2015 Health Reform & Reimbursement Outlook

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Review of 2014 Election Results
ACA/Health Reform Update and Outlook
Medicare & Medicaid Update
Other Reimbursement Issues
Q&A/Discussion
2014 Election Results: Senate

Net Gain of 9 Seats Gives Republicans Majority in the US Senate for First Time Since 2007

<table>
<thead>
<tr>
<th>113th Congress</th>
<th>114th Congress</th>
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<tbody>
<tr>
<td>45 Rep</td>
<td>54 Rep</td>
</tr>
<tr>
<td>53 Dem</td>
<td>44 Dem</td>
</tr>
<tr>
<td>2 Ind</td>
<td>2 Ind</td>
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New Senators -- Class of 2015

- Shelly Moore Capito (R-WV)
- Steve Daines (R-MT)
- James Lankford (R-OK)
- Mike Rounds (R-SD)
- Thom Tillis (R-NC)
- Bill Cassidy (R-LA)
- Joni Ernst (R-IA)
- David Perdue (R-GA)
- Ben Sasse (R-NE)
- Tom Cotton (R-AR)
- Cory Gardner (R-CO)
- Gary Peters (D-MI)
- Dan Sullivan (R-AK)
2014 Election Results: House

Net Gain of 13 Seats Gave Republicans Largest Majority in the US House Since 1928*

113th Congress

234 Rep

201 Dem

114th Congress

245* Rep

188 Dem

Class of 2014 includes:

• 44 new Republicans, 16 new Democrats
• 48 men and 12 women, inc. youngest woman ever elected (Elise Stefanik, R-NY, 30 yrs)
• First wife to succeed her husband (Debbie Dingell, D-MI)
• First African-American Republican from Texas (Will Hurd, R-NY)
• First African-American Republican woman (Mia Love, R-UT)
• Several successful tea-party primary challengers, two pastors, one physician and one dentist

*Resignation of Michael Grimm (R-NY) on 1/5/15 has created one open seat and reduced Republican majority to largest since 1947.
New Federal Health Policy Leaders

SENATE LEADERSHIP
Mitch McConnell – Majority Leader
John Cornyn – Majority Whip
Roger Wicker – NRSC Chair

Harry Reid – Minority Leader
Dick Durbin – Minority Whip
Jon Tester – DSCC Chair

HOUSE LEADERSHIP
John Boehner – Speaker
Kevin McCarthy – Majority Leader
Greg Walden – NRCC Chair

Nancy Pelosi – Minority Leader
Steny Hoyer – Minority Whip
Ben Ray Lujan – DCCC Chair

SENATE COMMITTEES
Lamar Alexander – Chair, HELP
Orrin Hatch – Chair, Finance

Patty Murray -- Ranking, HELP
Ron Wyden -- Ranking, Finance

HOUSE COMMITTEES
Fred Upton – Chair, Energy & Comm.
Paul Ryan – Chair, Ways & Means
Joe Pitts – Chair, E&C Health
Kevin Brady -- Chair, W&M Health

Frank Pallone -- Ranking, E&C
Sander Levin -- Ranking, W&M
2014 Election Results:
Governorships

Net Gain of 2 Gives Republicans 31 State Governorships, Greatest Majority Since 1998
Net Gain of 11 Chambers, Gives Republicans Control of 31 State Legislatures

2014 Election Results: State Legislatures

Republican (31)
Democrat (11)
Split Control (8)
2015 Plan Offerings
Enrollment Projections
Implementation Issues
Pending Legal Challenges
Potential Legislative Action
In ACA’s 2\textsuperscript{nd} Year, Increases in Current Plan Costs are Being Mitigated in Part by New, Lower Cost Plan Options

- **Gross Premium Costs of Many Plans Are Up**
  - Avg. Premium Cost of Re-filed Lowest Cost Plans Up 10%
  - If All Who Could Re-enroll in Same Plan Did, Average Costs Would Increase by 9%

- **But, New Entrants Are Offering Lower Cost Options**
  - Number of Participating Carriers in 2015 Up by 19%
  - Total # of Plan Offerings Up 27% Nationally; Average # of Plan Choices Increasing from 30 to 40

~75% of Current Enrollees Will Have Access to a Similar (Same Metal Tier) Lower Premium Plan Option – But Higher Cost-Sharing and Narrower Provider Networks May Be Required

ACA 2015 Premium Changes

Lowest-price silver net premium change

Net premium change in 2014 lowest-price silver to 2015 lowest-price silver

$ PMPY premium change for all QHP-eligible consumers

## Average Cost-Sharing by Cost-sharing Category by Exchange Plan Type, 2015 FFE* Plan Filings

<table>
<thead>
<tr>
<th>Cost-sharing Category</th>
<th>Bronze</th>
<th>Silver</th>
<th>Gold</th>
<th>Platinum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deductible, Individual</td>
<td>$5,181</td>
<td>$2,927</td>
<td>$1,198</td>
<td>$243</td>
</tr>
<tr>
<td>Deductible, Family</td>
<td>$10,545</td>
<td>$6,010</td>
<td>$2,626</td>
<td>$489</td>
</tr>
<tr>
<td>Primary Care Copay</td>
<td>34%</td>
<td>$29</td>
<td>$23</td>
<td>$18</td>
</tr>
<tr>
<td>Specialist Copay</td>
<td>34%</td>
<td>$57</td>
<td>$45</td>
<td>$29</td>
</tr>
<tr>
<td>Annual OOP Max, Individual</td>
<td>$6,373</td>
<td>$5,775</td>
<td>$4,298</td>
<td>$1,971</td>
</tr>
<tr>
<td>Annual OOP Max, Family</td>
<td>$12,749</td>
<td>$11,555</td>
<td>$8,986</td>
<td>$3,942</td>
</tr>
<tr>
<td>Annual Rx Deductible, Indiv. (if app.)</td>
<td>$435</td>
<td>$274</td>
<td>$173</td>
<td>$64</td>
</tr>
<tr>
<td>% of plans requiring Rx Deductible</td>
<td>5%</td>
<td>40%</td>
<td>52%</td>
<td>61%</td>
</tr>
</tbody>
</table>

*Note: Data are from plans in the 34 states that CMS designates as having federally facilitated exchanges in 2015 for which cost-sharing data was included in CMS’s 2015 Qualified Health Plan (QHP) Landscape file, and from data from similar files for the OR, NM and NV exchanges which CMS designates as federally supported exchanges, all three of which are using the HealthCare.gov IT platform in 2015. Source: [http://www.healthpocket.com/healthcare-research/infostat/2015-obamacare-deductible-copayment-coinsurance-out-of-pocket#.VKg2I4rF9HE](http://www.healthpocket.com/healthcare-research/infostat/2015-obamacare-deductible-copayment-coinsurance-out-of-pocket#.VKg2I4rF9HE)
ACA Plan Networks

2015 Plan Filings Confirm Carriers Are Using Narrower Provider Networks To Offer Lower Premium Offerings


- In 2015, 47% of the lowest cost silver plans are HMOs, as compared to 32% in 2014
- In 2014, premiums for comparable plans using broad networks were 13 to 17% higher than those using narrow hospital networks
- In 2014, 70% of the lowest cost silver plans utilized narrowed networks
◆ Prevalence of high coinsurance requirements and specialty drug tiers high in 2014

- Rx cost-sharing in Silver plans estimated to be 36% higher overall than pre-ACA individual market plans
- A PhRMA study found over 50% of Silver plans maintained co-insurance tiers of 30% or more for all drugs in at least one of 19 critical drug classes
  - Study found 76% of plans put ALL oncolytic molecular target inhibitors and 64% of antiangiogenic agents on the highest copay tier

◆ Preliminary analyses suggest 2015 plans will be similar, if not more restrictive
ACA Plan Enrollment

Despite initial enrollment problems, enrollment in ACA exchange plans is growing steadily

- In 2014, over 8 million people enrolled in an individual health exchange plan
  - 5.4M enrolled via HealthCare.gov
  - 86% qualified for financial assistance

- As of mid-January, more than 9.5 million have enrolled for 2015 (inc. auto renewals)
  - Includes 7.1M from 37 HealthCare.gov states and 2.4M from 14 state-administered exchange states
  - 42% of enrollees on HealthCare.gov are new this year
  - ~87% qualify for subsidies; ~35% are under age 35
  - Open enrollment ends on 2/15

Sources: HHS statements; ASPE
2015 ACA Implementation Issues

- Individual Mandate Penalty Kicks In, 1/1/15
  - Fines = > of $95 per person or 1% of income in 2015, to increase to $695 per person or 2.5% of income by 2017

- Delayed Enforcement of Employer Mandate
  - Effective for companies w/>100 FTEs in 2015; >50 FTEs in 2016

- Grandfathered & Non-Compliant Plans
  - Federal compliance deadline delayed to 2017, renewals only

- Medicaid/Low-Income Coverage Gap
  - No subsidies between Medicaid and Exchange eligibility levels in states with no Medicaid expansion

- Medicaid Cancer Screenings
  - ACA’s $0 copay for preventive care only applicable to newly covered Medicaid population, ASCO has proposed fixing this
King vs. Burwell (4th Circuit Court of Appeals)

- Oklahoma taxpayer challenge to subsidies in FFE
- Sites ACA provision granting tax credits to those who purchase insurance “through an Exchange established by a state”
- SC agreed to hear case in September, oral arguments expected in March 2015, decision by July

Related case, Pruitt vs. Sebelius (E.D. Okla.)

- Citing same ACA provision, OK AG challenging employer penalties in states that haven’t established an exchange
- Court dismissed HHS motion for summary judgment in Sept, further proceedings stayed pending SC review of King case

If ruled illegal, >7 million enrollees in up to 37 states could lose subsidies, undermining the ACA
Potential ACA-Related Legislation in 2015

- Full repeal
- Delay or repeal of individual mandate
- Delay or repeal of employer mandate
- Redefinition of full-time employee for purposes of employer mandate threshold
- Extension of non-compliant plans deadlines
- Review of required benefits, “copper” plan?
- Repeal of ACA taxes, inc. medical device tax?
- Repeal of IPAB
ACA-Related Medicaid Expansion

Medicare Physician Fee Schedule/SGR

Medicare Drug Reimbursement

Payment Reform Update
ACA Medicaid Expansion

As of August 2014, ~68M Americans had coverage through Medicaid or CHIP, up 14.86% from 2013

Note: AR, IA, MI and PA have Sec. 1115 waivers in effect that have expanded Medicaid eligibility. IN was granted a Sec. 1115 waiver on 1/27/15. It will go into effect on 2/1/15.

While no formal expansion proposals have been adopted in AK, MT, TN, UT, VA and WY, Governors in those states have pledged to pursue expansion.

Source: CMS, KFF
Medicare Physician Fee Schedule Update

- **Temporary SGR Fix Passed Last March**
  - 0% update, conversion factor set @ $35.80 thru 3/31/15 – if Congress doesn’t act drops 21% to $28.22

- **2015 Final MPFS Rule issued in October**
  - Hematology/medical oncology CPT codes increased by 1% on average due to PE reevaluations
    - Four drug administration codes identified as high-volume, potentially misvalued procedures – will be re-evaluated going forward
  - Proposed cuts in radiation oncology codes dropped from final rule, CMS to re-evaluate in 2016
  - CMS to use PO code modifier to begin collection of physician-owned vs. hospital-owned practice expense data, voluntary in CY2015, to be required in CY2016
  - Rule includes 7 final oncology PQRS measures
Congress expected to act before April 1 deadline

HR4015/S2000 likely to be basis for a bipartisan permanent fix proposal

- Would set near-term, nominal (0.5%) or flat updates for MPFS & rely on inducements for physicians to join an alternative “merit-based incentive payment system” (MIPS) over time
  - MIPS would be developed by CMS & expose participating MDs to variable up & downside risk depending on quality scores
    - CMS’ Oncology Care Model, ASCO consolidated payment proposal & oncology medical home concept are all intended to influence the ultimate alternative payment systems for oncology

However, no agreement on financing

- Budget estimate of long-term fix >$100B
- Could result in another short-term SGR fix, pushing issue off until reconciliation or later
Part D – OIG Concern over Manufacturer Couponing Bleeding Over from Private Plans
- OIG Special Advisory Bulletin issued in Sept
- OIG actions, comments on applicability to Exchange plan enrollees being carefully watched by industry

Part B – 2% budget sequestration cuts continue, reducing ASP-based payments
- HR1416 – Cancer Patients Protection Act proposed in 2014

HOPD Final Rule
- 9 drugs, including asparaginase, glucarpidase & pertuzumab lost pass-through status on 12/31/14
- 22 drugs, including ado-trastuzumab emtansine, carfilzomib, obinutuzumab, omacetaxine mepesuccinate, tbo-filgrastim, vincristine sulfate liposomes & ziv-aflibercept qualify for pass through payments in 2015
CMS intent on moving from “volume” to “value” based reimbursement models

Already many ongoing demos & targeted initiatives

- Examples: ACOs, Bundled Payments initiative, EHR-meaningful use program, Hospital Readmission and Acquired Condition Reduction initiatives, Hospital Value-Based Purchasing program, PQRS
- ACA gave CMS CMMI broad authority to pilot alternative payment systems

“Better Care, Smarter Spending, Healthier People”

- Payment reform initiative announced by CMS on 1/26/15
- Aims to have 30% of fee-for-service (FFS) payments paid through alternative payment models (e.g. ACO) by 2016, and 50% by 2018
- Similarly, seeks to tie 85% of all traditional Medicare FFS payments to some quality or value measure (e.g. PQRS) by 2016, and 90% by 2018
- Initiative seeks to coordinate with private payers

Source: CMS CMMI
Accountable Care Organizations (ACOs)

◆ **ACOs showing mixed results, but remain favored**
  ▪ Now over 420 Medicare ACOs, serving over 7.8M Medicare beneficiaries
  ▪ >120,000 providers or suppliers have ACO affiliations
  ▪ Total estimated savings to date ~$417M
  ▪ Oncology-specific ACOs have been formed in Florida

◆ **Medicare Pioneer ACOs**
  ▪ 19 local provider organizations, most in NE, upper mid-west or Southern California – down from 33 in year one
  ▪ Held per cap growth rate to 0.45% less than FFS in Year 2

◆ **Medicare Shared Savings Program (MSSP) ACOs**
  ▪ ~50% reduced costs vs. targets in year one, saving ~$380M
  ▪ Improved on most of 33 required quality measures
  ▪ 89 New MSSP ACOs entering program in 2015

Source: CMS CMMI
Oncology Payment Reform Spectrum

Bundling/Aggregation Across Providers

- Traditional FFS
- Chemotherapy Fee Replacing Drug Mark-up
- Pathways Compliance Fee
- Medical Oncology Home Care Management fee
- Episode/Bundle Payment Physician and Hospital Services
- Episode/Bundle Payment for Physician Services
- Oncology ACO
- Population-Based, System-Wide Capitation Payment

Case-Based Physician Payment

## Physician Payment Reform Initiatives

<table>
<thead>
<tr>
<th>Overview</th>
<th>ASCO CPOC</th>
<th>COA</th>
<th>Oncology Medical Home</th>
<th>United Healthcare Pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value-based, performance adjusted, consolidated payments proposal, with option for shared savings</td>
<td>Four year phased shift from FFS to episode of care payments</td>
<td>Practices use enhanced care coordination services to provide a patient-centered oncology medical home</td>
<td>3 year pilot involving &gt;800 patients in 5 practices; focus on breast, colon &amp; lung cancer</td>
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### Structure

| Replaces all EM & drug admin fees with 11 potential PMPM payments based on patient status. Annual PQRI-like value-based payment adjustments. Drug costs paid separately. | Interim FFS payments, w/PQRI-like adjustments, while episode payment structure piloted & refined | Additional PMPM care management fee typically paid to managing practice. Use of savings targets and designated diagnostic and clinical treatment pathways may be used. | Adjustable prospective per episode payment paid to replace est. drug margin and case management services. Drugs reimbursed at cost. Office services reimbursed using FFS schedule. |

### Performance Measurement

| Clinical pathways adherence, quality & ER visit avoidance measures | 19 clinical, resource, survivorship & end of life measures | Care coordination functions required, measured at the practice level | ~60 quality & cost measures |

### Status

| Some elements being piloted. Will help inform ASCO comments on CMS actions. | Some elements being piloted. Will help inform COA comments on CMS actions. | Various pilots ongoing, including CMS’ COME HOME oncology medical home pilot | Published initial results in July. Saved 34% overall while drug $ increased. Expanding pilot to head & neck cancers with MD Anderson. |
CMS’ Oncology Care Model

- Draft payment reform model distributed by CMS’s CMMI in August

- Would pilot new episode-based reimbursement system using three components:
  - Traditional FFS payments for Part A, B and D services
  - Prospective PMPM management payment
  - Retrospective, risk-adjusted, performance-based payment adjustments using 37 quality and resource use measures & pre-established expenditure targets

- Enhanced practice services would be required
  - E.g., patient navigators, care plans, 24/7 clinician access, EHRs

- CMS now reviewing preliminary comments on the proposal

Source: CMS CMMI’s Preliminary Design for an Oncology-focused Model, August 2014.
Explosive Growth in 340(b) Program Has Had Disruptive Effects & Generated Litigation; Mega-Rule Withdrawn; Potential For Legislative Action Uncertain

- ACA expanded institutions eligible for 340(b)
- 340(b) sales increased 96% between 2010 and 2013
- Total sales $1.1B in 1997; $7.1B in 2013
- Growing # of 340(b) hospitals using pharmacy networks, inc. specialty pharmacies

Sources: HRSA; BRG Healthcare, Growth of 340(b) Program. November 2014.
Other Potential 2015 Issues

- Continued scrutiny of Sunshine Act & Medicare physician-level payment data
- Oral therapy parity laws – state & federal
- Expanded payer use of clinical pathways
- Clinical trials reporting requirements
  - Expanded NIH reporting rule released in Nov. 2014, apply to all NIH funded trials and other trials using unlicensed or unapproved products
- Clinical trial participation, reimbursement
  - ASCO proposal to extend to Medicaid
Prognostications

- Only targeted modifications to ACA likely – SC case is the potential wild card
- Continued scrutiny of high cost therapies, specialty volumes by CMS
- Bipartisan support, continued advancement of payment reform, performance-based initiatives, in public and private plans
- Permanent SGR fix possible, but <50% likely
- Reconciliation may become vehicle for bolder Medicare changes, ACA tax revisions, particularly if tax reform effort takes off
Questions/Discussion?
Thank You!

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