

FINANCE COMMITTEE QUESTIONS FOR THE RECORD

Hearing on the nominations of:

María Pagán, *for Deputy USTR (Geneva)*
Brent Neiman, *for Deputy Under Secretary of the Treasury
for International Finance & Development*
Josh Frost, *for Assistant Treasury Secretary for Financial Markets*
Sam Bagenstos, *for HHS General Counsel*
Chris Wilson, *for Chief Innovation/IP Negotiator, USTR*

October 26, 2021

Questions from Chairman Wyden

Questions for Sam Bagenstos

Question 1: Transplant System Reform

Mr, Bagenstos, my staff have become aware of a legal determination, made by HHS, which has potentially dire consequences for Americans waiting for a transplant. As I've said before, reforming the transplant system is an urgent health equity issue. Communities of color are much more likely to need lifesaving organ transplants. For example, Black Americans are three times more likely to suffer from kidney disease than white Americans. Furthermore, experts project a dramatically increased need for transplants as a result of COVID-19, which is likely to compound the disparities already experienced by minority populations.

- **My question for you: do you believe it is appropriate for HHS to reconsider its legal determination on how the Organ Procurement and Transplantation Network contract is awarded to ensure competition in the next contract cycle?**

Answer: Because I am not at HHS, I have not been involved with legal issues concerning the Organ Procurement and Transplantation Network (OPTN) contract. But I would be very glad, if confirmed as General Counsel, to work with the attorneys in my office and with program experts at the Health Resources and Services Administration (HRSA) to optimize the OPTN contracting process and the Department's role in ensuring the efficient and equitable operation of this crucial life-saving program.

- **As HHS General Counsel, if confirmed, what will you do to address the critical inequities in the transplant system?**

Answer: One of the top priorities of the Biden-Harris Administration is to address equity issues across the health care sector, including throughout the organ transplant community. HHS is making numerous adjustments to its policies to help close these health equity gaps.

I understand that the Centers for Medicare and Medicaid Services (CMS) recently finalized changes to organ procurement organization (OPO) outcome measures to improve the quality of OPO services and hold underperformers accountable by using objective, transparent, and reliable data. I also understand that CMS recently finalized modifications to the End Stage Renal Disease (ESRD) Treatment Choices Model – one of the agency’s first CMS Innovation Center models to directly address health equity – to encourage certain health care providers to decrease disparities in rates of home dialysis and kidney transplants among ESRD patients with lower socioeconomic status. CMS has also announced an intention to issue a request for information that would seek public input on all aspects of the organ donation and transplant system.

If confirmed, I intend to work with HRSA and CMS to assist in using available authority to improve the function of the organ transplant system. I am also committed to working with Congress to support appropriate oversight efforts related to organ procurement.

Question 2: Telehealth Following the Public Health Emergency

As the coronavirus began to spread in the spring of 2020, I think one of the most important actions that HHS and Congress took together was to provide new flexibilities for telehealth services, especially in Medicare. During this pandemic, these flexibilities have allowed patients to continue to receive care from their doctors, while maintaining social distancing and reducing the spread of the virus. Many of these flexibilities are authorized via waivers that last through the end of the public health emergency.

- **Mr. Bagenstos, if confirmed as General Counsel at HHS, will you work with this Committee to ensure a smooth transition for these telehealth flexibilities as the public health emergency ends and Congress considers long-term approaches to modernizing telehealth policies in Medicare?**

Answer: Telehealth, supported by investments in broadband infrastructure, is an important tool to that can address health equity and improve access. My understanding is that HHS continues to examine the telehealth flexibilities developed for the current public health emergency and determine how we can build on this work to improve health equity and improve access to health care. CMS recently stated that certain telehealth services that were available for Medicare payment during the public health emergency will continue to be available through December 31, 2023 to allow additional time to evaluate whether these telehealth services should be paid by Medicare permanently. If confirmed, I intend to assist HHS with its review of these important services that improve access to health care.

Question 3: Home & Community Based Services (HCBS)

For too long, American families have struggled to help their mom, dad, relative or child with a disability find good quality long-term care at home. Millions of Americans receive home and community based services through Medicaid today. But many Americans sit on waitlists -- sometimes for years -- before they can access the services they need.

- **Mr. Bagenstos, you have been a powerful advocate on behalf of people with disabilities throughout your career. As you know, Congress just made major investments in home and community based services through the American Rescue Plan, and we're on the precipice of a historic investment through Build Back Better.**
- **How will your experience advocating on behalf of those with disabilities inform your work at HHS, should you be confirmed, and how would you help to ensure these investments in home and community based services will benefit American families?**

Answer: I appreciate your leadership in this area. My own experience working to expand home- and community-based services across the Nation gives me an acute understanding of just how far we need to go to make these programs a reality for those who want to be served in their own homes rather than in nursing homes and other institutions.

As you noted, the American Rescue Plan Act of 2021 temporarily provides additional Medicaid funding that allows states to enhance, expand, or strengthen HCBS under the Medicaid program. I understand that CMS is working with states to improve the HCBS system, both in response to the COVID-19 public health emergency and in response to longstanding priorities.

If confirmed, I look forward to working with CMS on further improving HCBS for all Americans.

Questions from Senator Richard Burr

Mr. Samuel Bagenstos, Nominee to be General Counsel of the Department of Health and Human Services

1. The Family First Prevention Services Act created a new federal category for settings that deliver trauma-informed treatment for foster children with serious emotional or behavioral issues in a residential setting, known as Qualified Residential Treatment Programs (QRTPs). QRTPs are one of the few residential settings that are eligible for Title IV-E reimbursement.

On October 19, 2021, the Centers for Medicare and Medicaid Services (CMS) confirmed QRTPs with more than 16 beds meet the definition of an Institutions for Mental Diseases (IMDs), preventing Medicaid reimbursement for care in these facilities. Specifically, the CMS guidance document stated:

CMS does not have the authority to utilize general enforcement discretion or compliance action to authorize reimbursement of services provided to children residing in QRTPs that the state has assessed as meeting the definition of an IMD.

On a recent call with staff of committee members, you mentioned that you have spent a great deal of time thinking about the IMD exclusion from Medicaid payments but have not thought about the merits of a potential policy change for QRTPs. On the same call, you indicated that you had not previously contemplated whether or not you feel there is a distinction between

these specialized facilities for vulnerable children and other IMDs, namely inpatient psychiatric hospitals.

You have been serving as the General Counsel for the Office of Management and Budget (OMB) since January of 2021. Typically, OMB serves as a clearinghouse for agency documents before they are made public. According to its website, one of the office's five main functions is "Coordination and review of all significant Federal regulations from executive agencies, privacy policy, information policy, and review and assessment of information collection requests."

- a. Did OMB see the CMS guidance prior to its release on October 19, 2021?
- b. Did you see the CMS guidance prior to its release?
 - i. If yes, why did you tell my staff that you had not considered the issue previously?
 - ii. If no, why would the OMB General Counsel, who has decades of experience in disability law and has been nominated to serve in the same position as HHS, not review such an important policy guidance?
- c. Have you provided any more consideration to the issue of whether or not QRTPs should be exempted from the IMD payment exclusion, allowing children in foster care to have Medicaid coverage in these placements?
- d. Do you support the exclusion of QRTPs from the definition of IMDs? Please provide a yes or no answer.

Answer to a through d: The issues surrounding QRTPs are important and complex. I understand that CMS's Section 1115 Demonstration Opportunity went through appropriate clearance within the Biden-Harris Administration. I understand that this demonstration opportunity was developed to provide federal matching funds for Medicaid services provided to foster children residing in QRTPs. If confirmed, I am committed to working across HHS – with both CMS and the Administration for Children and Families (ACF) – to broadly evaluate all available administrative and legislative authorities to ensure that children in foster care receive the medical care that they need and to which they are entitled, in a safe and nurturing setting that fosters their growth and development. I will similarly work to ensure that children in foster care receive necessary medical care without disruption.

2. The rapid pace of medical innovation has led to the development of novel technologies intended to prevent infectious diseases with the potential to benefit individuals with a variety of diseases in the future, such as those used in some of the COVID-19 vaccines. The Advisory Committee for Immunization Practices (ACIP) establishes the list of pediatric vaccines distributed by the Secretary through the Vaccines for Children (VFC) Program. In establishing its list, ACIP may include FDA licensed or authorized vaccine products, including those that leverage novel and innovative technology, to help prevent infectious diseases in children.

- a. Can you assure the Committee that you will provide assistance, to the best of your ability, as appropriate, and to the fullest extent of your legal authority, to help ensure appropriate access to innovative pediatric immunizations for American children?

Answer: Yes.

3. The inability to fully leverage our testing infrastructure in the U.S. during the early days of the COVID-19 pandemic left the U.S. government unable to accurately track the spread of the virus, hampering our ability to effectively control the spread of the virus. Thankfully, over the last 18 months, the private sector has been highly innovative in developing advanced technology to aid in testing and surveillance.
 - a. How does HHS plan to leverage advanced or novel technology developed by private sector partners in the near and long-term to help rapidly scale surveillance and testing capabilities and capacity to better prepare for future pandemics?

Answer: As HHS continues to respond to the COVID-19 pandemic, it is important that the Department also look ahead to what can be integrated to better prepare for future pandemics. If confirmed, I will support this ongoing work.

- b. Are there any barriers to effective partnerships with private sector innovators?

Answer: ASPR's Biomedical Advanced Research and Development Authority (BARDA) continuously and effectively partners with private sector innovators. BARDA provides an integrated, systemic approach to the development of necessary vaccines, drugs, therapies, and diagnostic tools for public health emergencies, including the current COVID-19 pandemic. If confirmed, I will support this ongoing work.

4. Through the Coronavirus Preparedness and Response Supplemental Appropriations Act of March 2020 and otherwise, Congress appropriated billions of dollars for the development of COVID-19 therapeutics and diagnostics. However, I have heard that multiple highly promising candidates did not receive funding, and it remains unclear whether and how the funding earmarked for the development of COVID-19 therapeutics and diagnostics was spent.
 - a. If confirmed, will you commit to investigating on what activities and programs the funds appropriated to HHS for the purposes of COVID-19 therapeutics and diagnostics through the Coronavirus Preparedness and Response Supplemental Appropriations Act were spent, and publicly release (in a manner that does not affect national security) such information, in addition to the amount of funding that remains unobligated or unspent?

Answer: I believe in transparency, and if confirmed, will carry out my new role with that perspective in mind. My understanding is that the Office of General Counsel at HHS has been consistently involved in decision-making regarding the use of HHS's COVID funding, in coordination with the Office of the Assistant Secretary for Financial Resources and the HHS Operating and Staff Divisions, and I would have a better view of this issue once confirmed.

Questions from Senator Young

Questions for the Record for Samuel R. Bagenstos

While the questions below are numerically separated by theme for clarity and convenience, some may include sub-part questions denoted alphabetically. **Please note that individual responses to each sub-question are expected** and that a single response to multiple sub-questions will be treated as unresponsive.

For the purposes of questions that clearly end in “yes or no,” answers other than “yes” or “no” will similarly be deemed unresponsive to such questions.

Question 1

The Department of Health and Human Services (HHS) finalized reforms in November of 2020 to ensure that organ procurement organizations (OPOs) will be held accountable to objective data for the first time and that failing OPOs will lose their contracts. The new regulation, however, currently does not allow HHS to decertify a failing OPO until 2026.

What actions can HHS take to accelerate that timeline?

Answer: I understand that CMS recently finalized changes to OPO outcome measures to improve the quality of OPO services and hold underperformers accountable by using objective, transparent, and reliable data. If confirmed, I look forward to working with you, other Members of Congress, and CMS to use available authority to hold OPOs accountable for their performance.

Question 2

The Organ Procurement and Transplantation Network (OPTN) contract has been held by only one entity, the United Network for Organ Sharing (UNOS), since 1986. When the contract is up for renewal, UNOS is historically the only bidder for the contract due to contract requirements set forth by the Health Resources and Services Administration (HRSA) that make it nearly impossible for other entities to apply.

- (a) *What specific steps should HHS take to ensure that all future OPTN contracting cycles – including the next, immediate cycle – have a robust, competitive bid process?*

Answer: It is my understanding that future contracting cycles will utilize past experience and market research to gauge interest and capabilities of vendors to handle the entirety of the OPTN operational functions. If confirmed, I intend to work with HRSA and CMS to ensure we use available authority to improve the function of the organ transplant ecosystem.

- (b) *What oversight is HHS providing to ensure UNOS is living up to the requirements set out in statute?*

Answer: It is my understanding that the current contract includes requirements that OPTN policymaking be consistent with existing statutes and regulations. If confirmed, I will work with Congress to support their oversight efforts related to organ procurement, where appropriate.

Questions from Senator Thune

Questions for the Record for Sam Bagenstos

Question 1

Mr. Bagenstos, if confirmed, do you anticipate that you would uphold the legal opinion offered by your predecessor related to 340B contract pharmacies, which stated that the plain meaning of 340B statute requires manufacturers to offer drugs at or below ceiling price without qualifiers?

Answer: The 340B Drug Pricing Program is an important program for our safety-net providers serving some of our most vulnerable populations. If confirmed, I look forward to working with you and other Members of Congress to uphold the law and ensure this vital program is able to continue supporting vulnerable communities.

Question 2

Mr. Bagenstos, as you know, there have been multiple providers of concern at the Indian Health Service. As the Department's attorney, how would you ensure that abusive providers are held to account and that the Department is transparent with Congress?

Answer: I am aware of this very troubling issue. If confirmed, I am committed to supporting the Indian Health Service's (IHS) policy of no tolerance for abusing patients or failing to prevent or report abuse in the Indian health system. I will also commit to ensuring that HHS follows the law and holds all employees and contractors accountable to the advancement of our mission and maintenance of the public's trust in our services and programs. If confirmed, I will work with IHS to ensure continued transparency regarding sexual abuse within the IHS system and to being transparent with Congress and the public.