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Summary of legal challenges to the Affordable Care Act

As of February 17, 2011, there have been many lawsuits filed throughout the United States challenging the constitutionality of the Patient Protection and Affordable Care Act (ACA) (Public Law 111-148). As the litigation has progressed, the major issue that has emerged is whether Section 1501 of the ACA, which establishes the "minimum essential coverage" requirement—better known as the "individual mandate" —is constitutional. Starting in January of 2014, the law will require all legal residents of the United States to obtain minimum health insurance coverage for each month or pay a penalty that will be assessed on the individual's federal tax return.

Four US District Courts have decided the issue of constitutionality. Two (one in Michigan and one in Virginia) have affirmed the constitutionality of the law, whereas two (one in Virginia and one in Florida) have found the law to be unconstitutional. The cases are now headed to the US Court of Appeals for the Fourth, Sixth , and Eleventh Circuits. Although challenges to the ACA have focused on the "individual mandate," there have been three general arguments made as to why the law is constitutional:

1. The individual mandate is a permissible exercise of Congress's powers under the Commerce Clause in Article 1 of the Constitution.
2. The individual mandate is permissible under Congress's powers to tax for the general welfare in Article 1 of the Constitution.
3. The individual mandate is permissible under the Necessary and Proper Clause in Article 1 of the Constitution.

Courts that have found the individual mandate unconstitutional have also been asked to determine whether the mandate can be "severed" from the ACA, leaving the rest of the Act's provisions intact.

Brookings Institution hosts Accountable Care Organization Briefing

On February 1, 2011, the Brookings Institution hosted a discussion on "Achieving Better Care at Lower Costs through Accountable Care Organizations." Key among the discussion topics were the importance of patient-centered care, rewarding value, and better support for integrated care.

Centers for Medicare and Medicaid Services Administrator Don Berwick said the Notice of Proposed Rulemaking (NPRM) on accountable care organizations (ACOs) will be out "soon." Although he could not discuss the details of the proposed rule, he said the goals are to put patient and family in the center of care, create a seamless transition in care, respect resources, focus on reducing waste, and invest in value. For example, resources should go where they are needed such as preventing avoidable hospital readmissions. He also said the core of ACOs is authenticity; there should not be attempts to repackage the status quo.

The challenges facing ACOs are:

- What will risk look like?
- Patient protection—How to avoid "cherry picking"?
- Measurements—How many and what type?
- Privacy/data sharing—What data can be shared?
- Generating capital—Who can invest?
- Antitrust/stark—How to maintain integrity in the market?

Debra Ness, President of the National Partnership for Women and Families, said consumers and patients must be at the table from the beginning of establishing an ACO. If

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patients do not take part from the beginning, they will not embrace it. She noted that patients do not like the term *medical home*. They want communication and coordination of care. ACOs must build in core patient protections and trust. ACOs must be able to care for the highest-risk and highest-cost patient. Ness said ACOs need strong measures on accountability and ACOs must be fully transparent on cost and quality information.

Francis Crosson, Associate Executive Director of the Permanente Medical Group, said ACOs should invest to ensure that the physician-patient relationship is strong.

John Rother of the American Association of Retired Persons said ACOs will require extraordinary leadership and a real commitment to culture change. He said it will be difficult to reorient the health care profession, patients, and so on. To avoid the managed care backlash, he states that ACOs should not emphasize cost containment. The focus on keeping patients out of the hospital is more attractive. ACOs need to be voluntary; otherwise there is a risk of backlash.

Mark McClellan of the Brookings Institution discussed payment models under ACOs to give providers more flexibility on how to provide care, which would mean moving away from traditional payment systems.

John Goodman, President and CEO of the National Center for Policy Analysis, said so far the evidence is not there to indicate that benefits outweigh the costs in evidence-based medicine; electronic medical records are not delivering on their promises; pay-for-performance in the United Kingdom did not work; and low-cost, high-quality health care "is like pornography"—"we know it when we see it, but can't define it."

These discussions highlighted the many complexities in developing ACOs that will work across the country. One recommendation was to change the name from Accountable Care Organizations to "Coordinated Care Organizations."

January 2011 Council on Graduate Medical Education Meeting

At its January 19-20 meeting, the Council on Graduate Medical Education (COGME) discussed recommendations intended to make GME more accountable for meeting the needs of the nation. Keith Watson, DO, is a new member of COGME, representing the profession.

Kicking off the discussion was a presentation on optimizing GME by John Prescott, MD, Chief Academic Officer of the Association of American Medical Colleges; Paul Rockey, MD, Director of Graduate Medical Education of the American Medical Association; and Stephen Shannon, DO, MPH, AACOM President and CEO. Michael Whitcomb, MD, Professorial Lecturer in Health Policy at George Washington University's School of Public Health and Health Services, who spoke on major challenges to GME, including deliberations, at a recent Macy Foundation conference, joined Drs. Prescott, Rockey, and Shannon in a question-and-answer session after the presentations.

COGME also heard presentations on:

- A Lewin Group study of primary care physician projections by state
- Introducing accountability into GME by evaluating the output and outcomes of GME programs
- Recent GME recommendations to Congress from the Medicare Payment Advisory Commission (MedPAC)
- GME performance measures and the new National Center for Health Workforce established by the ACA

The second day of the meeting focused on COGME's 20th Report, "Advancing Primary Care," which was released at the meeting. The report is posted on the Council's Website (http://cogme.gov).

Center for Medicare and Medicaid Innovation meeting

ACOFP staff recently attended a discussion with Mandy Cohen, MD, a senior advisor within the Center for Medicare and Medicaid Innovations (CMMI).

The purpose of CMMI is to identify, test, and validate new ways of delivering and paying for health care. Under CMMI's authority, if it finds a promising model of care through a demonstration, it does not need congressional action to expand on that model; CMMI can do so through regulatory channels. According to Dr. Cohen, CMMI is an agent of change within the Centers for Medicare and Medicaid Services. Dr. Cohen also said cost saving is a high priority through improving care.

According to Dr. Cohen, CMMI has been funded $10 billion over the next 10 years and can invest in initiatives. The Innovation Center is putting a process in place to solicit Request for Proposals (RFP). Dr. Cohen briefly reviewed the initiatives that will test the medical home concept: the Multi-Payer Advanced Primary Care Practice Demonstration, Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration, and the state plan option under which Medicaid enrollees could designate a provider as a "health home." In addition, CMMI is calling for state proposals to better coordinate care of "dual eligible" beneficiaries who qualify for both Medicare and Medicaid.

Dr. Cohen said CMMI will explore how primary care can reach underserved communities at a lower cost and how to coordinate care. In addition, Dr. Cohen described ACOs as the "unicorn in health care"—you recognize it when you see it. However, she said there are different payment structures within ACOs that need to be explored. She did not know when the NPRM on the ACOs would be released, but she suggested that may come soon, possibly this spring.

CMMI will rely heavily on stakeholders, including payers, to determine what delivery and payment models have worked. She acknowledged that data are necessary to improve the current system; however, determining the right

data and dealing with statutory limitations and privacy concerns are major challenges. CMMI is looking for ways to bring together all the members of the health care team, e.g., physicians, nurses, technicians, pharmacists, and so on, to better coordinate care.

Dr. Cohen said CMMI will work with Dr. Berwick on how to best validate their findings and how to take it to the next level. She could not give a specific timeline for CMMI initiatives, noting that it will be a matter of weeks before the Center is "open for business."

Permanent Health Information Technology Certification Program Final Rule

The Office of the National Coordinator for (ONC) for Health Information Technology (HIT) published on January 7, 2011 the final rule on the permanent certification program for HIT. This rule establishes the permanent certification program under which HIT can be tested and certified for use by eligible professionals and hospitals to meet requirements specified under meaningful use. The permanent certification program will replace the current temporary certification program, which is scheduled to end on December 31, 2011.

An ONC-Authorized Certification Body (ONC-ACB) will be authorized under this program to certify electronic health record (EHR) technology, to include complete EHRs and/or EHR modules and other types of HIT as well. Testing and certification under the permanent program are anticipated to begin on January 1, 2012. The ONC-ACBs are required weekly to provide to ONC with a current list of complete EHRs or EHR modules that have been tested and certified and could be used to meet the definition of certified EHR technology.

In addition, the ONC-ACB is required to report clinical quality measures to which a complete EHR or EHR module has been tested and certified, and, where applicable, any additional software on which a complete EHR or EHR module is relying to demonstrate its compliance with certification criterion/criteria adopted by the Secretary. This additional information will enable eligible professionals and hospitals to identify and adopt a complete EHR or EHR module that includes the quality measures that are relevant to them to implement. It will also assist them to assess and determine whether a particular certified product is compatible with their current HIT.

ONC will maintain and post on its website a Certified HIT Products List (CHPL), which will be the source of all certified complete EHRs and EHR modules that could be used by eligible professionals to meet requirements of using certified EHR technology. Eligible professionals and hospitals that elect to use a combination of certified EHR modules also may use the CHPL webpage to validate whether the EHR modules they have selected satisfy all of the applicable certification criteria. It is incumbent on the eligible professional or hospital to ensure that EHR modules properly work together to meet all of the required capabilities necessary to meet the definition of certified EHR technology.

Regardless of the year and the stage of meaningful use at which eligible professionals or hospitals enter the EHR incentive programs, they must use certified E HR technology, which will include new and revised certification criteria that have been adopted since their EHR technology was certified. Certification is meant to provide assurance that a complete EHR or EHR module will perform according to the certification criteria to which it was tested and certified. Any modification to a complete EHR or EHR module after it has been certified has the potential to adversely affect its capabilities. If the complete EHR or module no longer performs as it did when it was certified, it may compromise an eligible professional or hospital's ability to achieve meaningful use. If an eligible professional or hospital wants complete assurance that a complete EHR's or EHR module's capabilities have not been affected by modifications, they may choose to have the complete EHR or modules recertified.

The final rule can be found at: http://www.access.gpo.gov/su_docs/fedreg/a110107c.html.