Prescription for Change: Congressional Actions Impacting Healthcare Providers

Kimberly Brandt, JD
Chief Oversight Counsel, U.S. Senate Committee on Finance

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

114th Congress - Senate

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

History:
- During the 18th Congress (1815–1817), the Senate created the Select Committee on Finance to handle some of the proposals set forth on 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

Democrats
- Dick Durbin
- Debbie Stabenow
- Michael Bennett
- Mark Warner
- Bob Casey
- Chuck Grassley
- Johnny Isakson
- John Cornyn
- Pat Roberts
- Mike Crapo
- Dan Coats
- Tim Scott

Republicans
- Mitch McConnell
- Ron Wyden
- Tim Scott
- Steve Daines
- John Barrasso
- Tammy Baldwin
- Jerry Moran
- John Thune
- Sherrod Brown
- John Walsh
- Joni Ernst
- Tom Cotton
- Steve Daines
- Dean Heller

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
  - Clinton or Trump – who will prevail???
  - Election on November 8th
Recent Legislative & Policy Changes Impacting Physician Practices

Audits and Appeals

RAC Controversy

- What’s the big deal?
  - RACs are paid on a contingency-fee basis.
  - CMS coding standards are complex and constantly changing.
  - RACs have been able to audit healthcare providers for up to three years.
Understanding the RACs Appeals Process

- **Problems with the appeals process:**
  - Overloaded system, causing at least a two-year delay at the ALJ level.
  - High cost of RAC appeals.

Updates on RACs

- RACs were statutorily prohibited from auditing short stay observation services through September 30, 2015.
- June 4, 2015 – CMS withdrew Requests for Quotes for the next round of RAC contracts.
- October 1, 2015 – CMS shifted enforcement of the Two Midnight Rule from RACs to Quality Improvement Organizations (QIOs), with caveats after January 1, 2016.
- January 1, 2016 – RACs may conduct patient status reviews for providers referred by the QIO as exhibiting persistent noncompliance.
- May 3, 2016 – CMS issued updated guidance on Additional Documentation Limits for Medicare Institutional Providers (i.e., Facilities).

OMHA Workload – Appeal Receipts

*Includes appeals with RFH Date in listed fiscal year and excludes reopened appeals. Revised Date: December 31, 2015. FY15 and FY16 complex red changes in methodology to reflect actual matters including conditional appeals.*
FY15 dispositions through September 2015. Appeals decided in listed fiscal year and excludes remands. Run Date: December 15, 2015

OMHA Workload – ALJ Productivity

OMHA Initiatives

- Settlement Conference Facilitation (SCF) Pilot
- Statistical Sampling Pilot
- Attorney On-The-Record (OTR) Initiative
- Electronic Case Adjudication Processing Environment (ECAPE)

OMHA Settlement Conference Facilitation

- Alternative Dispute Resolution (ADR) process.
- CMS and the appellant are the parties to the negotiation; OMHA is a neutral facilitator.
- Both parties must agree to the settlement.
  - If the parties reach agreement, a settlement agreement is signed and OMHA dismisses the appeals.
  - If no agreement, appeals return to prior status and place in queue.
- Distinct from CMS Part A inpatient hospital settlement.

See OMHA website for more detailed requirements, instructions, and a description of the process. Email questions to OMHA.SCF@hhs.gov.
OMHA Settlement Conference Facilitation

- Over 330 providers, suppliers, and stakeholders attended October 15, 2015, Open Door teleconference.
- 39 Expressions of Interest have been received since Phase II began.
- OMHA has 16 trained facilitators.
- Phase III (some Part A) expansion is tentatively planned for 2016.

Data current as of January 5, 2016

OMHA Senior Attorney OTR Initiative

- Began July 1, 2015, with 4 Senior Attorneys.
- In consultation with an ALJ (who reviews and signs the decision), Senior Attorneys review and draft decisions for appeals in which a decision can be made on the record under the rules (e.g., hearing waived).
  - To date, 904 appeals assigned, most from Q3/4 FY2013 receipts.
  - 408 appeals decided.
- Average time from assignment to decision = 56.5 days.
- Currently 9 Senior Attorneys assigned to initiative.

Data current as of January 5, 2016
OMHA Statistical Sampling Pilot

- Appellants may request or be invited to participate if they have a sufficient number of pending Part A/B claims that meet pilot criteria (currently 250).
- Employs Medicare Program Integrity sampling methodology (CMS Pub. 100-08, Ch. 8).
- OMHA furnishes statistical expert.
- ALJ decides sample claims, OMHA statistician extrapolates the sample results to universe of claims, and CMS effectuates.

See OMHA website for more detailed requirements, instructions, and a description of the process. Email questions to OMHA.stat.sampling@hhs.gov.

OMHA Electronic Case Adjudication Processing Environment (ECAPE)

ECAPE Release Schedule

- Release 1 (spring 2016)
  - Phase 1 of Appellant Public Portal
- Release 2 (winter 2016/2017)
  - Case Adjudication (assignment through decision)
- Release 3: (spring 2017)
  - Phase II of Appellant Public Portal

Release schedule is subject to change

OMHA Appellant Outreach and Transparency

- OMHA Website
  - http://www.hhs.gov/omha/
  - ListServ
- ALJ Appeal Status Information System
  - http://aasis.omha.hhs.gov/
- Appellant Forum
  - http://www.hhs.gov/omha/, go to OMHA Appellant Forum
Audit & Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015 (AFIRM)

On June 4, 2015, the U.S. 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.

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.

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.
Fraud and Abuse

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

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<th>PROBLEMS</th>
<th>SOLUTIONS</th>
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<td>Complex and rigid law with difficult exceptions</td>
<td>H.R. 2914 (2013) – limiting scope of DHS and narrowing in-office ancillary services exception</td>
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<td>Diverged from original intent</td>
<td>H.R. 3776 (2013) – reducing penalties for technical violations</td>
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<td>Not aligned with health care delivery reform</td>
<td>Expanding Medicare Shared Savings Program Waivers</td>
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<td>Complicating efforts to implement alternative payment models like ACOs and bundled payments</td>
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Recent CMS Changes to Stark Regulations

  - New Exceptions
    - "Assistance to compensate a nonphysician practitioner (NPP)" exception
    - "Timeshare arrangements" 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 2016 – Reviewing submissions and preparing
  a white paper on proposed legislative fixes for the law.
- July 2016 – Committee Hearing on issues with Stark
  law – 3 witnesses, great discussion.

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 distributors, and the companies’ owners.
- **May 2015** – A Michigan neurosurgeon, previously involved in a FCA complaint, pleaded guilty to $11 million in fraud for unneeded surgeries and patient harm.
- **November 2015** – Finance Committee PODs hearing examining pros and cons of issue.
- **May 2016** – Finance Committee issues updated report on marketplace impact of PODs post OIG fraud alert.
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 Vets 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?

Contact Information

Kimberly Brandt
Kim.Brandt@finance.senate.gov
(202) 224-4515