



October 28, 2014

The Honorable Ron Wyden
Chairman
Senate Committee on Finance

The Honorable Orrin Hatch
Ranking Member
Senate Committee on Finance

The Honorable Tom Harkin
Chairman
Senate Committee on Health,
Education, Labor and Pensions

The Honorable Lamar Alexander
Ranking Member
Senate Committee on Health,
Education, Labor and Pensions

The Honorable Fred Upton
Chairman
House Committee on Energy and
Commerce

The Honorable Henry Waxman
Ranking Member
House Committee on Energy and
Commerce

The Honorable Dave Camp
Chairman
House Ways and Means Committee

The Honorable Sander Levin
Ranking Member
House Ways and Means Committee

Dear Senators and Congressmen:

We are writing on behalf of the nation's Medicaid Directors to provide insight on the challenges posed to Medicaid agencies by new and emerging treatments for one of our nation's most pressing public health problems – hepatitis C. We also wish to begin a dialogue with you on federal policies which strike a better balance between appropriate access to new pharmaceutical cures and treatments for consumers and the long-term fiscal health of the Medicaid program which currently covers nearly 70 million low-income, vulnerable individuals and families. Our letter identifies several ideas to ground these conversations.

NAMD is a bipartisan, non-profit organization which represents Medicaid Directors in the fifty states, the District of Columbia and the territories. The Association was created in large part to develop consensus among Directors on critical issues, specifically those that have national policy implications.



The evolving situation with high-cost breakthrough drugs is an issue that has brought together the state Medicaid Directors. The current experience with hepatitis C has rightly commanded national attention, both for the promise that these new treatments hold, as well as their associated costs.

While the immediate focus and challenges present with hepatitis C treatments, we know this is a harbinger of the promises and challenges that will emerge in the years ahead. Publicly available information indicates that additional specialty drugs are currently moving through the drug pipeline. These are expected to enter the market by 2020 and will treat conditions including new immunotherapy treatments for cancer, cholesterol management, Alzheimer's disease, and multiple sclerosis reversing therapies.

This situation requires an immediate federal solution. We have noted the bipartisan engagement in efforts such as the "21st Century Cures" initiative, which seek to examine the steps federal policymakers can take to accelerate the pace of cures in America. However, we believe Congress has *not* sufficiently addressed the full continuum of issues associated with this process and related drug approval processes. Specifically, policymakers have failed to address the cost and reimbursement issues associated with faster or increased pathways for the development of high-cost therapies and treatments. This is particularly concerning when there is limited information about the evidence base for these products.

Policymakers must begin developing a new framework for conceptualizing the comprehensive costs and value associated with highly effective treatments in public health insurance programs, including Medicaid. In this process, policymakers and the public must also be realistic about the choices and trade-offs involved when taxpayer dollars are used to fund high-cost services and products. This conversation will be difficult, but it is one we believe federal policymakers must immediately begin with states and stakeholders.

The Hepatitis C Situation

In the short term, state Medicaid agencies are deeply concerned about the situation they face with new hepatitis C prescription drugs. As a primary payer for breakthrough treatments for hepatitis C, Medicaid agencies are using the limited tools they have to manage the very serious cost implications of emerging products. They are also weighing complex ethical questions, scientific evidence and public health needs to maximize appropriate access to new treatments.

This situation has several parallels to experiences with other products, namely those for the treatment of HIV/AIDS. As with HIV/AIDS prescription medications, there is sound, but still emerging, scientific evidence, a moral imperative to treat and a high cost based on investment and market dynamics.

However, as compared to HIV/AIDS, experts estimate that hepatitis C affects a much larger population. The Centers for Disease Control and Prevention (CDC) estimates that 3.2 million Americans are infected with hepatitis C. However, most people living with a chronic hepatitis C infection are unaware of their infection status. The CDC describes the disease's progression as "insidious, progressing slowly without any signs or symptoms for several decades."¹

We anticipate the number of identified infected Americans will increase as more at-risk Americans are tested per CDC and 2012 United States Preventive Services Taskforce (USPSTF) recommendations and Medicare policy. With respect to Medicaid, precise estimates of the Medicaid-specific infected population are not widely available. We do know that experts believe the universe of infected individuals is disproportionately low income, and thus will likely be Medicaid-eligible in the majority of states.

The Challenges for Medicaid Agencies

Of significant concern to state Medicaid programs and other payers is the high cost of a Sovaldi treatment, which at a minimum is \$84,000 wholesale acquisition cost per course of treatment, or \$1,000 per pill. Still, Medicaid is no stranger to high-cost medications and therapies. Some of the most medically needy and expensive patients in the country are covered by the Medicaid program.

The challenge Sovaldi and other new hepatitis C medications pose for the Medicaid program is the intersection of a high-cost therapy and a potentially large population eligible for the therapy. To date, several states have reported that their first quarter 2014 prescription drug expenditures for hepatitis C treatments has doubled or tripled compared to their entire 2013 spending, which may reflect patients and providers waiting for these new treatments to enter the market. Another hepatitis C combination therapy targeted towards the most common types of hepatitis C infections, Harvoni, was released in mid-October 2014, with an even higher price point of \$94,500 per 12 week course of treatment. Other drug manufacturers have signaled that they do not intend to compete on price when they introduce their own breakthrough therapies in 2015. These

¹ <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#b1>

facts suggest that the challenges posed by new hepatitis C therapies are likely to persist over many years.

States have one primary tool, the prior authorization (PA) process, to manage appropriate access to and act as competitive purchasers of prescription drugs. Unlike medical services, states are required to cover any drug which receives FDA approval and for which the manufacturer enters into the mandatory Medicaid drug rebate agreement. While states are employing their PA authority in a range of ways that fit the available evidence and their program structures, this tool is limited and should not be seen as a long term solution for new hepatitis C therapies and similarly-priced products for other diseases and chronic conditions.

For example, states are not well positioned to secure meaningful supplemental rebates for Sovaldi. As mentioned above, Medicaid is required to cover any outpatient drug which receives FDA approval, in return for receiving a mandatory 23 percent rebate from manufacturers. Typically, many states secure supplemental rebates on top of the required rebate by entering into negotiations with manufacturers. But just as Sovaldi is not a typical treatment, these typical approaches have not yielded results for the states.

To date, the supplemental rebates states have secured for Sovaldi are minimal, with any further concessions predicated on unrestricted access to the drug. States, neither individually nor collectively, are sufficiently equipped to secure the concessions required to make Sovaldi-like pricing a sustainable proposition. This is true for this product and for other comparatively priced products moving through the prescription drug pipeline. Though there is potential for more state negotiating power as new drugs enter the market, we cannot speculate as to how effective these negotiations will be in light of the possibility that these drugs will be priced similarly to Sovaldi.

Further, the pricing strategy introduced with Sovaldi is one which is modeled on trading high upfront costs for a believed accrual of savings to the overall healthcare system. This product is priced to reflect the value of its ability to cure, rather than manage, a debilitating infectious disease. As such, the upfront costs of providing Sovaldi are said to be offset by the money saved in not being required to manage the effects of untreated hepatitis C.

This may be true in the aggregate, though Sovaldi is different from prior therapies in that it can potentially benefit a broader range of patients than those who would have needed transplants or other treatments under the prior treatment paradigm. Regardless, this pricing strategy does not comport with the reality we face today. Individuals frequently transition on and off of public health insurance programs, between plans and programs,

or eventually transition from being Medicaid eligible to eligible solely for Medicare or dually eligible for both Medicaid and Medicare.

It is worth noting that Sovaldi's clinical trials were not conducted on patients with comorbidities, such as HIV/AIDS, that may impact treatment efficacy and effectively lower its overall cure rate. Such populations are more common among Medicaid programs. As a result, there may be significant additional costs to states for patients who are not cured or, for whatever reason, fail to complete the initial full course of treatment and need to be retreated (potentially more than once). Additionally, data are lacking on the long-term "cure" potential of Sovaldi and similar hepatitis C medications. Thus, in the future, patients may potentially need to be maintained on these drugs for longer periods of time.

The long-term pricing strategy applied in this situation – which is also likely to be applied for future breakthrough products – does not align with the underlying Medicaid financing structure. At the state level, Medicaid is financed on an annual or biannual funding cycle, with funding appropriated in the context of balanced budget requirements in all but one state. It is not practical to expect Medicaid programs to finance the significant upfront costs of Sovaldi and other breakthrough hepatitis C treatments, at the expense of providing other needed services, on the promise of seeing savings 10, 20, or 30 years later. In this timeframe, the beneficiary will likely have transitioned to another source of coverage, as discussed above. The potential savings associated with the initial Medicaid purchase of Sovaldi would therefore not accrue to the state's Medicaid program, but rather to another payer. It is not reasonable to expect states to finance the full cost of an expensive treatment whose associated savings likely accrue to another entity decades in the future.

Some reports indicate that while Sovaldi may prove efficacious, its pricing presents a low value proposition to the health care system due to the potentially high costs of treating such a large number of patients with a very expensive medication.² We believe further research and analysis is needed to better understand the impact of this and emerging products for Medicaid and the broader health care system.

The Long Term Outlook Calls for Federal Solutions

Simply put, the federal Medicaid statute is not designed to allow states to respond to this new pricing approach for pharmaceuticals. Sovaldi is just the first of many such

² California Technology Assessment Forum, "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection."
http://ctaf.org/sites/default/files/assessments/CTAF_Hep_C_Apr14_final.pdf

exceptionally high-cost “curative” specialty drugs. As more of the specialty drugs that are brought to market adopt this same pricing rationale, new thinking and approaches are required to safeguard the financial integrity of state Medicaid programs and ensure low-income patients are able to access appropriate medical innovations.

We believe federal policymakers must begin to discuss the menu of policy solutions available to address the affordability issue for high-value products. We also urge caution and close inspection of proposed trade provisions to ensure that they do not undermine or limit the ability of states or the federal government to moderate escalating prescription drug, biologic drug and medical device costs in public programs, particularly new costlier drugs or treatments.

Here, we offer an initial list of policy strategies. We anticipate that a more comprehensive and transparent discussion of the issues will generate additional options to ensure this treatment and other high cost treatments are appropriately addressed.

At this time we are not endorsing any single solution on this list. We believe each solution carries advantages and disadvantages, but all merit further exploration by Congress and other federal policymakers and stakeholders.

As a start, we encourage you to solicit other recommendations and begin to evaluate the feasibility of the following:

- **Solutions for all public payers:** Congress can exert downward pricing on Sovaldi and similarly-priced specialty drugs targeting large patient populations. While we recognize that direct price controls would be a politically volatile topic which could be expected to encounter substantial pushback, a strong case can be made for the unique circumstances of hepatitis C in particular. Many of the potential patients for these drugs are covered by federal taxpayer dollars, whether they are covered by Medicare, the federal prison system, the Veterans Health Administration, or Medicaid. There is also a vested public health interest in the potential to eradicate this deadly disease, which is currently responsible for more annual deaths in the country than HIV/AIDS.
- **Mitigating the cost to Medicaid:** Congress could also choose from a menu of policy options that do not directly affect Sovaldi or other breakthrough drug pricing or coverage policies, but would still mitigate state Medicaid programs’ exposure. These options include the following:

- Federal purchasing of the available supply and/or the supply chain, with subsequent discounted distribution of product to the states or a requirement that states pay only the administrative fee (modeled on federal purchasing of vaccines for children and other public health emergency situations);
- Enhanced federal match rates for this, or other such “curative” specialty drugs;
- Mandate additional rebates from a manufacturer, for example one that is triggered if a disease state or condition affects a certain percentage of the Medicaid population;
- Modify the “best price” policies for breakthrough drugs to include the selling price in other countries;
- Risk corridors or other reinsurance approaches, based on subsidizing any state spending in excess of clearly articulated federal projections of coverage and costs;
- A separate federal program created for the sole purpose of financing the provision of this drug to the affected population, similar to the Ryan White and state ADAP programs for HIV/AIDS drugs, with Medicaid serving as a payer of last resort; and
- Allow Medicaid programs to utilize cost-effectiveness research to identify whether or not a particular drug will be included in the program’s formulary by granting Medicaid the flexibility to exclude products that are found to not be cost-effective; and
- Create waiver flexibility allowing states to contract with drug manufacturers outside of the Medicaid rebate program structure to allow innovative payment arrangements. For example, allow states to enter into outcomes-based contracts with manufacturers, where payment is made per successful course of treatment rather than per pill.

Sovaldi – both in its medical potential and its price – represents a new frontier for specialty drugs, which are anticipated to enter the market in the near future at increasingly high price points. Federal thinking on Medicaid financing must reflect these developments in order to maintain the fiscal strength of the program in the coming years.



Working through our association, we are prepared to work with you to address the complexities of this critical public health care issue. Please contact NAMD's Executive Director, Matt Salo, to discuss how we can further assist you in this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Darin J. Gordon".

Darin J. Gordon
TennCare Director
Department of Finance and Administration
State of Tennessee
President, NAMD

A handwritten signature in black ink, appearing to read "Thomas J. Betlach".

Thomas J. Betlach
Arizona Health Care Cost
Containment System Director
State of Arizona
Vice-President, NAMD

Cc:

- Members of the Senate Finance Committee
- Members of the Senate Health, Education, Labor and Pensions Committee
- Members of the House Energy and Commerce Committee
- Members of the House Ways and Means Committee