OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

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October 19, 2015

The Honorable Senator Ron Wyden
The Honorable Senator Chuck Grassley
221 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to provide updated information on the challenges presented in Oregon by the incidence and prevalence of the Hepatitis C Virus (HCV) and the cost implications for health care reform. Thank you also for your work on this complicated and important issue.

The emerging HCV treatments of Sovaldi, Harvoni and Olysio contribute to the problem of rapidly increasing health care costs. When Sovaldi came to the market, Oregon Medicaid was both eager to provide access to the promising new treatment and shocked by the unpredicted price tag. Since then, we've seen Harvoni and Olysio, and still other new agents are on their way. Even with the promise of added competition, we have no cause to anticipate a lower, sustainable cost for HCV medications. Meanwhile, we struggle to provide appropriate coverage of other new specialty pharmaceuticals that also have high price tags. Some of these show much less promise in terms of meaningful therapeutic benefit.

Much has been said already about Sovaldi and the other recently-released HCV agents. It is a significant concern for all payers, but especially for Medicaid and Medicare. HCV patients are disproportionately beneficiaries of Medicaid or Medicare. This is true nationally, and Oregon is no different. What sets Oregon somewhat apart is that Oregonians have a higher incidence of hepatitis C than the national average. The mortality rate in Oregon from HCV was nearly twice the national average in 2011. Thus, Oregon is especially interested in life-saving, effective treatment, and is especially vulnerable to exceptionally high costs for that treatment.

We previously shared an analysis performed by Dr. Dan Hartung. This analysis identified 10,164 Medicaid clients as of September 2014 who appeared to be good potential candidates for the newly-available HCV treatment.

The gross cost of treatment was estimated to be between $84,000 and $150,000 per patient, depending on the treatment length indicated. Our entire gross drug spend for all drugs in 2014 was $591,191,199. This cost and demand meant that if we treated only half of the potential HCV candidates, we could end up more than doubling the previous year's entire drug spend.

With guidance from experts, we developed a strategy to target and prioritize treatment to those patients identified as the best candidates to successfully complete and benefit from treatment. Prescribing hepatologists and gastroenterologists help ensure treated patients are appropriate and prepared to successfully receive treatment. The Hartung analysis indicated that treating the more advanced patients was cost effective when compared to the previously available treatments. Based on historical utilization and assumptions regarding provider capacity, we concluded approximately 500 patients would be treated annually at a projected cost of up to $51 million per year for the first six years.

Since the new agents came on the market, total expenditure for these new HCV drugs continues to increase. Based on year-to-date expenditures, we expect to exceed $30 million in expenditure for 2015. Again, these appear to be well-tolerated, cost effective therapies that we anticipate will result in a reduction in costs for other services. However, the upfront costs to provide the treatment continue to drive substantial increases in the pharmaceutical budget.

The national attention paid to the new HCV treatments is well-deserved, but the concern over dramatic pharmacy budget increases is not limited to HCV. There are newer treatments for chronic conditions that, unlike the hepatitis drugs, do not provide a cure and will need to be taken by patients every year for the rest of their lives. For example, the PCSK9 inhibitors will be prescribed to treat high cholesterol and will result in a gross cost increase of approximately $14,000 to $29,000 per patient per year. New treatments for cystic fibrosis will exceed $250,000 per year for one patient. The estimated number of patients who meet current FDA-approved indications for the new cystic fibrosis treatment is very small but will still result in a significant financial impact of approximately $4 million per year. With the recent FDA approval of Orkambi (ivacaftor/lumacaftor), and anticipated expansion of FDA-approved indications, many more patients will likely qualify for treatment and the additional annual costs could be as high as $46 million.

What we face is not a drug cost problem; it is a drug price problem. State Medicaid programs are limited in our ability to control pharmacy benefit expenditure, particularly as federal law requires us to provide a pathway to coverage for all FDA-approved drugs, no matter how minimal the likely benefit per dollar spent. While federally mandated rebates help, they provide limited relief.
This limitation is especially evident for generics, for which we do not have the same rebate protections when the manufacturer raises their average price in excess of the Consumer Price Index.

Again, thank you for your work and attention on the financial impacts of these very expensive pharmaceuticals. Please let me know if you have any questions about this letter or would like further information. I can be reached by telephone at 503-945-6777 or via email at Lynne.Saxton@state.or.us.

Sincerely,

Lynne Saxton

Lynne Saxton
Director

CC: Jeremy Vandehey
Karmen Fore
Drew Johnston

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

September 23, 2015

The Honorable Ron Wyden
The Honorable Chuck Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Wyden and Senator Grassley:

Specialty pharmacy drugs have long constituted a portion of total pharmaceutical costs. These medications have historically been used to treat a limited number of medical conditions that affect relatively small numbers of the U.S. population.

More recently, effective, safe and very expensive specialty pharmaceuticals have become available for a wider number of medical conditions. While some of these pharmaceuticals target less common conditions such as cystic fibrosis and multiple sclerosis, others are used to treat very common conditions such as chronic hepatitis C and high cholesterol.

Newer treatments for chronic hepatitis C that have come to market in the last two years have posed especially difficult challenges for payers. Hepatitis C is a chronic infection caused by the hepatitis C virus. It affects one percent of the U.S. population and is the leading cause of cirrhosis, liver cancer and liver transplantation in the U.S.

In Washington State, it is estimated that between 75,000 and 85,000 people harbor the hepatitis C virus; based on available epidemiologic and clinical data, the Washington State Health Care Authority (HCA) estimated that as of July 2014, more than 23,310 Medicaid clients were chronically infected with hepatitis C. The especially high prevalence of hepatitis C in the Medicaid population reflects the increased prevalence of risk factors for hepatitis C in this population.

In November 2013, the Food and Drug Administration (FDA) approved Sovaldi (sofosbuvir) in combination with ribavirin and interferon for the treatment of hepatitis C. Sovaldi, manufactured by Gilead Sciences, represents a major breakthrough in the treatment of hepatitis C because of its effectiveness and lack of toxicity. However, Sovaldi still needed to be used in combination with two older medications – ribavirin and interferon – both associated with a high degree of toxicity.

The State was aware of Sovaldi's impending approval, but had no way of knowing that Gilead would set the price at $1000 per pill (Sovaldi is taken daily for 12 weeks when used in the treatment of the most common type of hepatitis C virus; hence, the cost of treating 1 individual is $84,000, based on Average Wholesale Price at the time). Moreover, the State recognized that within 1 year of Sovaldi's market entrance, additional less toxic and safer hepatitis C regimens would likely become available; these regimens would not require ribavirin and interferon as part of treatment.

The HCA anticipated relatively modest utilization of Sovaldi in 2014 because it needed to be used in combination with more toxic medications; as well, the medical community was eagerly anticipating the availability of much less toxic treatment regiments by early 2015 and "warehousing" patients with the purpose of treating them when the superior regimens became available. Approximately 350 Medicaid patients were treated with Sovaldi in calendar year 2014, a small proportion of those estimated to qualify for treatment. In January 2015 a new less toxic drug, Harvoni was released and HCA has estimated approximately 8,000 individuals will be eligible for treatment.

Taking into account both the federal and Washington State rebate negotiated with Gilead, in FY 2016 alone, the State anticipates spending more than $242 million to treat eligible Medicaid patients ($60,680,000 State; $181,630,000 Federal). Of note, this estimate is based on Medicaid's current clinical policy, which does not provide treatment for those who are infected with hepatitis C and evidence a lower risk of developing severe liver disease or cirhhosis). HCA's current pharmacy budget including Fee for Service and Managed Care is a little over $1 billion. ***If HCA were to pay for hepatitis C treatment for all Medicaid clients infected with hepatitis C, the cost would be three times the current total pharmacy budget.***

The new hepatitis C medications represent the "tip of the iceberg" with respect to the potential impact of new, effective and extraordinarily expensive pharmaceuticals that have recently or will soon come to market. For example, the FDA just approved two new cholesterol-lowering medications. These drugs, known as "PCSK9" inhibitors have been priced at about $14,000 annually. Like the new hepatitis C drugs, these medications treat a common condition; however, whereas people with hepatitis C usually have their hepatitis C virus eliminated with a single 90-day course of treatment, those treated with these new and expensive cholesterol-lowering agents will require treatment on an ongoing basis, i.e. $14,000 will be a recurring annual cost over the course of an individual's lifetime. It is estimated that up to 25 percent of people who need cholesterol lowering treatment cannot tolerate currently available medications (so called "statins," which are pennies per pill). Therefore, the cost implications of the "PCSK9" drugs for payers and national health care costs are staggering.

It is important to note that the new and expensive specialty drugs, while effective in reducing the burden of disease, are priced as such that they do not produce a net savings over time. That is, while treatment costs for the underlying condition will be reduced over time, they are not reduced to the extent that the dollars saved exceed the dollars expended on the drug. While

"cost-effective," these newer agents are NOT cost saving; they will add to the total cost of health care in the U.S.

State Medicaid programs will continue to be challenged to cover these new and emerging treatments. States may be forced to make difficult choices related to coverage for other Medicaid services in order to afford these new and very expensive drugs. We are interested in continuing to work with Congress to find relief for states as more drugs come onto the market.

Please let me know if you have any questions about this letter or would like further information. I can be reached by telephone at (360) 725-1863 or via email at MaryAnne.Lindeblad@hca.wa.gov.

Sincerely,

MaryAnne Lindeblad, BSN, MPH
Medicaid Director
Washington State

cc: Bob Crittenden, Special Assistant, GOV
Peter Gartrell, Committee Staff, U.S. Senate

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HUMAN SERVICES

OCT - 2 2015

The Honorable Ronald L. Wyden
The Honorable Charles E. Grassley
United States Senate
Senate Committee on Finance
Washington, D.C. 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to describe Pennsylvania's experience with coverage of the newest Hepatitis C agents in the Pennsylvania (PA) Medicaid program. Sovaldi and Harvoni (manufactured by Gilead), Daklinza (manufactured by Bristol-Myers Squibb), and Viekira Pak and Technivie (manufactured by AbbVie) are all covered under the PA Medicaid program and available in both the fee-for-service (FFS) and the managed care delivery systems. All of the recently-approved drugs for the treatment of Hepatitis C are very costly. The high price of the newer Hepatitis C medications sparked national and international debate over fair pricing which, combined with several unknowns that made overall costs unpredictable, generated significant concern over potential cost of care and indirectly impacted policy decisions on coverage and access.

Cost Concerns and Potential Impact

The Department of Human Service's (Department's) clinical pharmacists routinely monitor the pipeline for new drugs coming to market. They were aware of the anticipated release of each of the new oral Hepatitis C drugs and their promise of higher cure rates with fewer side effects compared to previous treatment options. Like all new drugs, the pharmacists were not aware of costs until the drugs received final approval from the U.S. Food and Drug Administration (FDA) and became available in the market. When the prices were announced, PA Medicaid, like every other public and private third party payer in the nation, experienced "sticker shock."

Concerns about the cost of the new Hepatitis C drugs were exacerbated by a number of unknowns that made total cost unpredictable. The biggest unknown was the size of the target population due to the following:

- Pent-Up Demand – Many people diagnosed with Hepatitis C decided to delay treatment until the newer Hepatitis C drugs were available, as the new drug treatment regimens were entirely oral and were anticipated to increase effectiveness, decrease side effects, and shorten treatment time compared to previously-available regimens.

- Centers for Disease Control (CDC) Recommendation for Testing – In 2012, the CDC recommended that everyone born between 1945 through 1965, also known as baby boomers, get tested for Hepatitis C. People with Hepatitis C often have no symptoms and can live for decades without feeling sick. The only way to know if a person has Hepatitis C is to get tested. The CDC recommended testing for early diagnosis and treatment to help prevent serious health problems, including liver damage, cirrhosis, liver cancer, liver transplants, and even death.

- Direct to Consumer Marketing – Manufacturers used television and magazine advertisements to promote their Hepatitis C drugs, targeting the baby boomer population.

Typically, the expenses associated with high-cost drugs, such as drugs to treat HIV/AIDS and hemophilia, are spread out over time and are predictable. In this case, pent-up demand, increased testing, and greater consumer awareness of the new drugs, combined with a shorter treatment time of 8 to 12 weeks for most patients, creates the potential for a one-time immediate spike in demand for the recently-approved high-cost treatments and challenges traditional fiscal projections and planning.

The PA Medicaid program prepared a rough estimate of the cost impact if every PA Medicaid beneficiary infected with Hepatitis C was treated. According to that estimate, the cost could range from $2.87 billion to $3.05 billion paid to the dispensing providers, or $1.58 billion to $1.73 billion after the federal drug rebates are collected. The ranges reflect the difference in paid amounts and net costs and are dependent upon which drug is designated as preferred on the FFS Preferred Drug List (PDL).

The PA Medicaid managed care organizations (MCOs) voiced their concern about the high cost of the drugs and the unpredictability of demand. The Department's actuary included Hepatitis C drug costs when they developed the calendar year 2015 MCO rates. However, the MCOs remain skeptical that the rates are sufficient given the high demand for access to treatment. The Department continues to monitor MCO expenditures in response to MCO demands for further financial adjustment.

PA Medicaid Efforts to Mitigate Cost

Both the PA Medicaid FFS program and the MCOs immediately implemented strategies to manage utilization and mitigate cost impact. Those strategies included prior authorization of the new Hepatitis C drugs and reinforced emphasis on its already robust collection of federal drug rebates on these drugs. The FFS program also worked with its state supplemental rebate contractor to negotiate supplemental rebates for these products. (NOTE: Drugs paid for by PA Medicaid MCOs do not qualify for state supplemental rebates. The MCOs negotiate and collect their own market share

rebates.) Initially, Gilead offered a very modest supplemental rebate for Sovaldi on the condition of a guarantee of unfettered access: no prior authorization, and no requirements for prescriptions to be written by, or in consultation with a medical specialist. When Gilead introduced Harvoni and AbbVie introduced Viekira Pak to the market, Gilead claimed willingness to negotiate supplemental rebates but negotiations were unproductive. Currently, Viekira Pak is designated as preferred on the FFS PDL; Harvoni, Sovaldi, Daklinza and Technivie are designated as non-preferred. They are covered and available when determined to be medically necessary. All of the drugs, including Viekira Pak, require prior authorization.

Current Utilization and Cost

The following chart reflects the current utilization and spend for Hepatitis C drugs in both FFS and managed care in PA Medicaid. The total spend does not account for rebates collected by PA Medicaid.

Hepatitis C Drug Utilization and Spend in PA Medicaid January 1, 2014 through August 8, 2015			
	Recipient Count	Claim Count	Spend
Total	2,041	11,969	$186,116,252

Policy Impact

PA Medicaid provides coverage of all FDA-approved drugs of manufacturers who participate in the Federal Drug Rebate Program. Consistent with federal Medicaid requirements, PA Medicaid's policy is to provide coverage for all medically-accepted indications. Both FFS and the Medicaid MCOs rely on package labeling, national and international treatment guidelines, and peer-reviewed medical literature to identify the guidelines to determine medical necessity.

In this case, expert consensus panels published treatment guidelines that shifted the emphasis on determining medical necessity from the clinical merits of these breakthrough treatments to an accommodation of the exorbitant costs. Instead of focusing their guidelines on the clinical merits of the drugs and their medically-accepted indications, treatment guidelines recommended prioritizing treatment for the "sickest" patients due to potential cost and access issues. And, unlike other communicable diseases such as HIV/AIDS, there was no emphasis on reduction in transmission to stem the spread of the disease through education and intervention at the point of transmission. One positive outcome of the concerns about high cost for Pennsylvania was the development and adoption of consistent guidelines to determine medical necessity of the newer Hepatitis C drugs among FFS and all of the PA Medicaid MCOs to ensure equal access across delivery systems.

I hope that this information is helpful. If you need additional information, please contact Mr. Abdoul Barry, Director, Office of Legislative Affairs, at (717) 783-2554.

Sincerely,

Theodore Dallas
Secretary

c: The Honorable Robert P. Casey, Jr.

Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

FEB 9 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510
Peter_Gartrell@finance.senate.gov

Dear Mr. Gartrell:

This letter is in response to your recent questions of the Iowa Department of Human Services (DHS) regarding Medicaid pharmaceutical expenditures.

The request was to provide a list of the top twenty-five drugs ranked by total amount paid for calendar year 2014. Additionally, the request was to include claim count, wholesale acquisition cost (WAC), drug quantity, days' supply and the number of unique recipients. It was also requested to include the same information for the drugs Sovaldi® and Harvoni™, if they were not included in the top 25 drugs by amount paid. Iowa Medicaid reimburses pharmacy claims based on a state specific average acquisition cost (AAC) and uses WAC when an AAC is not available. Therefore, the Iowa AAC has also been included in the data where applicable. Please note that both the WAC and AAC can change over time so the average WAC and AAC for calendar year 2014 is provided. The data requested is provided as an attachment.

All prescription drugs are through the fee for service (FFS) program, so the data provided represents all outpatient prescription drug expenditures. Iowa Medicaid currently covers 560,000 Iowans. Approximately 63,000 Medicaid members, or 11 percent of the total population, are covered by an HMO managed care plan (Meridian Health Plan of Iowa); however, pharmacy is carved out of the managed care plan.

Regarding the questions specific to Hepatitis C Virus (HCV), the state estimates 5,406 HCV patients in the Medicaid program. The Iowa DHS has not implemented any special funding provisions (special budget line items, etc.) for coverage of these drugs, but it has incorporated the cost of specialty drugs (including HCV medications) into its current and future Medicaid budget requests.

The Iowa Medicaid program participates in the Sovereign States Drug Consortium (SSDC) for supplemental drug rebates. To date, the program has not accepted a supplemental rebate for any of the HCV medications; however, the rebates offered are under consideration and will be discussed at the April Pharmaceutical and Therapeutics (P&T) Committee meeting.

If you have additional questions, please contact Susan Parker, Pharmacy Director, at sparker2@dhs.state.ia.us or (515)256-4634.

Sincerely,

Charles M. Palmer
Director

CMP:slp

Attachment:
1 – Iowa Medicaid Top 25 Drugs by Paid Amount CY2014

AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
Thomas J. Betlach, Director

July 17, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

The AHCCCS Administration submits the requested information in response to your July 8, 2015 correspondence requesting a list of the top 25 drugs ranked by total amount paid for calendar year 2014. The attached spreadsheet includes the following:

Fields requested:	Field descriptions on the excel spreadsheet:
Claim count	Number of Prescriptions
Wholesale acquisition price (WAC)	Health Plan Paid Amount
Drug quantity	Quantity Dispensed
Days of supply	Days Supply
The number of unique recipients	Distinct Members

The first and second tabs on the spreadsheet are the Top 25 Drug by Cost for the Fee-For-Service (FFS) and Managed Care Organizations (MCOs) respectively. The third and fourth tabs are the specific reports for Sovaldi and Harvoni for the Fee-For-Service and Managed Care Organizations (MCOs) respectively.

The current AHCCCS enrollment is 1,746,175 members. Of these members, 1,471,809 are enrolled in MCOs and 116,747 are in the FFS program. An additional 50,483 are in Medicare Savings Programs and 107,136 are in a program that provides emergency services only. Excluding the Medicare Savings Program and emergency services populations, 92.7% of the remainder of the AHCCCS population is enrolled in MCOs and 7.3% is in FFS.

You also requested additional information and the Administration's responses are below.

Has the state agreed to any supplemental rebate with Gilead for Sovaldi or Harvoni? If so, when?

Yes. The effective date of our agreements is January 1, 2015.

Also, many states have had to make special budget line items or other special provisions for Sovaldi and other new HCV drugs because of the cost. Has your agency had to make any special funding provisions that your state has had to request or adopt to cover the cost of these drugs?

There was an existing $15 million in the MCO capitation rates for treatments that Sovaldi and Harvoni are replacing. These dollars were left in the rates to cover a portion of the costs of Sovaldi and Harvoni. Arizona added an additional $30 million in funding to the capitation rates to address the additional costs of Sovaldi and Harvoni, for total funding of $45 million.

Lastly, is there any estimate of the number of HCV patients in the Medicaid program?

There are approximately eighteen thousand identified HCV patients within the AHCCCS program. It should be noted that the national consensus among health care professionals is the number of Hepatitis C patients is understated due to lack of testing.

In the event that you have additional questions, please contact me at your convenience.

Sincerely,

Thomas J. Beltach
Director

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

October 19, 2015

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman and Ranking Member:

Thank you for asking about the Florida Medicaid Program's experience with the new generation of Hepatitis C drugs that became available beginning in December of 2013.
Florida Statute directs the Agency to implement a Medicaid prescribed-drug spending control program and the Agency utilizes a Preferred Drug List (PDL) as part of that program. The Preferred Drug List (PDL) is a listing of cost effective therapeutic options recommended by the state's Medicaid Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee is an advisory committee of physicians and pharmacists that ensures that the drugs available on the PDL allow providers a selection that guarantees quality of care and cost containment.

In Florida, most Medicaid recipients are enrolled in the Statewide Medicaid Managed Care (SMMC) program. Under the SMMC program, the Agency negotiated capitation rates and entered into contracts with fully risk bearing health plans to provide services, including prescription drugs, to Medicaid enrollees beginning in May of 2014. Health plans are required to utilize the Agency's PDL and develop prior authorization criteria and protocols, which cannot be more restrictive than that used by the Agency, for reviewing requests for brand name drugs that are not on the Agency's PDL.

The Agency, working with the Pharmacy and Therapeutics Committee, established clinical criteria for the new Hepatitis C drugs as they became available on the market. Below is the original date the criteria was established. Please note, the medications used to treat Hepatitis C are an evolving group and guidelines for treatment may have been modified since the original posting date.

Medication	**Original Date of Criteria**
Harvoni	10/24/2014
Olysio	2/13/2014
Sovaldi	12/17/2013
Viekira Pak	1/20/2015

Medicaid health plans expressed concern that utilization of these new drugs would be high, and if the cost was high, the financial impact would be greater than anticipated in the capitation rates that were negotiated with the Agency. To address the rate impact, Agency staff and the Agency's contracted actuaries established a temporary "kick payment" for Hepatitis C drugs. A kick payment is a rate mechanism to manage the uncertainty of the number of people who will need high cost Hepatitis C Treatment. A kick payment allows the Medicaid program to pay the health plans based on expected costs for each enrollee who is prescribed the drugs for treatment. The goal was to help the plans cover the costs of the treatment until such time as utilization and expenditure data was available to incorporate the cost for these drugs into the capitation rate.

The Agency set new capitation rates for 2015-16 that became effective September 1, 2015 that included coverage for the new Hepatitis C drugs. One of the main drivers of the increase includes prescription drug trends and specialty drug growth. Kick payments for these drugs were discontinued, except for certain enrollees with a diagnosis of HIV/AIDs.

This data below represents expenditures under the fee-for-service program and managed care encounter data relating to the Hepatitis C drugs for the time period of January 1, 2014 – August 7, 2015. Expenditures reported here are gross costs as paid by FFS and as reported paid by the managed care plans; thus do not include offsets for rebates received.

Drug	FFS Claims	MCO claims	FFS Expenditure	MCO Expenditure	Total expenditure FFS + MCO
Harvoni	13	1027	$415,702.00	$31,570,787.99	$31,986,489.99
Olysio	232	309	$5,167,978.11	$6,880,999.86	$12,048,977.97
Sovaldi	958	1617	$26,944,190.01	$45,009,256.10	$71,953,446.11
Viekira	14	85	$394,706.48	$2,349,020.21	$2,743,726.69
Totals	**1,217**	**3,038**	**$32,922,576.60**	**$85,810,064.16**	**$118,732,640.76**

We hope this letter provides you with a high level understanding of Florida Medicaid's experience with the new generation of Hepatitis C drugs.

Sincerely,

Justin M. Senior
Deputy Secretary for Medicaid

JMS/ks

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

Steven L. Beshear
Governor

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Audrey Tayse Haynes
Secretary

Lisa D. Lee
Commissioner

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington, D.C. 20510

October 21, 2015

Re: High Cost Price of HCV Treatment

Dear Senators and Congressmen,

One of the most pressing concerns facing states and the nation's public health is hepatitis C. It is no secret that Kentucky has been challenged with the onslaught of heroin addiction, and we have been very aggressive legislatively with treatment to fight this problem. Heroin not only brings about a public health concern, but also the impact of newer hepatitis C virus (HCV) treatment options on state health care/Medicaid budgets. This is not only a problem for Kentucky but a national public health concern.

Kentucky's spending related to HCV has increased to about 7 percent of its total Medicaid budget, providing new hepatitis C drugs to a relatively small number of recipients. Sovaldi® has a list price of $84,000 for a typical 12-week course of treatment. Harvoni®, made by the same company, Gilead Sciences, has a list price closer to $100,000. Newer additions may be available but are also similarly high in cost. Although some manufacturers offer discounts to Medicaid programs, these do little to offset the cost of care.

We are concerned about the sharp rise in costs for Kentucky Medicaid beneficiaries diagnosed with hepatitis C. Our state's opiate problem and the increased testing of people who have injected drugs contribute to the upward trend.

Kentucky will soon start providing hepatitis C screening tests at all its county health departments, just as it does for H.I.V. Although precise estimates of the Medicaid population infected are not readily available, we would expect based upon the available data that the majority of infected individuals are of disproportionately low-income and Medicaid eligible status. Once members are HCV confirmed the question of when to initiate treatment must still be considered. Given the current cost of the newer treatment options and to remain fiscally responsible we will be forced to make difficult decisions regarding who does and does not get access to treatment medications upon diagnosis.

Kentucky is not alone in its concern. Through our multi-state rebate contract negotiating pool we have engaged HCV product manufacturers for various pricing level considerations. However, these efforts have been met with little to no success.

The evolving situation associated with such high cost breakthrough treatments has a great impact upon sensitive and strained health care budgets. Newer HCV products are often acclaimed as curative. Noteworthy here is that clinical trials are rarely focused on co-morbidities found most often among Medicaid recipients which often have a profound impact on treatment efficacy. Although we fully support innovation in treatments, policymakers must begin developing frameworks that address the comprehensive costs and value of treatments in public health insurance programs such as Medicaid. As a primary payer, Kentucky continues to use the limited tools available to manage the cost implications of emerging HCV products, such as prior authorizations, weighing the available scientific evidence to guide access, and continuing to pursue price competition and supplemental rebates despite the fact that the state is not well positioned to secure savings. The price charged by drug companies is the one item where the state has little control.

Drug manufacturers have been reluctant to competitively price these breakthrough therapies as they emerge and we have concerns regarding the increasing challenges which are likely to continue for many years. We welcome any opportunity for open dialogue regarding federal level policies that could create some balance between appropriate access to new treatment options and long-term fiscal sustainability of Medicaid programs.

Thank you for your time and attention to this important issue.

Kindest Regards,

Samantha McKinley, B.S., J.D., D.C., Pharm.D.
Department for Medicaid Services
Pharmacy Director
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TEXAS HEALTH AND HUMAN SERVICES COMMISSION

CHRIS TRAYLOR
EXECUTIVE COMMISSIONER

August 14, 2015

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senator Wyden and Senator Grassley:

Thank you for exploring the financial impact that Gilead Sciences, Inc.'s (Gilead) Sovaldi — and other second generation direct acting antiviral medications for the treatment of the Hepatitis C virus (second generation HCV drugs) — has on Medicaid programs. Unfortunately, the high cost of these drugs forced the Texas Health and Human Services Commission (HHSC) to carefully examine which Medicaid beneficiaries are truly in medical need of these products and required HHSC to implement strong prior authorization requirements.

The HHSC Pharmaceutical and Therapeutics (P&T) Committee first reviewed Sovaldi in January of 2014 and recommended a preferred status, contingent upon implementation of prior authorization criteria. HHSC began developing a medical necessity and prior authorization criteria for second generation HCV drugs, based on reliable and appropriate evidence. In July that same year, HHSC requested detailed clinical outcome data from Gilead (see Attachment 1). The associate director for medical sciences for this company, Michelle Puyear, was extremely helpful and provided and explained the data. In addition, HHSC enlisted the services of the Oregon Health Science University Medicaid Evidence Based Decisions Project to help review the data and assist with drafting appropriate prior authorization criteria. Texas Medicaid eventually determined that second generation HCV drugs are medically necessary for beneficiaries if they are diagnosed with the Hepatitis C virus and experience a METAVIR score of F3 or F4. The METAVIR test assesses the level of liver fibrosis on a scale of increasing severity from F0 to F4.

For most of 2014, HHSC program staff focused on the clinical aspects of the drugs, but the high drug cost remained a concern. Because Sovaldi was not yet on the Texas Medicaid formulary, Gilead leadership asked to meet with HHSC executive leadership, and a meeting was conducted on August 6, 2014. The Gilead executives and representatives in attendance were:

- Kacy Hutchison, Vice President of Government Affairs
- Coy Stout, Vice President of Managed Markets
- Justin Crum, Director, National Accounts, Strategic Accounts Central
- Tyler Hunter, Executive Manager, National Accounts

HHSC's former Executive Commissioner, Dr. Kyle Janek, expressed his displeasure with Gilead's pricing. He reminded the Gilead executives and representatives of the impact of their drug to the state budget. Given the size of the Texas Medicaid population, Dr. Janek also asked for a discounted rate. He referenced the drug's availability at a fraction of the price in other countries and the likelihood that it would be cheaper for Texas to fly Medicaid recipients to those countries for treatment than to treat them in the U.S. Gilead executives and representatives explained that the company limited access to the drug in other countries to citizens of those countries and then defended their pricing model. Gilead offered no meaningful discounts until January 2015 when two other second generation HCV drugs entered the market: Harvoni (also by Gilead) and AbbVie, Inc.'s (AbbVie) Viekira Pak.

In October 2014, HHSC's Preferred Drug List (PDL) vendor, Magellan Medicaid Administration, sent solicitation letters to all manufacturers of second generation HCV drugs. These letters solicited manufacturers to provide their supplemental rebate offers so the same could be presented to the P&T Committee in its January of 2015 meeting. During this period, but prior to the P&T Committee meeting, HHSC and Gilead discussed coverage criteria and drug price/rebates on multiple occasions. Attachment 2 lists the conversations HHSC held with representatives of Gilead in 2014 and 2015.

In early January 2015, news outlets reported that Express Scripts—the nation's largest pharmacy benefits manager—had signed an exclusive arrangement with AbbVie to make Viekira Pak its sole preferred second generation HCV drug. Shortly after that announcement, and leading up to the January P&T Committee meeting, Gilead met with Texas HHSC again and offered a more substantial supplemental rebate. The deadline for submitting supplemental rebate offers had expired, but HHSC made an exception because of the particular nature of the situation. To be fair, HHSC also allowed AbbVie to revise its offer (post-deadline) and AbbVie did.

Upon completion of their January 2015 review, the P&T Committee recommended Viekira Pak as the preferred product for recipients in both fee-for-service traditional Medicaid and managed care Medicaid. The committee's decision was based on the understanding that both Harvoni and Viekira Pak were effective treatments, but because AbbVie submitted more aggressive rebates to HHSC's PDL vendor, Viekira Pak was more cost effective.

In Texas, almost 90 percent of Medicaid recipients receive benefits through a managed care organization (MCO). When Sovaldi was the only U.S. Food and Drug Administration (FDA)

approved second generation HCV drug, there was much uncertainty about potential expenditures, and calculating an actuarially-sound MCO premium rate that took this drug into account was not possible. Therefore, HHSC was forced to develop an MCO contract amendment and obtain approval from the Centers for Medicare & Medicaid Services to reimburse MCOs for the cost of second generation HCV drugs through a separate non-risk-based payment process. In Texas' managed care Medicaid, second generation HCV drugs are the only products that are "carved-out" of the MCO premium rate. HHSC's policy has consistently required MCOs to assume the risk for all prescription drugs.

Like all states, Texas struggles with the challenge of trying to provide beneficiaries with maximum access to second generation HCV drugs without compromising its Medicaid program's solvency. In Texas, approximately 17,000 Medicaid recipients (primarily adults) were identified with a primary diagnosis of Hepatitis C. Based on HHSC's medical-necessity criteria, product indications, and HCV population demographics, HHSC forecasted potential utilization, and estimates that approximately 1,200 recipients per fiscal year will obtain second generation HCV drugs. The table below provides the estimated net costs per year after all rebates.

	FY 2015 (Apr - Aug)	FY 2016	FY 2017	FY 2018
All Funds*	**$ 20.1**	**$ 65.8**	**$ 53.4**	**$ 54.7**
Federal Funds*	$ 11.7	$ 27.1	$ 23.3	$ 23.9
TX General Revenue*	$ 8.4	$ 38.7	$ 30.0	$ 30.9

Notes

- ** All dollar amounts in millions*
- *Analysis is based on three Hepatitis C treatments: Viekira (12-week), Viekira + Ribavirin (12-week), and Sovaldi (24-week).*
- *Assumed effective date April 2015 with pent-up demand assumed in State Fiscal Year (SFY) 2015.*
- *HHSC System Forecasting, March 2015*

The state's experience with second generation HCV drugs prompted the 84th Texas Legislature to pass a rider on the state's appropriations act in June 2015. The rider requires HHSC to estimate the potential cost of all new outpatient drug products prior to covering the products. All products with an estimated annual cost of greater than $500,000 must be submitted to the Legislative Budget Board for review. This requirement may increase the amount of time between approval of a new treatment by the FDA and provision of that treatment to Medicaid clients.

In January 2015, Texas Medicaid began limited coverage of Sovaldi and Olysio (manufactured by Johnson and Johnson) on an exception basis for recipients with HCV and the most urgent medical needs. In April 2015, Texas Medicaid fully implemented its coverage of the second generation HCV drugs.

The rebate revenue from manufacturers lessens the impact of second generation HCV drugs on the state's Medicaid budget. However, given the exorbitant price of these medications, the rebates are insufficient and these drugs jeopardize the solvency of the state's Medicaid and public health programs. Manufacturers lowering the price at which these drugs are sold to providers would be more beneficial than rebates to the Texas Medicaid program and would also benefit its state-funded health programs.

HHSC is hopeful that as new HCV and other breakthrough drugs are approved, market forces will reduce costs. Otherwise, Texas and all other states will experience budgetary difficulties that could negatively affect the Medicaid program.

Your exploration of these issues is greatly appreciated. If you would like additional information or have additional questions, please contact me at 512-707-6142 or by email at Andy.Vasquez@hhsc.state.tx.us.

Sincerely,

Andy Vasquez
Texas Health and Human Services Commission
Medicaid/CHIP Deputy Director, Vendor Drug Program

Attachment 1

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

KYLE L. JANEK, M.D.
EXECUTIVE COMMISSIONER

July 29,2014

Ms. Stephanie Tran
Associate Manager, Medical Information
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Ms. Tran:

We are writing to request clinical data from Gilead Sciences to answer pertinent questions on the Hepatitis C drugs, Sovaldi (sofosbuvir) and the combination drug, ledipasvir/sofosbuvir.

Chronic Hepatitis C is estimated to affect 3.2 million people in the United States and has a high prevalence rate in patients with income below the poverty line. Hepatitis C affects a large number of Texas Medicaid patients and, with the high cost of treatment, it will represent a significant cost to the state of Texas.

The preliminary clinical evidence prompted the FDA to grant Sovaldi a Priority Review and Breakthrough Therapy designation, which it awards products for indicating substantial improvement over available therapies for patients with serious or life threatening diseases, can cut the FDA review time from 10 months to 6 months. The FDA has also granted ledipasvir/sofosbuvir a Breakthrough Therapy designation. There is evidence of the benefits Sovaldi, and by extension ledipasvir/sofosbuvir, will bring to our Hepatitis C patients. However, the full extent of benefits, as well as potential deficits, remains out of reach. The state of Texas is dedicated to providing the most prudent, cost-efficient, and beneficial health care to our Texas Medicaid clients. We have been diligently reviewing clinical information, as well as several guidelines to help form an appropriate clinical edit. As we recommended by our Drug Utilization Board, we have been reaching out to stakeholders for additional input and concerns.

The available guidelines and reviews have been helpful in our draft of a clinical edit. In our review of both the guidelines and the available studies, questions have remained that need to be answered so we can guarantee every step of our clinical edit is founded on the most current and complete information. With such a significant impact on the state health care budget, there is

very little room for error. We appreciate that some information has been published and provided for both products, but there is still data that would be crucial to providing the most accurate representation of cost-effective treatment, based on available clinical evidence.

In order to help us address these items, we are asking Gilead Sciences for the following:

- All data on adverse effects from all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
- All data to calculate incidence of relapse after SVR12 for all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
- A flow diagram showing what happened to all people who were initially screened for enrollment in any study studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
    - Study investigators should complete a full CONSORT flow diagram (available at www.consort-statement.org/).
    - For each outcome reported there should be a clear indication of the numerator and denominator for each of the outcomes analyzed.
    - SVR12 and SVR 24 data for all studies that have been published, presented at a meeting, or available to the investigators or manufacturers.
    - Please include data that may have been incomplete from any studies that have been sent to HHSC staff.
- Quality of life data for all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir..

We ask that all material be provided in a format that staff can employ to adjust our clinical edit criteria. We appreciate your continued cooperation and timeliness in this matter.

Please let me know if you have any questions or need additional information. Joshua Dominguez Pharm. D., Vendor Drug Pharmacist, serves as the lead staff on this matter and can be reached by telephone at 512-462-6390 or by email at Joshua.Dominguez@hhsc.state.tx.us.

Sincerely,

Andy Vasquez
Medicaid/CHIP Deputy Director, Vendor Drug Program

Attachment 2

Meetings between Health and Human Services (HHSC) staff and Gilead Sciences, Inc. regarding clinical and financial considerations of Texas Medicaid coverage of Sovaldi and Harvoni.

Meeting Date	Description
May 6, 2014	Discuss coverage status of Sovaldi. Gilead representatives include: Tyler Hunter
June 2, 2014	Discuss coverage status of Sovaldi. Gilead representatives include: Tyler Hunter
June 20, 2014	Clinical update on Sovaldi Gilead representatives include: Tyler Hunter, Michelle Puyear
July 29, 2014	HHSC letter to Gilead requesting detailed clinical data
Aug. 6, 2014	Meeting with HHSC executive commissioner requested by Gilead to discuss coverage of Sovaldi Gilead representatives include: Kacy Hutchison, Coy Stout, Justin Crum, Tyler Hunter
Aug. 13, 2014	Detailed discussion of HHSC's clinical data request. Gilead representatives: Michelle Puyear, Tyler Hunter
Oct. 21, 2014	Initial discussion regarding Harvoni; including clinical and rebate considerations Gilead representatives include: Tyler Hunter, Michelle Puyear
Nov. 14, 2014	Discuss Gilead rebate offers for Harvoni and Sovaldi. Note: HHSC conveyed our continued, serious concerns with Gilead's pricing structure and they committed to taking our request to their management with response expected by the next week. Gilead representatives include: Coy Stout, Justin Crum, Tyler Hunter, Erin Smith
Nov. 20, 2014	Discuss enhanced Gilead rebate offer. Gilead offered slight increase from original offer for Harvoni and extended offer to Sovaldi. Gilead representatives include: Justin Crum, Tyler Hunter, Erin Smith (Gilead Government Affairs)
Dec. 4, 2014	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. Gilead representatives include: Justin Crum, Tyler Hunter
Dec. 17, 2014	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. Gilead representatives include: Justin Crum, Tyler Hunter
Jan. 7, 2015	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. HHSC offers extension to supplemental rebate offer submission deadline based on Gilead commitment to submit a new, revised final offer. Gilead representatives include: Justin Crum, Tyler Hunter
Jan. 16, 2015	Pre-P&T Committee meeting discussion regarding Gilead's final, revised offer. Gilead representatives include: Coy Stout, Kimberly Hawkins, Justin Crum

Ohio | Department of Medicaid

John R. Kasich, Governor
John B. McCarthy, Director

August 7, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

In response to your inquiry regarding any records of emails or meetings between Ohio Department of Medicaid (ODM) officials and Gilead where concerns were expressed about the price of the drug please see below:

June 26, 2014 conference call with Gilead and ODM: ODM staff included Margaret Scott, RPh, Michael Howcroft, RPh, Patricia Nussle, RPh, Anam Khan, college intern and Xerox State Healthcare (ODM contractor): Sandra Kapur, PharmD

David Kaufman
Manager, National Accounts
Strategic Accounts Central
Gilead Sciences
Cell: 919.791.8715
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Justin Crum
Director, National Accounts
Strategic Accounts Central
Gilead Sciences
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Justin.Crum@gilead.com

Sept. 24, 2014 In-person meeting with ODM Director John McCarthy, David Salisbury, Legislative Liaison, Margaret Scott, RPH, Debbie Saxe, Health Plan Policy Chief and Gilead representatives Rebecca O'Hara, Paul Miner, Justin Crum, local representation Joshua Sanders

Rebecca O'Hara
Associate Director
Government Affairs
Gilead Sciences, Inc.
Phone: 850-339-6211
Rebecca.O'Hara@gilead.com

Joshua R. Sanders, Esq.
Calfee, Halter & Griswold LLP
Phone 614-621-7763
jsanders@calfee.com

Paul Miner, PharmD, Assoc. Director
Medical Sciences
Managed Care & Government Accts.
Gilead Sciences, Inc.
810-333-5818 (c)
paul.miner@gilead.com

Sincerely,

John B. McCarthy, Director

EDMUND G. BROWN JR.
GOVERNOR

State of California
HEALTH AND HUMAN SERVICES AGENCY

DIANA S. DOOLEY
SECRETARY

October 14, 2015

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington D.C. 20510

Dear Senator Wyden and Senator Grassley:

Thank you for the opportunity to provide comments on California's experience with high-cost drugs, as you explore Gilead Sciences, Inc.'s pricing of the Hepatitis C drug Sovaldi. Our state Medicaid agency, the California Department of Health Care Services, previously provided your staff with more specific utilization and enrollment data for our state Medicaid program, called Medi-Cal, related to newly available Hepatitis C treatments. The purpose of this letter is to provide some context for California's efforts to understand and address the increased costs to the state and to consumers of these Hepatitis C treatments and high-cost drugs more broadly.

In January 2015, our proposed state budget specifically identified the high costs of newly available Hepatitis C treatments and noted that there are thousands of inmates in our state prisons, patients in our state mental hospitals, and participants in Medi-Cal and the AIDS Drug Assistance Programs who are infected with Hepatitis C. This budget proposal provided funding to cover these anticipated increased costs and tasked the California Health and Human Services Agency with convening a workgroup to refine these fiscal estimates and compare practices across our state departments and county governments.

Our agency convened several conversations with an internal workgroup consisting of state departments, county governments, and sheriffs, as well as with an external workgroup consisting of stakeholders representing consumers, organized labor, employers, health plans, providers, and the pharmaceutical industry. We have focused on three areas and have taken preliminary steps in these areas, by considering: what we can do through clinical guidelines, what we can do through procurement policies, and the value equation of high-cost drugs.

We are currently building our proposed budget for the next state fiscal year (July 1, 2016-June 30, 2017), which we will release in January 2016. Fiscal estimates for our departments will continue to account for the impact of these high-cost drugs. In addition, we'll continue to do what we can to manage these costs while providing high quality of care to the individuals in our public programs.

We appreciate your interest in the impact to states of the newly available Hepatitis C drugs, and look forward to continuing to work with our federal partners on these and other issues related to administering Medicaid and other important programs.

Sincerely,

Diana S. Dooley
Secretary