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**

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Vaccine Financing in the United States

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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

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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)

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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

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So What Does the ACA Mean for Immunizations?

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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**

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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**

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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

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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**

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* 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%***

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*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://kff.org/report-section/ehbs-2013-section-13/.

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

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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*

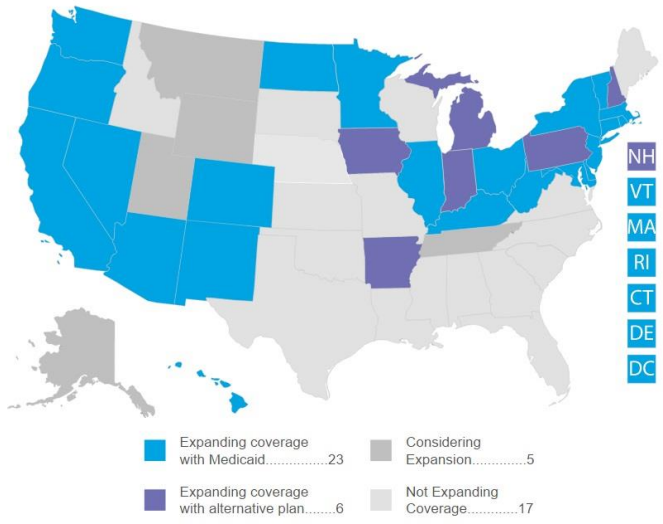
- **States offer new eligible enrollees an "alternative benefits package," which includes immunization services to children and adults at no cost sharing****
- **States decide whether existing Medicaid enrollees are to be covered for the alternative benefits package**
- **Creates disparity between newly 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/healthreform/upload/8332.pdf

**CMS Final regulation, July 5 2013. Available at: http://www.ofr.gov/%28X%281%29S%281vpecb3pcilomwwvusd4jf2b%29%29/OFRUpload/OFRData/2013-16271_PI.pdf.

Where states are on expanded Medicaid

February 11, 2015



28 states + DC expanding 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** These states will manage 2 different benefit packages	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

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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

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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)

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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.

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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)

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

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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

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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**

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*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.***

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* 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…

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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.

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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

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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

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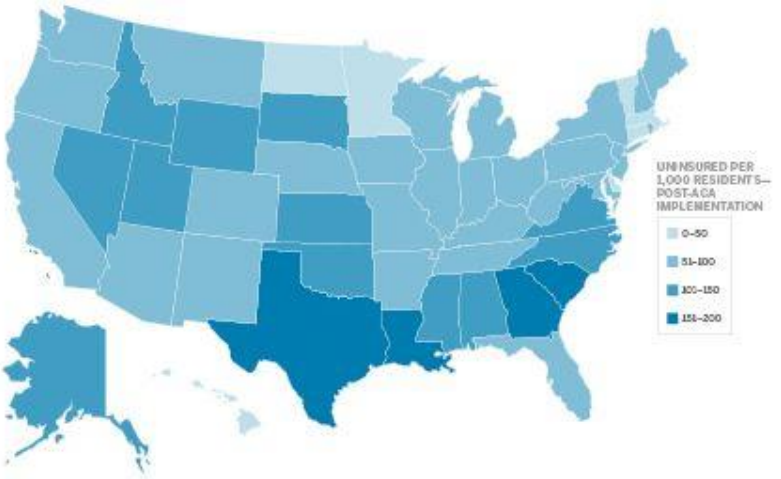
Where the uninsured populations are – by state, post-ACA



Notes: Based on literature review as of 6/14/13. All results possible to change without notice.
Results are estimates based on literature review, census data, and Advisory Board research.

Source: Nardin, et al, *The Uninsured After Implementation Of The Affordable Care Act: A Demographic And Geographic Analysis*, http://healthaffairs.org/blog/2013/06/06/the-uninsured-after-implementation-of-the-affordable-care-act-a-demographic-and-geographic-analysis, accessed: June 11, 2013; United States Census Bureau; Advisory Board research and analysis.

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, <u>adequacy of provider payment for vaccines and administration remains</u>!**

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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

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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

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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

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Costs of vaccine administration

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

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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

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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

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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…**

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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

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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)

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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**

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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

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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

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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

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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

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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

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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.

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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/HCRImplementation.

- **AAFP**

  http://www.aafp.org/advocacy/act/aca.html

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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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