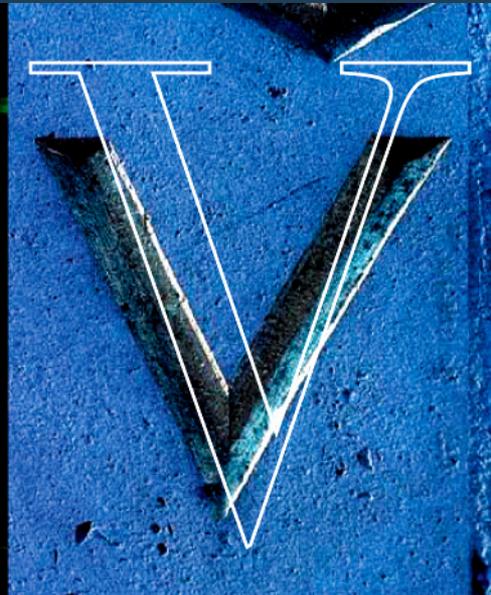
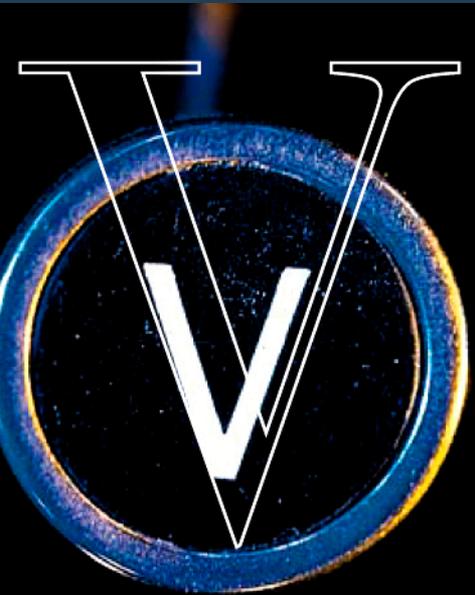


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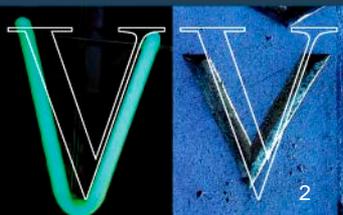
The Supreme Court Healthcare Ruling: What's Next?

JUNE 29, 2012



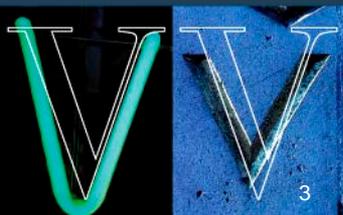
Agenda

- The Decision
- What's Next?
 - Congressional & regulatory action
 - Employers
 - State exchanges
 - Insurers
 - Life sciences companies
- Q & A
- What's Next From Venable?



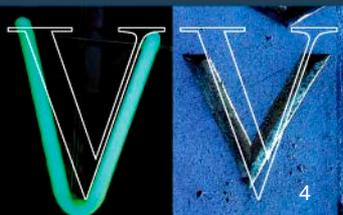
Our Team

- John Cooney is a senior regulatory litigator with forty years' experience in lawsuits involving federal agencies. Before joining Venable, John worked in the Solicitor General's Office, which represents federal agencies before the Supreme Court, and in the Office of Management and Budget, where he helped the White House plan for the outcome of Supreme Court decisions that might invalidate key regulatory statutes.



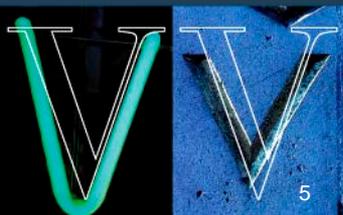
Our Team

- Will Nordwind, Chair, Venable's Legislative and Government Affairs Group & Former Counsel to the House Energy and Commerce Committee of the U.S. House of Representatives.



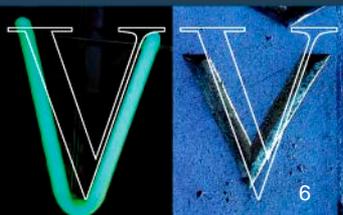
Our Team

- The Honorable Bart Stupak has been with Venable just over a year. Bart was Chair of the Oversight and Investigations subcommittee of the Energy and Commerce Committee. He served on the Committee for 16 years and was involved in the drafting of the healthcare legislation. The Energy and Commerce committee has jurisdiction over health care.



Our Team

- Thora Johnson is a partner in our Employee Benefits and Executive Compensation Group. She has been helping our employer clients navigate health care reform since its enactment. She has broad expertise in health plan compliance, including ERISA, the Internal Revenue Code, and HIPAA.



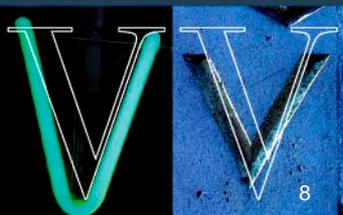
Our Team

- Chris Condeluci served as Tax and Benefits Counsel to the Senate Finance Committee from 2007 to 2010. As Tax Counsel to the Finance Committee, Chris actively participated in the healthcare reform debate and developed portion of the new healthcare law.



Our Team

- Ralph Tyler, Partner, Venable's Regulatory and Healthcare Practices & Former Maryland Insurance Commissioner, former Chief Counsel of the U.S. Food and Drug Administration (FDA)



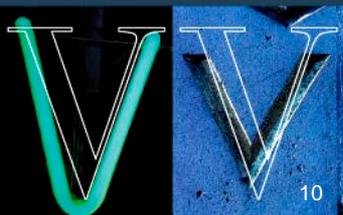
Our Team

- Michael Gollin, Chair, Venable's Life Sciences Group



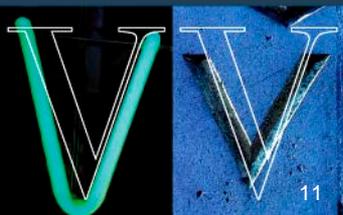
Our Team

- Ted Ramirez (Moderator), Partner Venable LLP, Chair, Healthcare Public Policy Group and Co-chair of the Healthcare Transactions Practice. His work in the healthcare industry includes experience as member of governance board committees for strategic planning, finance and audit, and legal affairs. As a Member of the Bar of the Supreme Court of the United States, he attended the Court's session that issued its ruling on the constitutionality of the Affordable Care Act.



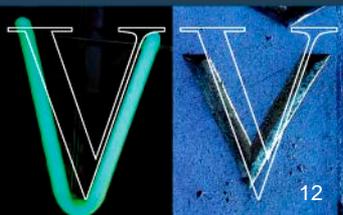
The Decision

The holdings in *National Federation of Independent Business v. Sebelius*



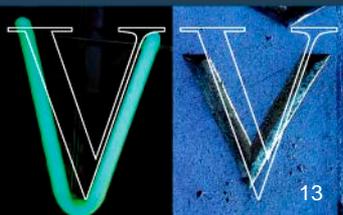
The Decision

- Chief Justice Roberts, writing for himself and four other justices, upheld the “individual mandate” (requiring persons to have insurance or pay a penalty) as a valid exercise of Congress’s taxing power.
- A majority of the Court rejected the government’s argument that the individual mandate of the Affordable Care Act (ACA) was enacted pursuant to a valid exercise of Congress’s power under the interstate commerce clause. In the end, however, the government’s loss on that point was irrelevant to the outcome of this case because the Court upheld the mandate under Congress’s authority to tax.
- The Court, also in an opinion by Chief Justice Roberts, upheld the Medicaid expansion, while limiting the federal government’s remedy against a state which declined to comply with the expansion to loss of the “expansion Medicaid funds,” and not, as the statute provided, to loss of all Medicaid funds.



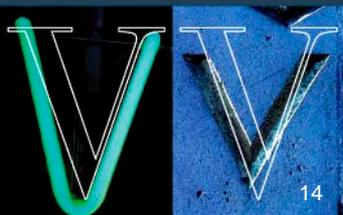
What's Next?

Congressional & Regulatory Action



Anticipated Congressional Action

- ACA will continue to be controversial. In Congress and in campaigns across the country, there will be lots of talk between now and the election in November about repealing the ACA. The law has no chance of being repealed in 2012 as Democrats control the Senate and the Presidency.
- The future of the ACA post-2012 will certainly be affected by the outcome of the presidential election and the political complexion of the Senate and House.
- Assuming the ACA is not repealed in 2013, there will likely be modifications to it in 2013 and beyond as specific implementation problems are revealed.
- Which committees and their leaders in the Senate and House will be most involved in repeal and/or modification efforts?



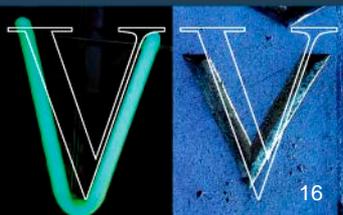
What's Next?

Employers



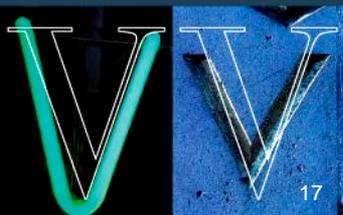
Implications for Private Employers?

- Decision highlights the importance of employer group health plans continuing with their compliance programs.
- The enforcement action that has already begun will certainly continue—particularly now that the uncertainty regarding the Supreme Court’s response is over.
- As a first step, employers should confirm their plans are in compliance with the many provisions that are already in effect. These include:
 - Coverage for adult children to age 26
 - Removal of lifetime/annual limits
 - And, of course, there are many more that are currently in effect



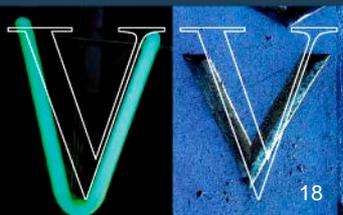
Next Set of Concerns for Employers?

- Employers need to prepare for provisions coming into effect in the near term.
 - The top of the list is the Summaries of Benefits and Coverage—these are the highly regulated descriptions of health benefits that need to be distributed beginning with open enrollment this fall. These are separate from SPDs.
 - Employers need to continue to track the Value of Employer Provided Health Coverage—so that they can meet the new W-2 reporting requirement that begins with the 2012 W-2s issued in January 2013.
 - There is also a small per participant tax imposed on plans that will be used for funding research on the effectiveness of treatment protocols. The tax already applies and is first due in 2013.



New Provisions and Coverage

- Looking ahead to 2014
 - In addition to the individual mandate, there is an Employer Mandate, commonly referred to as the play-or-pay provisions.
 - If an employer doesn't offer health coverage, or the coverage they offer is not good enough or is too expensive, the employer has to pay a penalty.
 - Employers should begin to model and plan for what their coverage, if any, will look like in 2014 in light of these new penalties.
 - Some ERs may wish to transition employees to the exchanges in favor of paying the penalties.
 - Others may wish to keep their health plan because – for instance – it is helpful in retaining/attracting employees.
 - » These employers need to begin to consider what that coverage will look like when some of the later reform changes kick in
 - » Such as automatic enrollment
 - » And the limits on waiting periods and cost-sharing.



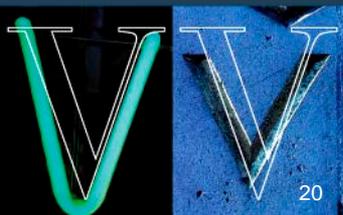
What's Next?

State Exchanges



What's Next for States?

- The Exchange is intended to serve as a marketplace through which insurance can be sold to health care consumers.
- Initially, the Exchange will service (1) individuals and families purchasing insurance in the individual market and (2) employees of small employers.
- In 2017, a State may elect to allow large group plans to be sold through the Exchange, but a State is not required to do so.
- Importantly, the Exchange will also serve as a delivery mechanism for the subsidies that will be made available to help low- to middle-income Americans purchase health insurance.



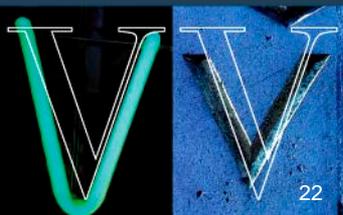
How Will the Ruling Affect the Establishment of Exchanges?

- To date, over \$1 billion have been awarded to States to help them establish their Exchange.
- However, the establishment and implementation of the new law's requirements has been slow going.
- Creating and/or modifying existing IT systems to perform many of the new Exchange functions has been most troubling for States.
- The lack of Federal guidance has also contributed.
- But in many States, it has been the politics of the State.
- Now that the law is the law, those States that have been waiting to move forward with their Exchange until AFTER the Supreme Court ruling are expected to start moving forward.
- They will have to move fast if they want to meet the arbitrary deadlines set forth in the statute for having a State-based Exchange in place



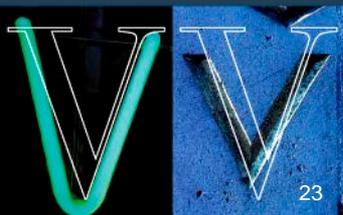
How Many States Will Have a State-based Exchange by the Statutory Deadline?

- The NAIC has recently indicated that it expects 25 States to have their Exchange up and running by January 1, 2014.
- We believe that number is high, but regardless, it is clear that a significant number of States – 25 and possibly more – will not have their Exchange up and running by 2014.



Implications of those State-based Exchanges

- It means that a number of States will rely on the Federal Exchange. That is, HHS will be running the Exchange in these States.
- A number of States will opt to enter into a partnership with the Federal government, where the HHS will perform certain Exchange functions and the State will perform other functions.
- At some point in the future, the States entering into this partnership will take over all of the Exchange functions and ultimately run its own Exchange.



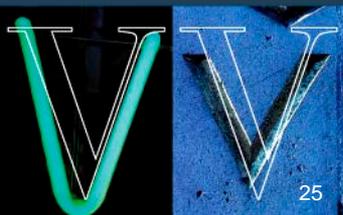
Will some States resist the new health care law even after the Supreme Court ruling?

- Currently it is unclear. But we do expect most if not all States to have some type of Exchange – a State-based Exchange, the Federal Exchange, or an Exchange run by the Feds and the State.



In Closing...

- In closing, now that the law is law – and because it is likely that most if not all States will have some sort of Exchange – all eyes now turn to whether the insurance carriers will want to participate in the Exchanges.
- If they do, carriers will need to modify their current insurance products to meet the minimum standards under the law, which carriers are currently doing.
- But, the carriers need more Federal guidance to standardize their plans. (who will issue that guidance?)
- And questions of whether there will be sticker shock in the Exchanges remain.
- Not to mention whether the reinsurance, risk adjustment, and risk corridor programs – programs which are intended to mitigate adverse selection in a State's insurance market once the new reforms come on-line – will actually work as intended.
- Finally, employers – including large employers – must get acquainted with the Exchange in the States they do business because the Exchanges will play a big role in determining whether an employer is subject to the employer mandate or not.



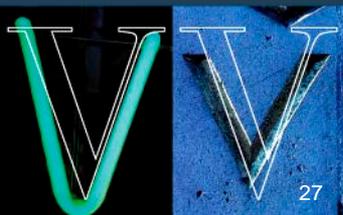
What's Next?

Insurers



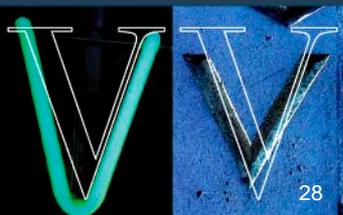
Overall Impact on Health Insurance Companies

- Overall, the outcome is a net positive for insurers. Insurance companies stand to gain millions of new customers, perhaps as many as 30 million, and to receive significant new federal premium subsidies.
- In addition, the decision eliminates the significant risk which insurers faced prior to the decision that the mandate to purchase insurance would be struck down but that the obligations to provide insurance irrespective of health status or pre-existing health conditions (“guaranteed issue) and not to base premiums on an individual’s health status (“community rating”) would stand. Without the mandate, these other provisions would have posed significant financial issues for insurers.



Changes Health Insurers Should Consider Making

- Broadly speaking, health insurers will need to consider changes in two major areas. First, and perhaps most obviously, they will need to make changes in their policies to conform with the federal requirements such as the obligation to insure people irrespective of pre-existing health conditions and to provide at least the specified benefits, including those related to preventative care and treatment. Health insurers have adapted rather easily to the changes currently effective, including the requirement to retain people up to age 26 on their parents' policy, so it is likely that these additional changes will be adopted with similar ease.
- A second area of change which will certainly pose technical and information technology challenges is building the infrastructure to handle all the new customers. Systems will need to be built to handle applications, claims, premium payments, and subsidy payments. These issues pose challenges currently for many insurers and those challenges will only increase.



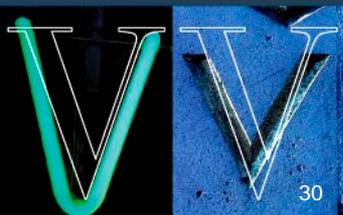
Changes in the Regulatory Space

- The biggest change will be that health insurers will increasingly answer to two sets of regulatory authorities. Insurance, unlike other financial services, is largely regulated by states and states will continue to have regulatory authority over health insurers. In addition, however, health insurers will be accountable to federal authorities and required to meet federal requirements, including making premium refunds when their “medical loss ratio” (the percentage of premium devoted to claims payment) falls below federal requirements and federal review of premium increases.



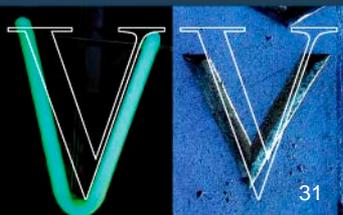
Most Immediate Issue Facing Insurers

- I would think insurers would want to work with their respective state authorities in the development of the health insurance exchanges because 2014 is fast approaching. There may be some states which continue to hold off on developing exchanges and in those states insurers will want to work with the Department of Health and Human Services (HHS) in the development of the alternative federal exchange.



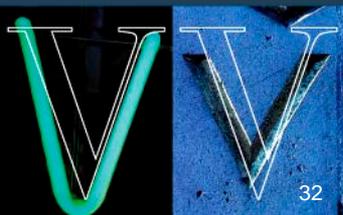
What's Next?

Life Sciences Companies

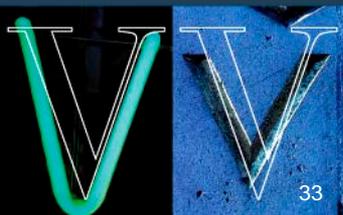


Impact on life sciences product companies, including branded and generic pharmaceutical companies, biologic therapeutic companies, and medical device companies

- General satisfaction with increased potential customers and opportunities for innovative products with strong clinical impacts, but concern with specific reimbursement and tax provisions, which may lead to industry-specific challenges in regulation and legislation.



Q & A



What's Next From Venable?



contact information

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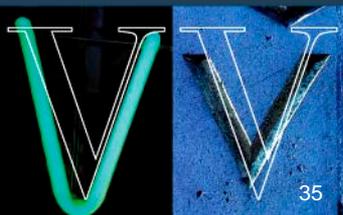
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