

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

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Disclosures

- 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.



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Objectives

- Vaccine Financing in the United States
- The Affordable Care Act (ACA)
 - ACA impact on immunizations
 - What are the challenges for immunization efforts in the era of the ACA
- Challenges Facing Providers of Adult immunizations



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 (compare with pharmaceuticals where patient fills prescription)



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



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**

Percentage of Covered Workers in a Grandfathered Health Plan	2011	2012	2013	2014
All Small Firms (3-199 Workers)	63%	54%*	49%	35%*
All Large Firms (200 or More Workers)	53%	46%	30%*	22%*
ALL FIRMS	56%	48%*	36%*	26%*

Percentage of Firms with At Least One Grandfathered Plan	2011	2012	2013	2014
All Small Firms (3-199 Workers)	72%	58%*	54%	37%*
All Large Firms (200 or More Workers)	61%	57%	43%*	34%*
ALL FIRMS	72%	58%*	54%	37%*

*p<.05; statistically different from previous year

**Kaiser Family Foundation and Health Research and Educational Trust, 2014. Employer Health Benefits 2014 Annual Survey. At: <http://www.kff.org/health-reform/poll-140714-employer-health-benefits-2014-annual-survey/>.



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



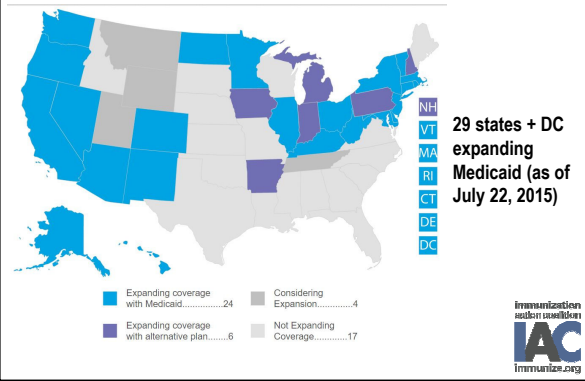
Medicaid Expansion

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

*National Federation of Independent Business v. Sebelius. Roberts, C.J., Slip Opin. at 50. Available at: <http://www.kff.org/healthpolicy/upload/8312.pdf>
 **CMS Final regulation, July 5 2013. Available at: http://www.cfr.gov/%26X%281%29%2811psecb3pci1omwwwu4d4z6%29%29%29FRUpload/OFRData/2013-16271_PL.pdf

Where states are on expanded Medicaid



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

WILL STANDARDIZE COVERAGE (n=1)	WILL NOT STANDARDIZE COVERAGE (n=20) 18 states = ACIP Coverage in 2012 2 STATES= DO NOT COVER TO ACIP in 2012			NO DECISION TO STANDARDIZE COVERAGE (n=5) 2 states = ACIP Coverage in 2012 3 STATES = DO NOT COVER TO ACIP in 2012	
Arkansas In 2012, did not cover: • Varicella • HPV • Zoster	California Connecticut Delaware Hawaii Iowa Maryland Mass. Michigan	Minnesota Missouri Nevada New Jersey N. Mexico N. York Oregon Utah Vermont Virginia	DC N. DAKOTA	Indiana Kentucky	ARIZONA COLORADO WASHINGTON

*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

Program	FY 2015 Appropriations	FY 20 President's Request	FY 16 Committee Recommendation
Section 317 Immunization Program	\$610,847,000	\$560,508,000	\$650,000,000



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

*See: <http://www.hrsa.gov/grants/apply/assistance/sbhcc/>.



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.*

* Available at: <http://www.dol.gov/ebsa/pdf/faq-aca12.pdf>



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

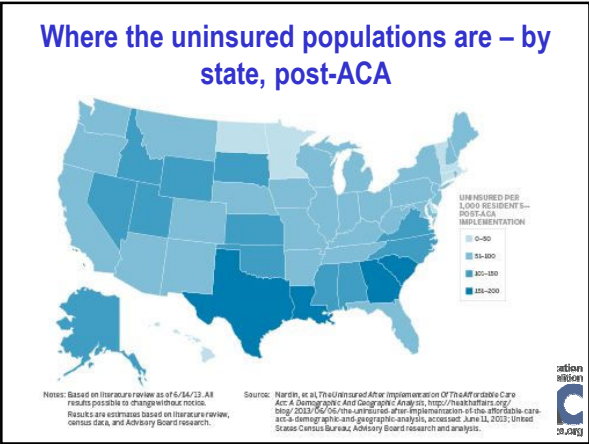
- Expansion and implementation of the Exchanges will be extremely varied given the variability in states' participation.
 - Differences will exist even in “expanded” states between newly enrolled and those enrolled before 2014
- “Traditional” Medicaid adult enrollees (in states that opt out of expansion) 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

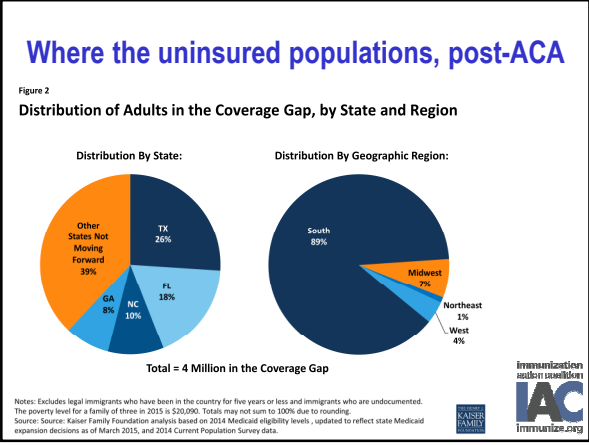


Challenges Remain

- **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







- ### Challenges Remain
- **~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!
- immunization
action
coalition
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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



Issues with the Purchase of 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**



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-9-CM codes (October 1, 2015 for ICD-10), 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 an appropriate diagnosis (ICD-9-CM) code...

- To each CPT code for the vaccine; and
- To the code for administration service
 - V03 codes relate to bacterial diseases
 - V04 codes concern viral diseases
 - V05 codes list single diseases
 - V06 codes specify for combinations of diseases
- Consider using a single, less specific ICD-9-CM code (V06.8) during non-preventive medicine service visits to allow for reduced administrative burden



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-9-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 either ICD-9 code V04.89 or V05.8



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**
<http://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/health-reform-law/Pages/Federal-Implementation-of-the-Affordable-Care-Act.aspx>.
- **AAPA**
http://www.aapa.org/the_pa_profession/federal_and_state_advocacy/AAPA_Navigating_Healthcare_Blog/item.aspx?id=6612&terms=aca.



ACA Web Resources

- **ACP**
http://www.acponline.org/advocacy/where_we_stand/affordable_care_act/.
- **ACOG**
http://www.acog.org/About_ACOG/ACOG_Departments/Government_Relations_and_Outreach/HCRIImplementation.
- **AAFP**
<http://www.aafp.org/advocacy/act/aca.html>



ACA Web Resources

- **CMS**
<https://www.cms.gov/about-cms/aca/affordable-care-act-in-action-at-cms.html>.
- **Office of Health Care Reform**
<https://www.healthcare.gov/prevention/index.html>.
- **Medscape**
<http://www.medscape.com/viewarticle/808532>
<http://www.medscape.com/viewarticle/824823> (on meaningful use)



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