The US Oncology Network
Health Policy Report

Tuesday, June 12, 2012

Government, Stakeholders Prepare for Supreme Court Decision on Health Care Reform

This month, the U.S. Supreme Court is expected to rule in the case of *Florida et al v. U.S. Department of Health and Human Services*, the lawsuit against the Affordable Care Act (ACA) filed by 26 states and the National Federal of Independent Business. As previously reported in the *Health Policy Report*, oral arguments in the case made at the end of March focused on four key issues:

- Applicability of the Anti-Injunction Act to the individual mandate penalties (the Act states that taxes in question generally must be paid before being challenged in court);
- Constitutionality of the law's individual coverage mandate, which requires individuals to secure a minimum level of insurance coverage or pay a penalty;
- Severability of the law, which refers to whether the rest of the ACA would stand if the individual mandate were struck down; and
- Constitutionality of the law's required Medicaid expansion, which requires states to cover individuals who earn up to 133 percent of the federal poverty level.

The Court has the power to maintain the entire law, to repeal only certain provisions, or to strike down the legislation in total. Key considerations regarding these potential outcomes include the following:

Outcome #1: The Entire Law is Upheld.

If the ACA survives its legal challenge, Democrats and the Obama administration will score a political victory. However, it could also spur Republicans to push against "Obamacare" in the elections and through legislative or regulatory vehicles next year.

In terms of the law's implementation, states awaiting a Supreme Court decision prior to establishing the state-run health insurance exchanges will have a tighter timeline to have the exchanges operational by the 2014 deadline under the ACA. If a state has failed to establish an exchange prior to the 2014 deadline, the federal government will have authority to step in and run that state's exchange.

Outcome #2: The Individual Mandate is Thrown Out, But the Rest of the Law Remains.

If the coverage mandate is struck down but the rest of the ACA is upheld, it is unclear how this will impact other provisions of the law. The individual mandate intends to generate increased revenues via premiums on new individuals entering the health care marketplace, and without this mandate there is no mechanism for ensuring there will be a steady pool of individuals purchasing insurance to adequately support the other provisions of the law – such as insurance market reforms and funding cuts to providers.

To help avoid skyrocketing health insurance premiums in the individual and small group markets, Congress could try to devise an alternative to the individual mandate designed to encourage larger numbers of younger, healthier people to buy insurance. Such approaches could include modifying open enrollment periods, creating late enrollment penalties, and providing access to personalized assistance for insurance enrollment, for example.

Outcome #3: Mandatory Medicaid Expansion is Overturned.

If states' mandatory Medicaid expansion is overturned, states could lose federal funding, and millions of program beneficiaries who would be added to Medicaid rolls after 2014 under the ACA would be affected. This decision could also open up legal challenges on similar grounds for many government programs that require states' action in exchange for federal support.

Outcome #4: The Entire Law is Overturned.

A decision to overturn the ACA would deal a political blow to President Obama and to Democrats; however, it could also increase pressure on Republicans to propose a concrete plan for offering popular reforms and consumer benefits under the ACA such as covering individuals with pre-existing conditions.

If the law topples, it is unclear how the government would manage ACA-related actions that occurred prior to the Supreme Court ruling. It is likely that enacted regulations, grants, and payments made based on ACA law will be retracted. ***(Continued on page 2)***

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Key delivery system reforms would likely continue as demonstrations, as the Centers for Medicare and Medicaid Services (CMS) has existing demonstration authority.

According to some experts, the ultimate future of the ACA may lie less with the Court and more with whichever party wins the White House and Congress in the November elections. If Republican presidential candidate Mitt Romney wins, for example, he has said he will dismantle the ACA, and House Speaker John Boehner (R-OH) has recently reiterated the GOP's commitment to fully repealing the ACA as well. If President Obama is re-elected, however, even if the ACA is struck down his administration and states supporting the law would have the option of advancing policies that would encourage more people to buy health insurance in the absence of the individual mandate.

House Energy and Commerce Health Subcommittee Holds Hearing on Standards for Radiation Therapy, Medical Imaging Technologists

On June 8, the House Energy and Commerce Subcommittee on Health held a hearing entitled "Examining the Appropriateness of Standards for Medical Imaging and Radiation Therapy Technologists." The hearing included testimony from practicing radiation oncologists and radiation oncology experts, government officials and industry representatives. It examined the current state of accreditation for medical imaging and radiation therapy technologists, identified potential areas of deficiency, and discussed the role of accreditation to maximize patient safety and reduce unnecessary duplication of services.

Witnesses included John Spiegel, Director, Medicare Program Integrity Group, Centers for Medicare and Medicaid Services (CMS); Leonard Gunderson, MD, MS, Chairman, Board of Directors, American Society for Radiation Oncology (ASTRO); Rebecca Smith-Bindman, MD, Professor, Departments of Radiology, Epidemiology/Biostatistics, and Obstetrics, Gynecology, and Reproductive Medicine, University of California, San Francisco; and Sal Martino, EdD, RT(R), FASRT, CAE, Chief Executive Officer, American Society of Radiologic Technologists (ASRT).

In addition to discussing the importance of accreditation for technologists, the committee and witnesses discussed the benefits of the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (CARE) Act, which would require personnel who administer imaging and radiation therapy to meet certain education, training and certification qualifications to help ensure the provision of safe, appropriate treatment.

Click here to read more about the CARE Act.

Click here to read a statement by the Access to Medical Imaging Coalition.

Congress Passes FDA User Fee Legislation

The US Oncology Network Shares Concerns Regarding Potential Bill Amendment

On May 24, the Senate passed by a vote of 96-1 the Drug Administration Safety and Innovation Act, and on May 30, the House of Representatives approved by a vote of 387-5 the Food and Drug Administration Reform Act of 2012.

The two similar bills would reauthorize prescription drug and medical device user fees paid by manufacturers when submitting new products for approval by the Food and Drug Administration (FDA) and create new user fees for the review of generic drugs.

In addition to reauthorizing user fees, the House and Senate passed legislation would also aim to strengthen FDA oversight of potential safety issues related to drugs and devices while ensuring that important products reach the market quickly, allow for the fast-tracking of products needed to treat patients with rare and/or serious illnesses, and establish new measures to address the nation's shortages of anti-cancer drugs and other life-saving medications.

Now, an informal conference will commence between lawmakers in both chambers in order to work out differences in some areas between the two bills.

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Congress Passes FDA User Fee Legislation *(cont'd)*

On June 5, The US Oncology Network, the American College of Radiology, the American Society of Nuclear Cardiology, the Cardiology Advocacy Alliance, the Council on Radionuclides and Radiopharmaceuticals, the National Association of Nuclear Pharmacies and the Society of Nuclear Medicine sent a letter to Representative Bill Cassidy, M.D. (R-LA) alerting him to an unintended but serious consequence that could result from the passage of a "Valid Prescription" amendment to the Federal Food, Drug, and Cosmetic Act, which is being considered for addition to the House-passed Food and Drug Administration Reform Act of 2012.

The amendment, which is intended to address objectionable practices of Internet pharmacies, would provide that a prescription drug may only be dispensed pursuant to a "valid prescription" of a practitioner licensed to administer the drug. The amendment defines a "valid prescription" to mean one that (among other things) is issued either by a licensed practitioner who has conducted at least one in-person medical evaluation of the patient within the previous 24 months; by a "covering practitioner;" by a practitioner engaged in telemedicine; or by an offsite telehealth practitioner.

The amendment as currently drafted could have a disruptive impact on current radiology, specialty or surgical practice and patient care. For example, when a practitioner who conducts an in-person evaluation of a patient orders a diagnostic procedure, the procedure is conducted in a hospital radiology department, clinic, ambulatory surgical center, or medical imaging center that is overseen by one or more radiologists or other specialists. A specialist orders the drugs that must be administered as part of the patient's procedure, and after the procedure the specialist reads and interprets the patient's scan and prepares a report for the referring physician. However, the procedure itself is often conducted, and the drugs administered by, technologists rather than the specialist. Typically there is no need for the specialist to conduct an in-person evaluation of the patient, since this has already been done by the referring physician, and a further visit is unnecessary for purposes of determining the correct drug and dosage to be administered and reading and interpreting the scan.

The amendment as currently drafted would preclude the efficient use of limited health care resources in the situations described above by prohibiting the specialist from ordering drugs for a patient procedure without first conducting a needless in-person evaluation of the patient, which was clearly not the intent of the Valid Prescription amendment.

The US Oncology Network and the other signatory organizations have proposed an exception providing that a valid prescription does not require an in-person medical evaluation of the patient where the prescribing practitioner is issuing a prescription or order for a drug for use in a diagnostic, therapeutic or palliative service or procedure that is requested or ordered for a patient by a licensed practitioner who has conducted an in-person medical evaluation within the past two years, or by a covering practitioner.

Leaders in both chambers have said they hope to send final user fee legislation to the President in coming weeks. A combined user fee bill must be signed by President Obama before October 1, when the FDA's current user fee agreement expires. The FDA has warned that if Congress delays reauthorization the agency may have to lay off as many as 2,000 staffers.

Click here to read the letter to Rep. Cassidy.