

The logo for K&L GATES, featuring the company name in white, uppercase, sans-serif font on a solid orange rectangular background.

K&L GATES

WASHINGTON ALASKA HFMA CONFERENCE:

**LEGAL ISSUES ROUND-UP:
MEDICAID/MEDICARE/ACA**

SOVALDI

- \$1,000/day Hepatitis C pill
- Potential \$227 billion annual price tag to treat all U.S. patients with Hepatitis C
 - Compares to \$260 billion spent in U.S. on ALL drugs
- Hepatitis C disproportionately impacts low-income patients
- Therefore, disproportionately impacts Medicaid

“LIGHTNING ROD” FOR DRUG PRICE ISSUES

- Claimed as the best drug on the market for effectiveness/reduced side effects with 90% cure rate
 - But see NAMD Statement on need for evidence-based reporting
- Gilead’s pricing based on country’s ability to pay
 - Germany: \$67,000 for 84 day course of treatment
 - Canada: \$55,000
 - Egypt: \$900

- December 2013 drug introduction (after capitation rates established) makes Medicaid problem worse
- Congressional questions regarding drug pricing
- Gilead purchased original developer for \$11.2 billion in 2012
 - On pace to recover entire investment in the first year of sale

STATE ELIGIBILITY GUIDANCE

- Alaska
- Drug will be covered for a subset of patients
 - Most seriously ill: cirrhosis or bridging fibrosis
 - Must have abstained from illicit drugs and alcohol for 3 months (shown by 2 months of negative urine tests)
 - Must agree to complete treatment regimen (dual/triple therapy)

- Washington
 - Most seriously ill: (Metavir Fibrosis Score \geq F3)
 - Must have abstained from alcohol/illicit drugs for 6 months
 - Exceptions considered at 3 months if receiving treatment
 - Interferon ineligible or intolerant patients who have failed triple therapy urged to wait for potentially more effective regimens expected in next 24 months
 - Friction between Medicaid guidelines and existing clinical guidelines, leading to charges of rationing

WHAT'S NEXT

- Lawsuits?
- Congressional hearings?
- Combined federal/state cost responsibility?
- Development of other treatments?
- Gilead modifying its pricing position?
- Other?

ACA AND “EXCHANGES ESTABLISHED BY THE STATE”

- 16 states and D.C. created exchanges, 34 states relied on federally facilitated exchanges
- IRS rule extends tax credit subsidies to low-income individuals who purchased through exchanges purchased on both state and federally facilitated exchanges
- D.C. Circuit (*Halbig v. Burwell*) rejects IRS rule
- Fourth Circuit (*King v. Burwell*) upholds IRS rule

TEST FOR AGENCY ACTIONS

- If Congress has “directly spoken to the precise question at issue” the agency must follow the unambiguously expressed intent of Congress
- If the statute is silent re the specific issue, agency action will be upheld if based on a permissible construction
- Fourth Circuit and D.C. Circuit reached opposite conclusions by emphasizing different prongs of the test

IMPACT

- In 34 states, taxpayers would still be subject to the individual mandate but would not get the subsidies designed to make insurance affordable
- Employers in these states would have no exposure, since employer penalties triggered when one or more employees qualify for premium tax credits (with complications for employers operating in multiple states)

FUTURE PROCEEDINGS

- Current request to have entire D.C. Circuit (not just 3 judge panel) reconsider *Halbig*
- *Halbig* decision currently stayed
- Plaintiffs in *King* seeking Supreme Court review
- If case goes to Supreme Court, unlikely to get decision prior to June 2015
- States could resolve the issue by establishing exchanges or Congress could resolve by amending the ACA—both have political problems

“PSYCHIATRIC BOARDING”

- *In the Matter or the Detention of D.W.*
 - Single bed certifications in ER and acute care centers no longer authorized
 - “Patients may not be warehoused without treatment because of lack of funds. Lack of funds, staff or facilities cannot justify the State's failure to provide [such persons] with [the] treatment necessary for rehabilitation.”
 - EMTALA conflicts

MEDICAID EXPANSION

- Alaska's decision not to expand Medicaid
 - Lewin Group report commissioned by DHSS regarding financial impacts
 - Complicated costs and savings calculations complicated by assumptions ("woodwork" effect, ACA enrollees, switched from other programs, etc.)
 - Non-expansion affects approximately 20,000 to 26,000 people (who would have gained coverage under a Medicaid expansion and who will remain uninsured)

- Washington's decision to expand Medicaid
 - Significant increase in enrollees (as of May 2014, 450,000 more newly eligible adults enrolled compared to six months ago)
 - Uninsured rate dropped from 16.8% in 2013 to 10.7% by midyear 2014
 - White House Council of Economic Advisers July 2014 report on benefits of expansion
 - Medicaid reimbursement rates bumped up to Medicare levels for 2014, but still some difficulties with supply of providers accepting Medicaid