Bipartisan Chronic Care Working Group

- **May 15, 2015** – Bipartisan working group formed.
  - Tasked with developing bipartisan legislative solutions to help patients battling multiple chronic conditions.

- **May 22, 2015** – Senate Finance Committee invites interested stakeholders to submit ideas on ways to improve outcomes for those in chronic care.

- **August-October 2015** – 580 stakeholder comments are received and studied.

Three Bipartisan Goals

**Proposed Policy:**

1. Increases care coordination among individual providers across care settings
2. Incentivizes the appropriate level of care for beneficiaries living with chronic diseases
3. Produces stronger patient outcomes while increasing program efficiency
Looking Forward

- **December 2015** – Bipartisan Chronic Care Working Group Policy Options Document released.
  - Intended to generate additional input from Finance Committee members and stakeholders in creating a more finite list of policy ideas.
- **Common Goal for the Future**: develop policy options based on data-driven input that aids in producing a legislative product that can be introduced in 2016.

Receiving High Quality Care in the Home

Home-based primary care teams seek to improve patient outcomes while reducing health care costs.

**Ideas for Consideration**

- Expand the Independence at Home (IAH) Model
- Expand Access to Home Hemodialysis Therapy
Advancing Team Based Care

For chronically ill beneficiaries, interdisciplinary health care teams can lead to stronger patient outcomes and reduce overall expenditures.

**Ideas for Consideration**
- Provide Medicare Advantage Enrollees with Hospice Benefits
- Allow End Stage Renal Disease Beneficiaries to Choose a Medicare Advantage Plan
- Provide Access to Medicare Advantage SNPs for Vulnerable Populations
- Improve Care Management Services for Those with Multiple Conditions
- Address the Need for Behavioral Health among the Chronically Ill

Expanding Innovation and Technology

Innovation in benefit design and technology can increase beneficiary access to services that are critical to improve chronic disease management.

**Ideas for Consideration**
- Adapt Benefits to Meet the Needs of Medicare Advantage Enrollees
- Expand Supplemental Benefits to Help Chronically Ill Enrollees
- Increase Convenience for Enrollees through Telehealth
- Provide ACOs the Ability to Expand Use of Telehealth
- Maintain ACO Flexibility to Provide Supplemental Services
- Expand Use of Telehealth for Individuals with Stroke
Identifying the Chronically Ill Population and Ways to Improve Quality

Plans, providers, and beneficiaries all benefit from policies that ensure the appropriate payment for and evaluation of care provided to chronically ill beneficiaries.

**Ideas for Consideration**
- Ensure Accurate Payment for Chronically Ill Individuals
- Provide Flexibility for Beneficiaries to be Part of an Accountable Care Organization
- Develop Quality Measures for Chronic Conditions

Empowering Individuals and Caregivers in Care Delivery

Providing timely, accurate tools and information can empower beneficiaries to better manage their chronic diseases.

**Ideas for Consideration**
- Encourage Beneficiary Use of Chronic Care Management Services
- Establish a One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness
- Eliminate Barriers to Coordination under Accountable Care Organizations
- Expand Access to Prediabetes Education, and Digital Coaching
Other Policies to Improve Care

**Ideas for Consideration**

- Increase Transparency at the Center for Medicare & Medicaid Innovation
- Implement Findings from Study on Medication Synchronization
- Implement Findings from Study on Obesity Drugs

Questions?
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