Legislative and Regulatory Update: Policy Changes for Long-term Care

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Disclosure

Brad Kile is an independent consultant and has no financial interest or relationships to disclose.

Learning Objectives

• Identify key dates and benchmarks set by the U.S. Department of Health and Human Services to transition Medicare payments to quality-based measures.
• Compare new policies to assess patient outcomes and measure quality in different care settings.
• Describe new Florida health care policy changes that impact pharmacists.
• List the main financial incentives under Value-based Purchasing, the Bundled Payments for Care Initiative, and Medicare Accountable Care Organizations.
Presentation Outline

• Congressional Agenda
• Affordable Care Act in 2016
• Key Regulatory Issues
• Questions and Answers

Congressional Agenda

2016 Congressional Agenda

• Election Year Politics
• House and Senate – Limited “work” days
• Themes:
  • Republicans Confident
  • No Standoff or Government Shutdown
  • Extended Summer Recess – partisan politics
  • Post-election “Lame Duck” Likely
### Congressional Accomplishments

#### Medicare Part B “SGR” Repeal (Signed into Law)
- The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) signed into law April 16, 2015
- Increase of 0.5% for 7/1/15 – 2019

#### 21st Century Cures (HR 6. Passed House; Pending in Senate)
- Streamline clinical trials
- Advance personalized medicine
- Incentives to develop drugs for uncommon but deadly diseases
- $1.75 billion per year in funding to the National Institutes of Health; $550 million in additional funding to FDA

### Pharmacy-Related Bills

- **Provider Status.** Pharmacy and Medically Underserved Areas Enhancement Act of 2015 (S. 314 / H.R. 592)
- **Preferred Network Access.** Ensuring Seniors Access to Local Pharmacies Act of 2015 (S. 1190 / H.R. 793)
- **Drug Abuse and Diversion.** Ensuring Patient Access and Effective Drug Enforcement Act of 2015 (S. 483 / H.R. 471)

### New Opioid Law

- Senate-passed “Comprehensive Addiction and Recovery Act”
  - Prevention, treatment, and recovery
  - Disposal of unused medications
  - Partial fills
- Signed into law July 2016
Opioid Law: Pharmacy Lock-In

Background:
- Policymakers passed a Medicare Part D “pharmacy lock-in” policy as part of CARA to address prescription medication abuse.
- Initial pharmacy lock-in language would have allowed a Medicare Part D drug benefit sponsor to limit (“lock-in”) certain at-risk beneficiaries to a specific pharmacy and a single prescriber for frequently abused drugs.

Polling Question #1

The new pharmacy “Lock-in” policy for Medicare Part D beneficiaries due to:
A. Concerns about recent mergers and acquisitions among pharmacy benefit managers (PBMs) and pharmaceutical manufacturers.
B. Sharp increases in prescription drug abuse and misuse.
C. Concerns about too many plan options for beneficiaries.
D. The low number of plan options for beneficiaries in rural areas.
E. All of the above.

Affordable Care Act in 2016
ACA IMPLEMENTATION

2010-13
Regulate Industry
- Insurance Reform

2014
Coverage Expansion
- Individual Mandate

2015-2020
Restructure Care Delivery
- Quality Ties to Payment

HHS Goals

Overall Medicare Payments - Alternate Care Models
- 2016 – 30% of Medicare payments
- 2018 – 50% of Medicare payments

Fee for Service Payments Linked to Quality & Value
- 2016 – 80% of Medicare fee-for-service
- 2018 – 90% of Medicare fee-for-service

Medicare in Transition

Medicare beneficiaries

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Medicare beneficiaries</th>
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<tbody>
<tr>
<td>2010</td>
<td>46,589,000</td>
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<tr>
<td>2011</td>
<td>47,672,000</td>
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<tr>
<td>2012</td>
<td>49,435,000</td>
</tr>
<tr>
<td>2013</td>
<td>52,000,000</td>
</tr>
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</table>
New Models of Care

Emphasis on Linking Care Across Settings
- Bundled Payment
- Hospital Readmissions

Emphasis on Quality Outcomes and Care Coordination
- Value Based Purchasing
- Accountable Care Organizations

Bundled Payment - Demo
- Single payment for episode of care
- Follows patients across settings
- Four models tested
- Organizations choose up to 48 clinical episodes of care to test
- Organizations enter into payment arrangements that include financial and performance accountability for episodes of care

Bundled Payment - Required
- Comprehensive Care for Joint Replacement (CJR) model
- Started April 1, 2016 in 67 geographic areas and is mandatory
- Hospital in which the hip or knee replacement and/or other major leg procedure takes place is accountable for the costs and quality from surgery through 90 days after discharge ("episode" of care)
- Based on quality and cost performance, hospital earns financial reward or, beginning in second year, be required to repay Medicare for a portion of the spending above target
Polling Question #2

Which of the following is NOT true regarding the Medicare Bundled Payments for Care Improvement Initiative?

A. Organizations enter into payment arrangements that include financial and performance accountability for episodes of care.
B. Providers in 48 geographic areas are required to participate.
C. Four models being tested.
D. Organizations choose up to 48 clinical episodes of care to test.
E. All of the above are true.

Value-Based Purchasing

Applies to hospitals now, Coming to NHs in 2018

- All providers “contribute” to pool with % of Medicare payments withheld
- Providers scored on quality measures
- Pool dollars distributed to high performers, other receive not additional dollars
- Sets up competition among providers
- Hospitals applying pressure to post-acute providers
Value-Based Purchasing

Where we are Headed
Hospital: refinement and expansion of measures
• ACA calls for VBP in nursing homes, hospice and ambulatory surgical centers
• Legislation signed into law in March 2014 requires nursing home VBP by 2019
• Nursing home: regulatory pathway

Accountable Care Organizations

ACOs: Quality Measures

ACOs MUST MEET QUALITY TARGETS before they are eligible for shared savings.

33 Quality Measures across 4 Domains
1. Patient/caregiver experience (7 measures)
2. Preventive health (8 measures)
3. At-risk population (12 measures)
4. Care coordination (6 measures)
ACOs

- Jan 2016, 100 new ACOs and 147 renewing
- Currently 434 ACOs serving 7.7 million Medicare beneficiaries.
- 55 Million total beneficiaries
- 14% of all Medicare beneficiaries in an ACO

Key Regulatory Issues

5-Star Ratings Across Medicare

- Nursing Home Compare
- Health Inspections
- Staffing
- Quality Measures

2015 and Beyond
- Hospital Compare
- Dialysis
- Home Health
Nursing Home Star-Rating System

• Created by CMS to help consumers compare nursing homes more easily
• Each nursing home gets new rating every year
• Website data updated monthly
• Total rating is based on:
  – Health inspections
  – Staffing
  – Quality measures

Nursing Home Measures

• Five Domains:
  – General information
  – Inspection results
  – Staffing
  – Quality measures
  – Penalties
• Overall rating, fines, and payment denials

Nursing Home Measures

Effective February 20, 2015
• Antipsychotics use (short stay/long stay)
• Improved calculations for staffing levels
• Higher standards to achieve a high rating on the quality measure dimension
Nursing Home Measures

May 2016
• 6 new quality measures added to the Nursing Home Compare website
• 3 of the 6 are first to be based on hospital Medicare-claims data
• Now total of 24 quality measures

% short-stay residents:
1. successfully discharged to community (claims-based)
2. with outpatient emergency department visit (claims-based)
3. re-hospitalized after a nursing home admission (claims-based)
4. with improvements in function (MDS-based)

% long-stay residents:
5. whose ability to move independently worsened (MDS-based)
6. receiving an antianxiety or hypnotic medication (MDS-based)

IMPACT Act

Standardizing Quality Measures in Post-Acute Care
• Passed by Congress on September 2014
• Improving Medicare Post-Acute Care Transformation Act of 2014
• PAC Settings:
  – Long Term Care Hospitals
  – Inpatient Rehabilitation Facilities
  – Skilled Nursing Facilities
  – Home Health Agencies
IMPACT Act

• Standardized patient assessment, quality measures, and resource use.
• Quality measures include:
  • functional status and change in function;
  • skin integrity;
  • medication reconciliation;
  • incidence of major falls; and
  • patient preference of treatment and discharge options.

IMPACT Act

• Will require more resources from PAC providers to collect and transmit data.
• Standardized data essential for transforming future payment reforms that drive quality and efficiency while protecting beneficiary access to appropriate services.
• Site-neutral payments?

Polling Question #3

The IMPACT Act will standardize patient assessments for which settings:
A. Skilled Nursing Facilities
B. Home Health
C. Long-term Care Hospitals
D. Inpatient Rehabilitation
E. All of the above
Long Term Care Mega Rule

• First significant policy update to LTCF conditions of participation in 25 years
  • Changes centered on person-centered care, quality, facility assessment, and care transitions

• Issues
  • Drug regimen review
  • Psychotropic medications
  • Infection control

Medication Therapy Management

Part D 2017

• Enhanced MTM model test in 5 Part D regions: Region 7 (Virginia); Region 11 (Florida); Region 21 (Louisiana); Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming); and, Region 28 (Arizona).

• Details at: http://innovation.cms.gov/initiatives/enhancedmtm/

Medication Management Services

• Policy Makes and Payors ID the critical role it plays for new incentives
  • Labels- MTM, DRR, Med Reconciliation, CMR, CDTM
  • Are these getting in the way of one another
  • Payment for services...hourly or per-patient model vs. outcome-based
  • Many options, how many real opportunities?
USP Chapter Updates

USP <795> Pharmaceutical Compounding - Nonsterile Preparations

- Current version released in 2011
- Minor edit in 2014, remove reference to sterile in reference to beyond-use date (BUD) in the table. BUD specific for nonsterile.
- USP review started in 2015
- No timeline for release, public comment, or effective date

USP <797> Pharmaceutical Compounding - Sterile Preparations

- Procedures/requirements for compounding sterile preparations
- Conditions/practices to prevent harm to patients
  - Proposed revisions issued in Dec. 2015: [www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision](http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision)
- Earliest published date Nov 2016 - implementation of May 2017.
  - May 2016 Notice: Based on public comments and significance of further revisions the chapter may be proposed for another public comment period.
USP <800> Hazardous Drugs - Handling in Healthcare Settings

- Published February 2016, implementation date July 1, 2018
- Standards to protect staff, patients, pharmacists, and environment when handling hazardous drugs.
- Covers all entities that handle, store, prepare, transport, or administer hazardous drugs.
- Specifies hazardous materials must be compounded within proper work environment and using proper equipment.
- Consistent with series of draft guidance FDA released in February 2016.

FDA Compounding Updates

How Did We Get Here?

- November 2013, President Obama signed the Drug Quality and Security Act (DQSA)
- Changes Federal Food, Drug, and Cosmetic Act (FDCA) and sets up two classifications: 503A Traditional Compounders and 503B “Outsourcing Facilities” that can be exempt from requirements:
  - FDA approval prior to marketing
  - Labeling with adequate directions for use
  - Compliance with current good manufacturing practice (CGMP) (exemption for 503A only)
FDA Compounding Policy

**FDA Rules and Guidance - Final**
- Compounding under section 503A
- Interim policies on compounding using bulk drug substances under sections 503A and 503B (two separate draft guidances)
- Guidance for entities considering whether to register as outsourcing facilities
- Outsourcing facility fees
- Registration of outsourcing facilities
- Adverse event reporting for outsourcing facilities

**FDA Notices and Draft Guidance**
- Repackaging non-biologics
- Draft MOU - how states will handle interstate distribution/dispensing
- Notice regarding procedure for inspections of entities – 503A
- Mixing, diluting, and repackaging biologics
- Compounded Drug Products that are Essentially Copies of a Commercially Available Drug Product (two separate draft guidances)
- Draft and revised draft product reporting guidance for outsourcing facilities
- Interim CGMPs for outsourcing facilities

**Key Areas of Concern**

Repackaging of Certain Human Drug Products (Draft)
- Would eliminate use of emergency kits
- Restricts remote dispensing technologies
- Places limits on the amount of pre-packaging conducted by pharmacies

Compounding Memorandum of Understanding (Draft)
- Confuses "dispensing" and "distribution"
- Caps the distribution of compounded products across state lines by pharmacies at 30%
- Fails to define the term "unit"

Procedure for Inspections of 503A
- Clarifies inspection process
- Compliance with CGMPs
A Look Ahead... 2016 Elections

2016 Elections

- What the presidential candidates are saying about health care reform
- Congress and the Agencies
  - House
  - Senate
  - CMS – FDA – DEA - EPA

Questions?
THANK YOU

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