



March 4th, 2016

The Honorable Sen. Ron Wyden
Ranking Member
U.S. Senate Finance Committee
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Sen. Charles Grassley
U.S. Senate Finance Committee
135 Hart Senate Office Building
Washington, DC 20510

Dear Ranking Member Wyden and Sen. Grassley:

On behalf of Providence Health & Services, thank you for the opportunity to provide feedback on questions raised from the 18-month investigation into pricing methodologies for breakthrough drugs to treat Hepatitis C and their implications on public and private health care programs in the United States.

Providence Health & Services is a not-for-profit Catholic health care ministry committed to providing for the needs of the communities it serves – especially for those who are poor and vulnerable. The comprehensive scope of services at Providence includes 34 hospitals, 475 physician clinics, home health and hospice, senior services, supportive housing and many other health and educational services. The health system and its affiliates employ more than 76,000 people across five states: Alaska, California, Montana, Oregon and Washington.

As a large, integrated health care system providing services to patients across the continuum of care – from primary to acute care to home health and hospice – we are committed to clinical excellence with compassion. We know that quality of life improves when individuals and families have broad access to high-quality, patient-focused, affordable care. Together, Providence ministries and secular affiliates are working at scale to improve overall health in every community we serve through innovation in care delivery, new economic models and expert-to-expert collaboration.

Providence applauds the important inquiry conducted on the issue of innovative, sole-source drugs and exploration of how pharmaceutical manufacturers develop pricing strategies. As health care providers, insurers and other industry stakeholders work to transform the delivery

and financing of health care to make it more affordable and improve the health of communities, the importance of developing solutions to ensure access to breakthrough drug therapies grows each year.

To that end, Providence offers our responses to the five questions posed to stakeholders along with our recommendations on how federal policy can help ensure that the maximum societal value can be realized from breakthrough innovator drugs coming on to the market.

General Comments:

Breakthrough drugs such as Sovaldi and Harvoni offer tremendous ability to improve the health status and lives of individuals suffering from the effects of Hepatitis C; other drugs coming onto the market are likely to offer similar benefits in terms of treatment for chronic illnesses. However, the extraordinary high cost of such drugs present a significant dilemma to policymakers, private insurance companies and health care providers seeking to improve the health of communities while working to reduce health care costs.

It is important to note that since implementation of the Affordable Care Act began in 2010, the collection of industry stakeholders listed above have pursued in earnest changes in care clinical delivery, organizational structures and financing mechanisms with a shared goal of constraining the upward curve of health care spending and cost to consumers, employers and government. According to the Centers for Medicare and Medicare Services (CMS), projected growth for 2016-2024 for the following health care sectors are as follows¹:

- Hospital spending was projected to grow 5.8 percent in 2015 and is projected to have an average annual growth of 6.1 percent;
- Physician and clinical services spending is projected to remain at or below the 4.8 percent growth rate for 2014;
- Prescription drug spending is projected to have grown by 12.6 percent in 2014 and is projected to grow at an average of 6.3 percent from 2016 through 2024.

These projections account for coverage expansions in the Medicaid program and health insurance exchanges, as well as constraints on physician and clinical services spending created by the Medicare Access and CHIP Reauthorization Act (MACRA), expiration of temporary increases in Medicaid primary care payments and increases in high-deductible health plans in commercial markets. They do not, however, factor in the costs of innovative new drugs coming onto the market.

As a function of accountability to taxpayers, it is imperative that policymakers be afforded the ability to conduct the necessary cost-benefit analysis of high cost drugs prior to their being introduced to the market.

Responses to the Questions:

Below is Providence's specific responses and recommendations addressing the five questions posed in the January 21, 2016 "Letter to the Health Care and Patient Community." Rather than answer each specific question independently, Providence offers our recommendations focused

on how federal policy can be improved to ensure that our patients and communities receive the best possible value from new drugs becoming available.

Evidence from the introduction of Sovaldi and Harvoni to the marketplace in 2014 indicates that a significant effect is a spike in overall prescription drug spending, with a flattening of spending in subsequent years as private payers and public programs respond. According to the Altarum Institute's December 2015 briefing on national health spending, growth in prescription drug spending spiked from 6.0 percent in October 2013 to 12.4 percent in October 2014, declining to 9.1 percent in October 2015. Analysts concluded that this spike in prescription drug spending was largely attributed to the introduction of Sovaldi and Harvoni to the market in late 2013 and early 2014.ⁱⁱ

According to the Washington Post, the Medicare program spending increased by \$4.5 billion in 2014 as a result of the introduction of Sovaldi and Harvoni.

While overall prescription drug spending declined in 2015, it was nonetheless three percentage points higher than at the same point two years earlier.

Of particular concern is the timing of such drugs coming onto the market. In the case of Sovaldi and Harvoni, the drug became available in late 2013/early 2014, after capitated payment rates were set by both Medicaid managed care plans and commercial carriers. As a result, claims for Sovaldi and Harvoni prescriptions were not factored into rates by health insurers, risking substantial financial losses for the plans absent actions to restrict access to the drugs to a more limited population of Hepatitis C patients.

State Medicaid programs in many cases acted to restrict coverage of Sovaldi and Harvoni, including the state of Oregon, which limited coverage for the Oregon Health Plan and Public Employees Benefit Board to only those patients with Stage 3 liver fibrosis.ⁱⁱⁱ

The Florida Agency for Health Care Administration in 2014 provided an add-on payment to Medicaid plans, coupled with a restriction that Sovaldi only be covered for patients at State 3 or 4 liver fibrosis, carry a specific genotype and agree to a set of lifestyle/behavioral requirements.^{iv}

In many cases decisions such as those above were derived as a result of state advisory bodies convening to analyze the cost vs. benefit of these drugs – after they were available on the market.

Recommendations:

Establishing a requirement for Cost-Benefit Analysis Prior to FDA Approval – To that end, it is critical that mechanisms be established as part of the Food and Drug Administration approval process that provide for an effective pre-market pharma-economic analysis that allows policymakers, payers and consumers to fully understand:

1. The rationale behind the pricing strategy for the drug;

2. The short and long-term health benefits for patients;
3. The relative cost versus other treatments, both pharmaceutical and non-pharmaceutical; and,
4. The expected impact on health insurance premiums, Medicaid and Medicare program costs.

An analogue to such a mechanism would be the Patient Center for Outcomes Research (PCORI), an independent, not-for-profit entity established by the Affordable Care Act to analyze and make recommendations on clinical effectiveness based on comparative effectiveness research. Providence recommends that Congress adopt legislation that would require a detailed cost-benefit analysis of new drugs, particularly those identified as sole-source, innovator drugs, prior to their being approved for use by the FDA. Such an analysis would include clinical effectiveness, costs of research and development and marketing for the drug and short- and long-term projections of the benefit to public and private health care programs.

Such a program currently exists in Britain with the National Institutes for Health and Care Excellence (NICE), which provides cost-benefit analyses for the National Health System (NHS) for new pharmaceuticals, including both clinical and coverage policy recommendations.^v

Allow Medicare to Negotiate Directly with Drug Manufacturers – Presently, the Medicare program, as established in the Medicare Modernization Act (MMA), is prohibited from negotiating with the pharmaceutical industry to lower the cost of drugs purchased under Medicare Part D. Instead, Prescription Drug Plans (PDPs) are required to negotiate directly with pharmaceutical manufacturers to obtain rebates and other discounts on drugs.

Providence recommends that CMS be given the authority to select a drug to enter into the negotiation process based on its total cost to Medicare and/or based on a year-over-year price increase in excess of a predetermined threshold. Such a determination could be based pre-market on the pharma-economic analysis conducted by the FDA (as recommended above), as well as other government sponsored or independent analyses post-market.

Another qualifying factor that should be considered is whether a drug has therapeutically equivalent substitutes, including generic drugs or other branded medications that produce similar patient outcomes.

Increase Transparency in the Cost of Research and Development and Pricing Strategies - To better facilitate pharma-economic analysis pre-market, Providence recommends that manufacturers be required to disclose the cost of research and development, as well as how they derived their pricing, to the FDA. This level of transparency and analysis will allow payers to make better informed decisions regarding the value proposition for the necessary trade-off in health care spending in covering high cost drugs.

Providence greatly appreciates the opportunity to provide feedback and recommendations to Sens. Wyden and Grassley on this important issue. If you have any questions, please contact

Steve Brennan, Director, Public Policy, at Steven.Brennan@providence.org or via telephone at (425) 525-3717. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Rod Hochman". The signature is fluid and cursive, with the first name "Rod" being more prominent and the last name "Hochman" written in a more compact, connected style.

Rod Hochman, M.D.
President and Chief Executive Officer
Providence Health & Services

ⁱ Center for Medicare and Medicaid Services, “National Health Expenditure Projections 2014-2024,” July 28, 2015

ⁱⁱ Altarum Institute Health Sector Economic Indicators, “Insights from Monthly National Health Spending Data Through October 2015,” December 11, 2015

ⁱⁱⁱ “State OKs new Hep C drug for Medicaid patients,” Bend (Ore.) Bulletin, Marc 5, 2015.

^{iv} “Medicaid Plans to Get Extra Drug \$,” Health News Florida, June 10, 2014.

^v National Institute for Health and Care Excellence website: “NICE consults on draft guidance on the drug sofosbuvir (Sovaldi) for treating hepatitis C,” June 16, 2014 <https://www.nice.org.uk/news/press-and-media/nice-consults-on-draft-guidance-on-the-drug-sofosbuvir-sovaldi-for-treating-hepatitis-c>