

U.S. Supreme Court's Decision Upholding Health Care Reform and What the Law Means for Medical Device Sellers

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Yesterday the United States Supreme Court issued its long-awaited decision and largely upheld President Obama's health care law as constitutional.

The major findings in the decision are

- The "individual mandate" – the requirement that all individuals maintain health care coverage – was upheld as constitutional under Congress' power to tax.
- The expansion of Medicaid, which is set to occur in 2014, was upheld. However, the Supreme Court ruled that if states refuse to participate in the expansion, the Federal government cannot withhold their funding for existing Medicaid programs.

The Affordable Care Act ("ACA") was enacted in 2010 to institute sweeping reforms of healthcare. The ACA contains many parts affecting health care providers, health insurance companies, health care consumers, manufacturers of medical products, and potentially distributors.

The ACA includes some popular provisions including rules against insurance companies limiting coverage for pre-existing conditions and allowing children to stay on their parents' policies until age 25. It also requires changes to the Medicare payment system, requires certain employers to make health insurance coverage available, and requires the development of health care insurance "exchanges."

A centerpiece of the ACA is the individual mandate, which goes into effect in 2014 and requires everyone to obtain certain minimal coverage. In addition, in 2014, Medicaid is expanded to cover all individuals with household incomes at or below 133% of the federal poverty level. The purpose of the individual mandate was to require individuals to take personal responsibility for paying for healthcare and to spread the cost of healthcare more evenly by requiring everyone to purchase healthcare, rather than having people wait until they are sick or older to obtain coverage. Individuals will be able to obtain health insurance through their employers, through the insurance exchanges that are created under the ACA, or through Medicare/Medicaid coverage. The ACA provides for income-based subsidies to individuals and tax credits to small businesses.

In upholding the constitutionality of the individual mandate, the Supreme Court held that the mandate was *not* constitutional under the Constitution's Commerce Clause, as the Government has suggested. Instead, the Supreme Court found that the penalty that the ACA imposes on individuals who do not comply with the mandate's requirement to obtain health insurance, and which is paid to the Internal Revenue Service with regular tax payments, is actually a tax. Accordingly, the Court ruled that Congress acted within its power to tax under the Constitution. In characterizing the penalty as a tax, the Court explained that not purchasing the required insurance is not like breaking a law, since the only real penalty for not getting health insurance was to pay the additional tax penalty. Chief Justice Roberts' opinion for the majority of the Court explained, "Those subject to the individual mandate may lawfully forgo health insurance and pay higher taxes, or buy health insurance and pay lower taxes. The only thing that they may not lawfully do is not buy health insurance and not pay the resulting tax."

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Interestingly, the argument was made to the Court that the Court could not yet rule on the individual mandate because the Anti-Injunction Act requires that a court cannot rule on the legality of a “tax” until after the penalty for non-compliance (i.e., not paying the tax) has already been imposed. Even though the Court found that the mandate was constitutional under Congress’ taxation power, the Court found that the penalty was not so much like a tax that it was not allowed to review the penalty. (Yes, I too am struggling a bit with that reasoning.)

The issue before the Court on the ACA’s expansion of Medicaid was whether it was constitutional under Congress’ spending power. Twenty six states challenged the expansion, arguing that Congress could not saddle the states with the financial obligation to cover more individuals under Medicaid. The Supreme Court held that Congress could not impose this additional requirement on a state without the State’s consent. The Court explained that Congress can offer funds to the states to expand Medicaid coverage and require that the States accept certain conditions (such as expanded coverage) to obtain the funds. However, Congress is not allowed to punish states that do not wish to participate in the new expanded Medicaid program by taking away a state’s *existing* funds.

How the ACA Affects the Sale of Medical Devices

Now that the Supreme Court has upheld the ACA, sellers of medical devices must be even more focused on those provisions that might directly impact your businesses.

Medical Device Tax

The ACA imposes a 2.3% excise tax on the sale of any taxable medical device by the manufacturer or importer of record of the device starting in 2013 (although exports are not subject to the tax). If the distributor is listed as the importer of record then the distributor is responsible for paying the tax. The IRS published proposed regulations in February providing guidance on how the tax will be applied. *Federal Register*, February 7, 2012, pp. 6028-38. According to the proposed regulations, the tax generally attaches when the title to the taxable article passes from the manufacturer to a purchaser. The tax does not apply to eyeglasses, contact lenses, hearing aids, or any other medical device that the public typically buys at retail for individual use.

Regarding kits, packs, and trays, the “kitter” is treated as a “manufacturer” and must pay the tax when the kit, pack, or tray is sold. All kits, packs, and trays that are listed with the FDA as a device are subject to the tax. The proposed regulations offer manufacturers two options for devices that will be incorporated into another device, like into a kit. First, the manufacturer may sell the device tax-free to a distributor and the distributor will be responsible for the tax on the kit. Alternatively, the manufacturer can sell a taxable medical device to the distributor for use in a kit at a tax-included price. The distributor will still be responsible for the tax on the kit, but the distributor can claim a credit or refund for the overpayment.

The ACA’s Reporting Requirements

The ACA additionally contains reporting requirements, often referred to as the Sunshine Law, for manufacturers that give something of value to doctors or teaching hospitals. But, distributors that purchase and resell product may also have to file such reports under the Sunshine Law. The purpose of these laws and the reporting requirements is to ensure that healthcare providers and those who can influence purchasing decisions are not influenced by any benefit other than the well-being of the patient.

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The reporting obligations cover any “transfer of value” to physicians and teaching hospitals that amounts to \$10 or more (or such lesser amounts, if they total more than \$100 over the course of a year). The nature of payment falls into a number of categories that are listed in the Act (such as consulting fees, research, gifts, entertainment, food, travel, education and charitable contributions). Therefore, under the Sunshine Law, even permissible benefits to a physician (such as modest travel expenses to attend a class) must be reported to the federal government. It may be legal to buy lunch for medical personnel during a teaching experience, but under the Law it will also be reportable.

Right now the government is still finalizing regulations that will flesh out the requirements of the Sunshine Act. The Centers for Medicare & Medicaid Services announced in early May a delay to the implementation of the Act. CMS will not require data collection until Jan. 1, 2013. In a blog entry published on May 3, 2012, CMS said the agency was delaying the implementation so that organizations would have more time to prepare for data submission and so that CMS could “sufficiently address the important input we received during the rulemaking process.”

We will work to keep you informed as developments about the ACA and its impact on your business in the months and years to come.

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