Vaccine Financing, the Affordable Care Act (ACA), and Immunizations

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Disclosures - Tan

• I have received honoraria from Pfizer, Novartis, Temptime Corp., TruMedSystems, and Sanofi Pasteur for service as a scientific consultant.
  – My honoraria is donated to the IAC

• I do NOT intend to discuss an unapproved or investigative use of a commercial product/device in my presentation.
Disclaimer

The opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the official positions of the Immunization Action Coalition, or the National Adult and Influenza Immunization Summit.

Objectives

I. Vaccine Financing in the United States

II. The Affordable Care Act (ACA)
   - ACA impact on immunizations
   - What are the challenges for immunization efforts in the era of the ACA

III. Challenges Facing Providers of Adult immunizations

IV. 3rd Immunization Financing Congress:
    Financing Across the Lifespan
I. Vaccine Financing in the United States

Vaccine Financing in the United States

• Vaccines For Children (VFC, ~45% of children)
  – Entitlement for children up to age 19 served by:
    • Medicaid
    • Without health insurance
    • American Indians and Alaska Natives
  – Underinsured children can receive VFC vaccines at Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs)
• Section 317
  – No longer be used to cover routine vaccination of children, adolescents, and adults who have public or private insurance that covers vaccination
  – Also has objective to improve adult IZ
  – Stagnant funding
Vaccine Financing in the United States

- **Medicare**
  - Covers vaccines for those 65 years and older
  - Influenza, Pneumococcal and Hepatitis B – Part B (by legislation)
  - All other vaccines – Part D (eg, shingles)

- **Medicaid**
  - Only public sector payer that provides for administration fee
  - Admin fee set by states with huge state-to-state variance; states have to contribute enough funds to draw the maximum federal matching contribution allowable
  - ACA updated the caps are set by CMS for admin fees but states do not have a floor.

- **Private Sector (~50% of children)**
  - Price of vaccine negotiated with distributors/manufacturers
  - Payment negotiated with payers
  - Providers responsible for administering vaccine then seeking payment

II. The Affordable Care Act

- Assure near-universal, stable, and affordable coverage by building on the existing system of public and private health insurance

- Note that intent was to improve access, not necessarily to improve payment to providers
  - While not the primary motivation in ACA, there are numerous instances where payment is improved

HHS enforces that intent through regulation
Millions of Americans Were Left Uninsured Before the Affordable Care Act

The Affordable Care Act Works to Improve Conditions for Consumers and Small Businesses

- **Pre-existing Conditions**
  - 129 million Americans with pre-existing conditions can now keep their plans

- **Affordability**
  - Insurance companies must publicly justify any rate increase of 10% or more.

- **Increased Choice**
  - Small businesses will have more options for affordable coverage.
The Affordable Care Act Has Had a Measurable Impact on Improving Access to Health Coverage for Millions of Americans

- 5.7 million young adults
- 9.4 million seniors with Medicare
- 16.4 million previously uninsured Americans now have health insurance
- 105 million Americans have had lifetime limits removed from their insurance
- 137 million Americans have private health insurance that provides preventive services without cost sharing

So What Does the ACA Mean for Immunizations?
Private Insurance and Group Health Plans

- **ACA mandates provision of ACIP-recommended vaccines at no cost-sharing**
  - Must cover adult children up to age 26 years
  - No pre-existing conditions for children <18 years
- **No plan is required to cover vaccinations delivered by an out-of-network provider.**
  - Plans that do cover out-of-network provider can do so at out-of-network cost-sharing standards

Self-Insured Group Health Benefit Plans (ERISA plans)

The ACA extended many of its standards to the self-insured ERISA group health plans

- In particular, all ERISA plans are subject to the ACA’s standards on preventive services coverage
- Thus, must cover all ACIP-recommended vaccines at no cost-sharing
What are Grandfathered Plans?

State-regulated private health insurance sold in individual and group health markets, prior to March 23, 2010, are grandfathered into the ACA.

Loss of grandfathered status

Grandfathered status is lost if:*  
- Plans reduce or eliminate existing coverage  
- Plans increase deductibles or co-payments by more than rate of medical inflation plus 15%  
- Plans require patients to switch to another grandfathered plan with fewer benefits or higher cost-sharing to avoid new patient protections implemented by ACA  
- Plans are acquired by or merge with another plan to avoid complying with ACA

*From: http://www.healthreform.gov/newsroom/keeping_the_health_plan_you_have.html
Change in Number of Grandfathered Plans**

- All Small Firms (3-199 Workers)
- All Large Firms (200 or More Workers)
- All Firms

* Estimate is statistically different from estimate for all other firms not in the indicated size, region, or industry (p<.05).


The Healthcare industry has greatest number of grandfathered plans**

<table>
<thead>
<tr>
<th>INDUSTRY</th>
<th>2015</th>
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<tbody>
<tr>
<td>Agriculture/Mining/Construction</td>
<td>22%</td>
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<tr>
<td>Manufacturing</td>
<td>24</td>
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<tr>
<td>Transportation/Communications/Utilities</td>
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<td>Health Care</td>
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* Estimate is statistically different from estimate for all other firms not in the indicated size, region, or industry (p<.05).

State regulated health insurance

ACA established market standards for state-regulated health insurance (eg, coops, FEHBP) regardless whether through an exchange or in open market

- Essential health benefits, including preventive services, must be covered
- State health insurance exchanges must be established by 2014 for small businesses

All state-regulated, non-grandfathered insurance plans must include ACIP-recommended vaccines at no cost-sharing

Medicaid Expansion

Effective 2014, all non-elderly persons with incomes up to 133% FPL, based on “modified adjusted gross income,” are Medicaid eligible, in states that opt in*

- States offer new eligible enrollees an “alternative benefits package,” which includes immunization services to children and adults at no cost sharing**
- States decide whether existing Medicaid enrollees are to be covered for the alternative benefits package
- Creates disparity between newly eligible and already enrolled persons in expanded states, and between expanded states and states with traditional Medicaid

Where states are on expanded Medicaid

31 states + DC expanding Medicaid, January 2016.

Available at: https://www.advisory.com/Daily-Briefing/Resources/Primers/MedicaidMap

Medicaid & ACA: Standardizing Immunization Coverage*

In States Implementing/Reviewing Expansion (n=32)

9 states did not respond to GW survey: IL, KS, NH, NC, OH, PA, RI, WV, WI = Standardizing IZ Coverage Unknown

<table>
<thead>
<tr>
<th>WILL STANDARDIZE COVERAGE (n=1)</th>
<th>WILL NOT STANDARDIZE COVERAGE (n=20)</th>
<th>NO DECISION TO STANDARDIZE COVERAGE (n=5)</th>
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<td>Virginia</td>
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<td>These states will manage 2 different</td>
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<td>HPV</td>
<td>benefit packages</td>
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<td>Zoster</td>
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Arkansas

WILL NOT STANDARDIZE COVERAGE (n=20)

18 states = ACIP Coverage in 2012
2 STATES = DO NOT COVER TO ACIP in 2012

WILL STANDARDIZE COVERAGE (n=1)

Arkansas

NO DECISION TO STANDARDIZE COVERAGE (n=5)

2 states = ACIP Coverage in 2012
3 STATES = DO NOT COVER TO ACIP in 2012

*Source: Milken Institute/SPH Medicaid Benefit Design and Cost-sharing Policy 2013 – Presented by Alexandra Stewart at 2014 NAIIS Meeting, Atlanta, GA
1% FMAP (Section 4106 of ACA) - Update

- To incentivize states to cover preventive services, ACA provides for a 1 percent increase in state’s FMAP for preventive services if they cover all USPSTF Grade A/B recommended preventive services and all ACIP-recommended vaccines without cost sharing.
- CMS has provided guidance on this provision
  - States will have to submit a state plan amendment in order to receive this benefit
  - 11 states have approved 4106 SPAs:
    - CA, CO, DE, HI, KY, NV, NH, NJ, NY, OH, WI
  - There is no deadline for states to submit SPAs and no end date for the 1 percent increase

Medicaid Primary Care Payment Increase

- Medicaid “Bump Up” - payment increase for primary care services to 100% of Medicare payment rates; 100% FMAP for first 2 years*
  - Increases immunization administration fee to Medicare levels for two years: 2013 and 2014
  - Intent was to encourage physician participation as Medicaid expanded.
  - Opportunity to show importance of adequate payment on coverage

*Section 1202 of the Affordable Care Act (ACA)
The “Bump Up” also updated the fee schedule for the VFC Program

- The final rule also updated the maximum administration fees for the VFC program.
  - This updated fee schedule is what states should use when determining the lesser of amount for the increased primary care payment for vaccine administration for children.
- Nationally, this raised the payment to about $25...
- However, no minimum payment level was established and states remain free to determine their state’s regional maximum administration fee after 2014.
- Reauthorization language introduced in 2014 but failed to make it out of committee. Eliminated in 2015 CHIP bill that was passed into legislation.

Medicare, Effective From 2011

- Any preventive service received in outpatient setting in hospital paid for at 100%
  - Improves access to immunizations provided under Part B of Medicare
- GAO study on impact of Medicare Part D payment on access to immunizations
  - Highlighted access problems with adult vaccine covered under Part D
  - Vaccines provided under Part D still have cost sharing.
  - Urges appropriate steps to address administrative challenges (eg, verifying beneficiaries’ coverage)
Post ACA - Federal Funding for Immunization Programs

- States may use state funds to purchase adult vaccines under CDC contracts
- Section 317 program was reauthorized, but...
  - Continued battle to sustain annual appropriations for Section 317 Program
  - CDC 2014 professional judgment - $1,071 million

<table>
<thead>
<tr>
<th>Program</th>
<th>FY 2015 Appropriations</th>
<th>FY 2016 President's Request</th>
<th>FY 2016 Committee Recommendation</th>
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<td>Section 317 Immunization Program</td>
<td>$610,847,000</td>
<td>$560,508,000</td>
<td>$650,000,000</td>
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Community Health Centers (CHC)

Community Health Center Fund established, $11 billion over 5 years to expand CHC operations

- Number of patients served expected to double to 35 million by 2019
  - Increases access to immunizations for millions of children and adults in medically underserved communities
  - Underinsurance still an issue until full implementation of the ACA
School-based Health Centers

>1,100 centers serving >2 million children

- HRSA has issued RFP: $75 million for an estimated 150 grants in FY 2013*
- Must provide comprehensive primary health services to be eligible
- While immunizations are not specifically included, increased funding provides opportunities to administer vaccines during school hours
- School-based health centers can also become VFC-registered providers


Other considerations

For private insurance

- ACIP recommendations that apply for certain individuals rather than an entire population are covered
  - If the vaccine is prescribed by a health care provider consistent with the ACIP recommendations, a plan or issuer is required to provide coverage.*

Other Considerations

For private insurance

• Concern remains about coverage for differences between an FDA indication and an ACIP recommendation

• Example – Shingles Vaccine
  – Shingles has FDA indication for ages 50 and above. ACIP recommendation is for ages 60 and above.
  – Provider provides vaccination to 55 year old based on professional opinion
  – Will it be covered? Not likely

• Travel vaccines are not covered unless indicated in the footnotes of the ACIP schedules...

Other Considerations

For private insurance

• Network Adequacy/Out of Network Providers
  – If payment becomes less of an issue, access to vaccinations becomes primary barrier to coverage.
  – Increase access points for getting vaccinated
    • All providers of care for adults have a responsibility to assess, counsel, recommend, and if feasible, deliver the vaccine
    • Need to improve the number of in-network providers
  – Complementary immunizers such as pharmacists, school-based clinics or public health clinics are considered out-of-network providers and thus ACA provisions do not apply
  – CDC “billables” project – contracting to make public health departments in-network providers.
Other Considerations

Medicaid Expansion

• Expansion and implementation of the Exchanges will be extremely varied given the variability in states’ participation.
  – Differences will exist even in “expanded” states between newly enrolled and those enrolled before 2014
• “Traditional” Medicaid adult enrollees (in states that opt out of expansion) will not be protected by the ACA provisions
  – About 20 million non-elderly persons comprising pregnant women, parents/caretakers of dependent children, low income parents, working age adults with disabilities.
  – Immunization is optional preventive service for adults
  – Need to advocate for immunization inclusion in Medicaid and Exchanges

III. Challenges Remain

• Public Education about “cost-free” vaccinations is necessary.
• Provider Outreach remains critical
  – They may not know who is covered
  – Complexities of coverage still remain
  – Need to maintain and enhance the provider immunization incentives...
• Health information technology
  – Integrating existing IIS into EHRs and meaningful use becomes critical with more providers
Where the uninsured populations are – by state, post-ACA

~30 million will remain uninsured so public health safety nets are still necessary
- ~56 million would be uninsured without ACA

Improved access for the newly insured but…
- Disproportionately lower income and residents of medically underserved communities

Continuing Medicare B/D challenge

How will health plans continue to implement new coverage still fuzzy…
- 2014 was relatively quiet; bigger changes in 2015 as the employer shared-responsibility provision in the ACA takes effect for large employers

While payment may not be an issue, adequacy of provider payment for vaccines and administration remains!
What Does It Cost to Immunize?

- Vaccine purchase
  - Ordering
  - Tracking inventory
  - Deferred reimbursement
- Vaccine storage
  - Refrigerator/Freezer
  - Back-up power/Alarms
  - Insurance
  - Opportunity cost of inventory
- Vaccine administration
  - Staff time
  - Supplies
  - Documentation
  - Figuring out the billing

Managing the Business of Vaccination: Providers

- Purchase of Vaccines
- Manage Inventory and Associated Supplies
- Payment for Vaccine and Vaccination Services

Vaccination Event

Figure: Shen, et al NVPO

THE NATIONAL VACCINE PROGRAM OFFICE
Issues with the Purchase of Adult Vaccines

- Newer vaccines are more expensive
- There is no federal vaccine purchase program for adults
- Vaccine prices can vary as much as 3-fold from provider to provider depending on negotiated prices, which are confidential
- Adult vaccine providers do not have the benefits of economies of scale that pediatric practices have

Cost of Vaccine Storage and Handling

- Equipment: refrigerator/freezer, temperature monitoring devices
- Up front purchase costs
- Labor costs to order, track, maintain supply
- Backup power
- Insurance for inventory
- Opportunity cost of hundreds of thousands of dollars tied up in inventory
Costs of vaccine administration

- **Staff time:**
  - Discussions with parents
  - Vaccine administration
  - Documentation
  - Training
- **Supplies**
- **Billing**

**Remember: Affordable Care Act (ACA) mandates coverage of all ACIP recommended vaccines**

- Coverage with NO cost-sharing
- Actual dollar payments often vary by insurer and by individual insurance plan
- Each claim submission requires appropriate Current Procedural Terminology (CPT®) and ICD-10-CM codes even if the insurer considers immunization a routine service
Good habits to know…

• Document the work done in a permanent record or log
  – The name of the vaccine and the manufacturer;
  – The lot number and expiration date;
  – The date of administration;
  – The name, address, title and signature (electronic is acceptable) of the person administering the vaccine;
  – The edition date of the Vaccine Information Statement (VIS) and date the patient or parent receives the VIS

Good habits to know…

• Know your payer and its rules
  – Private payer
  – Medicare Part B
  – Medicare Part D

• Look around for the most favorable vaccine pricing, seek out group purchasing agreements to take advantage of volume discounts, and buy direct from the manufacturer

• Steps to take…
Select the correct CPT code for the vaccine administered

• Codes should accurately reflect the documentation in the patient’s medical record

• Vaccine product codes are listed in the “Medicine” section of the CPT manual

• Represented by CPT codes 90476 through 90749
  • Eg, 90736 for zoster vaccine
  • Exception for 90568 for influenza and Medicare

Add the proper immunization administration CPT code

• Every vaccine administered and billed should have a related vaccine administration service code
  • These appear in the “Medicine” section of the CPT manual

• Represented by CPT codes 90460 through 90474.
  Codes account for:
  • age of the patient
  • order and route of administration

• If Medicare, use proper G code for Part B vaccines – influenza (G0008), pneumo (G0009), hep B (G0010)
Link the appropriate diagnosis (ICD-10-CM) code, Z23

• To each CPT code for the vaccine; and
• To the code for administration service
• ICD-10-CM code is now Z23 for all vaccines and vaccine services

Add Other CPT codes…

• For any evaluation and management (E/M) services
• Other services provided during the visit. Eg, include:
  – laboratory services
  – X-rays
  – Make sure to couple the service with the appropriate ICD-10-CM code describing why each service was performed
If applicable, attach the "-25" modifier for the outpatient office E/M code

• The "-25" modifier identifies a service unrelated to others performed during a patient visit. Eg,
  – If an adolescent receives a meningococcal vaccination while seeking treatment for an injured ankle
  – If the preventive medicine services codes 99381 through 99395 were used, the "-25" modifier is usually not necessary

What about Medicare Part D vaccines?

• Payment for Part D vaccines and their administration are made solely by the participating Prescription Drug Plan
• Physicians are considered out-of-network providers
• Charge the patient for the vaccine and its administration and then...
• Provide patient with CMS-1500 claim form for the vaccine and administration service for patient to file
• Enroll in TransactRx Vaccine Manager
Example with Shingles in a physician’s office

- If patient is 60 – 64 years of age, seek coverage under patient’s private insurance
- If patient is 65 years of age and older with secondary insurance to Medicare, seek coverage under patient’s private insurance
- If patient is 65 years of age and older who have enrolled in Medicare Part D, charge patient and provide CMS-1500 form
- Use CPT code 90736 for vaccine, CPT code 90471 for the administration fee, and ICD-10 code Z23

Manufacturers Provide Hotlines

- Many manufacturers provide hotlines to assist coders; these may also offer guidance for claims preparation, appeals, and specific payers’ vaccine coverage and reimbursement policies
- Contact your vaccine representative to learn more about their reimbursement support services
ACA Web Resources

• AAP

• AAPA

ACA Web Resources

• ACP
  http://www.acponline.org/advocacy/where_we_stand/affordable_care_act/.

• ACOG

• AAFP
  http://www.aafp.org/advocacy/act/aca.html
ACA Web Resources

• CMS

• Office of Health Care Reform

• Medscape

Visit IAC Resources!

• Read our publications!
  – http://www.immunize.org/publications/

• Visit our websites!
  – www.immunize.org
  – www.vaccineinformation.org
  – www.izcoalitions.org
  – www.preventinfluenza.org

• Stay ahead of the game! Subscribe to our updates!
  – http://www.immunize.org/subscribe/
IV. Goals of the NAIP

1. Strengthen the adult immunization infrastructure
2. Improve access to adult vaccines
3. Increase community demand for adult immunizations
4. Foster innovation in adult vaccine development and vaccination-related technologies

Immunization Congress: 1\textsuperscript{st} and 2\textsuperscript{nd}

\textbf{1\textsuperscript{st} Congress – Feb. 2007}
- Solution-oriented
- AAP Task Force on Immunization financing
- Interviews with stakeholders
- Bring partners together
- Partnered with AMA-AAP
- Inclusive of adults
- Served as the basis and foundation for NVAC pediatric and adolescent financing recommendations (adopted Sept. 2008) – Supplement 2009 Pediatrics

\textbf{2\textsuperscript{nd} Congress – Sept 2010}
- Continuation of solution-oriented dialogue
- Patient Protection and Affordable Care Act (PPACA) just signed on March 23, 2010
- The law aims to assure affordable, stable, and near-universal health care coverage by building on the existing public and private insurer system, thus allowing those who want to keep their current health care plan to do so
- Reference paper
IV. 3rd IZ Congress

- Congress is being summarized for publication in peer-reviewed journal – Highlights will be shared at Summit
- The issue areas will be discussed further at the June NVAC meeting
- Consider webinar with representatives of each of the groups participating to discuss next steps
- Engage CMS and private payors more actively
- Understanding MACRA release – PH immunization, quality measure, payment reform

More Information

Join the National Adult Immunization and Influenza Summit
http://www.izsummitpartners.org/

Attend our upcoming NVAC meeting
In-person or via live webcast
http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/index.html

Visit our NVPO webpage for more information or to download the National Vaccine Plan or the National Adult Immunization Plan:
http://www.hhs.gov/nvpo/index.html