House E&C O&I 03/17 Hearing on Medicare/Medicaid Fraud

Additional Questions for the Record

The Honorable John Joyce (R-PA)

1. Medicaid billing for therapy for children with autism, known as Applied Behavioral Analysis (ABA) services, is skyrocketing. A recent analysis of U.S. Centers for Medicare and Medicaid Services (CMS) data by *The Wall Street Journal* found that direct payments from state Medicaid programs to autism therapy providers went from $660 million in 2019 to $2.2 billion in 2023.[1] The U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) has also identified documentation inefficiencies with ABA services in multiple states. In some cases, Medicaid is reimbursing for childcare activities such as watching a movie or taking a nap, rather than structured therapy. What trends has CMS been seeing in its data with respect to high spending on autism services and documentation inefficiencies in ABA services that open the door to fraud in these programs?

    a. How is CMS working with states with high ABA spending to identify ways to normalize billing rates, lower costs, and ensure that Medicaid is only reimbursing permitted services?

Response:
State Medicaid agencies are responsible for determining what services are medically necessary for eligible individuals and are expected to adhere to long-standing Early and Periodic Screening, Diagnostic and Treatment (EPSDT) obligations. Recent findings from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and public reporting raise serious concerns about state oversight of rehabilitative and community support (RCS) services for children diagnosed with autism and interpreting services. These findings, combined with national trends and prior OIG and CMS reviews, underscore the need for immediate corrective action and enhanced transparency. As part of CMS's continued oversight of states, we have requested detailed information regarding program integrity, eligibility verification, and provider oversight within state Medicaid programs to ensure public confidence and protect beneficiaries. Based on this information, CMS will work with states to ensure appropriate follow-up actions are taken.

2. In Minnesota, whistleblowers alerting state leaders to fraud in social services programs were reportedly silenced. This can have a chilling effect on other whistleblowers' willingness to come forward. How does CMS support whistleblowers that reach out to expose fraud?
    a. Is CMS concerned about reports of whistleblower intimidation coming out of Minnesota and what actions are being taken, if any, to encourage whistleblowers to come forward?

Response:

CMS encourages anyone, including whistleblowers with knowledge of fraudulent behavior in any of our programs to come forward, and we oppose retaliation (which generally is unlawful) against individuals who do so. Ensuring appropriate action is taken in response to any report of fraud is critical to our efforts to crush fraud, waste, and abuse.

CMS requires states, managed care organizations, and many providers to maintain compliance programs and processes for identifying and reporting fraud, waste, and abuse. These requirements include employee training, internal reporting procedures, and options for anonymous reporting (42 C.F.R. § 438.608; 42 U.S.C. § 1396a(a)(68)).

3. Federal investigations into allegations of widespread Medicaid fraud in Minnesota are ongoing. Two defendants charged with defrauding the state's child autism therapy program of more than $6 million, have pleaded guilty. Is there anything you can share about fact patterns of alleged fraudulent activity in Minnesota's Medicaid program, and why it was so vulnerable to fraud?

    a. From what I understand, CMS was called into Minnesota last year when there were signs of fraud in the state's Housing Stabilization Services (HSS) program. Why was CMS called in to help and what did you learn about the way the state was managing program integrity in that particular program?
    b. After CMS weighed in, Minnesota shut down the HSS program due to rampant fraud. In the months since Minnesota's fraud was exposed, how would you characterize the state's willingness to cooperate with CMS and address fraud?
    c. What has CMS learned from its closer examination of Minnesota's Medicaid data?
    d. Are there any patterns coming to light in Minnesota that are informing program integrity audits and investigations in other states? If so, can you tell us more about CMS' efforts to be more forward-leaning in addressing systemic fraud?

Response:
There has been a history of fraud in Minnesota's Medicaid program for which CMS has sought accountability from the state. Last spring, the Trump Administration reached out to the state, requesting it look into concerning trends that CMS observed in its analysis of Minnesota Medicaid data. They committed to doing so. Months later, the state reached out to request additional help from CMS because they found the issue was much bigger than originally thought.

CMS notified Minnesota of its intent to both withhold certain federal funds (a prospective action) and defer other federal funds (a retrospective action). CMS will withhold federal funds until it is satisfied with the state's corrective action plan to address its program integrity shortcomings. CMS also notified Minnesota of its intent to conduct a review focused on program integrity to ensure federal funds were not going toward questionable claims.

CMS' review of Minnesota's Medicaid spending for the fourth quarter in FY 2025 resulted in a deferral of $259,505,491 in federal matching funds. This includes state expenditures of $243.8 million for unsupported or potentially fraudulent Medicaid claims and $15.4 million related to claims involving individuals lacking a satisfactory immigration status. The agency utilized both traditional financial management approaches and new program integrity oversight strategies to identify unusually high spending and rapid growth in certain service areas.

CMS is deferring those federal funds to protect taxpayer dollars while ensuring the state has the opportunity to respond and provide information and documentation during the ongoing review. Should Minnesota fail to clean up its significant program integrity vulnerabilities or demonstrate that the expenditures are allowable, CMS may defer more than $1 billion in federal funds over the next year. CMS also continues to intensely oversee Minnesota's efforts to carry out its corrective action plan to address the underlying causes of fraud, waste, and abuse within the state.

Post-hearing update: On May 21, 2026, the Justice Department announced the Minnesota Health Care Fraud Takedown, which resulted in criminal charges against 15 defendants, including owners of child care centers and various Medicaid providers, for their alleged participation in various fraud schemes involving over $90 million in intended loss, including the two largest Medicaid fraud cases ever charged in the District and first-of-their kind charges involving additional Medicaid programs. The Justice Department also announced a major investment in combatting Medicaid fraud through a significant expansion of the Division's Health Care Fraud Section, allocating funding to permit the hiring of 15 new Trial Attorney positions to combat Medicaid fraud across the United States.

4. CMS recently raised concerns with high-risk billing patterns in Maine's Medicaid program. In a letter to the state, CMS has expressed concerns with patterns in autism therapy services for children, interpreting services, psychosocial rehabilitation services, personal care services and residential habilitation services. Why have these programs been flagged by CMS, and what information has CMS learned so far from the state about its program integrity efforts?
    a. How would you characterize Maine's cooperation with CMS' requests for more information about Medicaid program integrity?

5. In New York, Medicaid home health and personal care services spending is skyrocketing. Between 2023 and 2024, the home care and personal care aide job category represented 38 percent of all job growth in the state. What does this indicate about the state's personal care services program, and does it raise program integrity concerns?
    a. What other trends or billing patterns are you seeing in New York's Medicaid program that have raised program integrity concerns and warrant further investigation?
    b. How would you characterize New York's cooperation with CMS' requests for more information about Medicaid program integrity?

6. CMS recently requested more information from the State of California about its Medicaid

program, also known as Medi-Cal. The In-Home Supportive Services (IHSS) program, which provides personal care services, is experiencing exponential growth. What trends or billing patterns is CMS seeing in Medi-Cal that have raised program integrity concerns and warrant further investigation?

a. How would you characterize California's cooperation with CMS' requests for more information about Medicaid program integrity?

Response (4-6):
Protecting the integrity of the Medicaid program is a shared federal and state responsibility. CMS routinely evaluates state Medicaid program integrity efforts and may request additional information when program vulnerabilities are identified. These evaluations are necessary to ensure public confidence and protect beneficiaries in state Medicaid programs.

In Maine, recent findings from the U.S. Department of Health and Human Services Office of Inspector General (OIG) and public reporting raise serious concerns about MaineCare's oversight of rehabilitative and community support services for children diagnosed with autism and interpreting services. These findings, combined with national trends and prior OIG and CMS reviews, underscore the need for immediate corrective action and enhanced transparency.

In New York, recent public reporting, federal prosecutions, and CMS analyses raise serious concerns about New York's oversight of personal care, home health, adult day care programming, non-emergency medical transportation, and behavioral health services. This evidence, combined with New York's elevated per capita Medicaid spending and workforce utilization patterns that significantly exceed national norms, underscore the need for immediate investigation, corrective action, and enhanced transparency.

California operates a state-only health care program for adults who are not eligible for full Medicaid benefits due to immigration status. As part of an increased oversight plan established last year, CMS began conducting focused financial reviews to ensure that California and other states that operate these programs do not receive FFP for non-emergency or full benefit Medicaid services for individuals with an unsatisfactory immigration status. CMS has identified over $1.6 billion in federal funds that the agency is recouping from California through voluntary recoveries and deferrals of future Medicaid payments to California. Additionally, in 2024 alone, spending for home health care in CA increased by more than 21% -- representing the largest growth rate of any major health category nationwide. Given these concerns, CMS requested that the State of California provide us with a comprehensive program integrity action plan that incorporates written responses and supporting documentation.

CMS appreciates continued state cooperation in safeguarding beneficiary access to services while ensuring that taxpayer funds are protected from fraud, waste and abuse. As states submit the information and plans that we've requested, we will be following up with the states if we need any additional information and will work with states to ensure appropriate follow-up actions are taken..

7. Although the Medicare program is federally administered, states play a role in provider oversight by licensing facilities, like hospice and home health companies, to qualify for Medicare provider enrollment. Are states, like California, taking the necessary steps to fully vet Medicare providers in the state licensing process?
    a. What role do accrediting organizations play in state licensing of Medicare and Medicaid providers?
    b. Is CMS currently undertaking any accrediting validation surveys for accrediting organizations for provider types, like home health and hospice, that are at higher risk for fraud?
    c. What is the next step when CMS has identified that a state is failing to accredit providers in line with federal requirements?

Response:
Medicare providers apply for participation directly with Medicare, and CMS requires providers and suppliers to be in compliance with federal and state licensure, certification, and regulatory requirements (42 C.F.R.§424.516(a)(2)).

CMS thoroughly screens applicants before they are allowed to enroll or reenroll in the Medicare program. Enhanced screening tools include fingerprint-based criminal background checks for high-risk providers and suppliers, unannounced site visits, license verification, database cross-checks, and ownership disclosure requirements. CMS uses the Provider Enrollment, Chain, and Ownership System (PECOS) to collect and store records for all Medicare provider and supplier enrollment data across Part A and Part B. CMS's Advanced Provider Screening (APS) system provides another sophisticated layer of protection. APS is an interactive screening, monitoring, and alerting system that identifies ineligible providers and houses a centralized provider repository of criminal activity, licensure status, and identity information.

CMS uses risk-based screening of providers and suppliers applying to enroll or reenroll in Medicare and when we see a concerning trend, we take action. For example, In July 2023, CMS implemented a Provisional Period of Enhanced Oversight (PPEO) for hospices newly-enrolled in Medicare and hospices that underwent a change in ownership in various states and by December 2025, 817 hospices have been subject to medical review under the PPEO. CMS has revoked the Medicare enrollment of 181 of these hospices.

Post-hearing update: Additionally, on May 13, 2026, CMS implemented a temporary nationwide enrollment moratorium on Home Health Agencies (HHAs) and Hospices. The moratorium applies to initial applications and includes non-exempt changes in majority ownership.

8. According to federal regulations, states must screen all initial applications and re-enrollment or re-validation applications for Medicaid based on a categorical risk level that is designated by the state. Depending on the risk level, certain screening requirements, like site visits, criminal background checks, and fingerprinting, must take place. Even when program integrity issues emerge, if a state does not adjust a program's

designated risk levels, the state may not be required to employ more robust screening. What guardrails are in place, if any, to hold states accountable to the accuracy of the categorical risk assessments they designate?

Response:
CMS has published and continually updates the Medicaid Provider Enrollment Compendium (MPEC), which consolidates guidance to state Medicaid agencies on implementing federal statutory and regulatory enrollment requirements. States may impose additional or more stringent screening methods than those in federal regulations. This could result in a change in the risk category assigned for certain types of providers.

Additionally, state Medicaid agencies may not assign a Medicaid provider type to a risk category lower than which Medicare has assigned to that same provider type.
CMS also has the authority to impose moratoria to temporarily prohibit new providers and suppliers from enrolling in Medicare or Medicaid as necessary to prevent or combat fraud, waste, and abuse.

9. Medicaid Fraud Control Units (MFCUs) are primarily responsible for Medicaid fraud investigations at the state level. In looking at MFCU data and announcements, there are some states that appear to bring little to no enforcement actions. Given that Medicaid fraud investigations are a core responsibility of MFCUs and are funded largely with federal dollars through the HHS-OIG, can you explain why some units appear to have little to no enforcement in recent years, and whether this reflects a lack of investigations, delays in bringing cases, or other operational challenges?
    a. What oversight does CMS conduct to ensure states are maintaining robust fraud investigations, and what corrective actions can CMS take when investigative activity declines?
    b. Would access to clearer performance metrics or enhanced reporting requirements by MFCUs help CMS better support their efforts?

Response:
HHS-OIG, in exercising oversight for the MFCUs, annually recertifies each MFCU, assesses each MFCU's performance and compliance with Federal requirements, and administers a Federal grant award to fund a portion of each MFCU's operational costs. CMS defers to OIG on MFCU oversight concerns.

10. Some states waive or limit their Medicaid Recovery Audit Contractor (RAC) programs. What role do RAC audits play in Medicaid program integrity and does CMS believe RAC audits are being used effectively?

Response:
As states and the federal government share in the cost of Medicaid, so too do the states and federal government share in overpayment recoveries. Unless CMS grants an exception, states must contract with one or more Medicaid RACs to identify and recover overpayments as well as identify underpayments made to Medicaid providers. States determine the operations and focus areas for Medicaid RAC audits. CMS

requires states to have an appeals process for providers seeking review of Medicaid RAC findings.

CMS reports the recovered federal share of Medicaid overpayments identified by Medicaid RACs in the fiscal year during which the recovery occurred. The calculation of the recovered federal share includes 1) the federal share of amounts collected by states within the one-year time limit, plus 2) the federal share of amounts refunded by states in cases when a state was not able to fully collect an identified overpayment within the one-year time limit, less 3) the federal share of Medicaid RAC fees. The recovered federal share includes any necessary adjustments to previously reported federal share amounts. For example, credit may be due back to the state for overpayment amounts previously refunded to CMS due to the expiration of the one-year time limit, but where the provider was subsequently determined as bankrupt or out of business.

11. Today, the majority of Medicaid beneficiaries receive coverage through managed care plans. How does CMS ensure that managed care organizations are accurately reporting encounter data and identifying potential fraud within their networks?

Response:
CMS shares your commitment to ensuring that Medicaid managed care plans (MCPs) comply with applicable federal and state requirements related to fraud detection and referral. CMS continues to take actions to strengthen oversight of MCP fraud, waste, and abuse referral practices. As part of this work, CMS is auditing more than 130 MCPs across 25 states. These audits include reviews of a selection of open and closed investigations to ensure that MCPs are using adequate program integrity controls and making referrals of potential provider fraud, waste, and abuse, as appropriate. While there are no regulatory requirements for an MCP to make a specific number of referrals, CMS generally expects to see referrals that are proportional to the size of the plan. When audits identify plans with proportionally low or no referral activity, CMS will notify the state and coordinate with them as they develop their own plans for corrective actions. We believe coordination on these corrective actions will enhance accurate reporting of fraud referrals. Further, for future audits of Medicaid MCPs, CMS will capture additional specific information about the number of referrals for potential fraud, waste, and abuse to further inform oversight efforts.

Additionally, CMS strives to address program integrity educational needs through the Medicaid Integrity Institute (MII). The MII provides training tailored to meet the ongoing needs of state Medicaid employees, downstream entities, and law enforcement responsible for protecting the integrity of the Medicaid program, with the goal of raising national program integrity performance standards and professionalism, at no cost to states. MII is a comprehensive program of study addressing many aspects of Medicaid program integrity, and its course content is responsive to known and emerging Medicaid program integrity risks. MII classes highlight emerging trends and strategies, and feature states' effective practices. For calendar year 2026, the MII will offer a multitude of classes addressing fraud, waste, and abuse, including a course focusing on Medicaid managed care law enforcement referrals that aims to improve referral quality, clarify

when investigations should proceed, and support a strong program integrity framework to protect Medicaid program resources.

12. CMS manages the Transformed Medicaid Statistical Information System (T-MSIS), which is made up of state-submitted data on Medicaid and CHIP. The quality of state reported data varies. Can you describe CMS' efforts to improve the quality of data submitted by states to T-MSIS?
    a. Is there additional state data or information that CMS would like to have access to in order to improve program integrity monitoring?

Response:

T-MSIS provides an increasingly rich source for data-driven decision making and improved health outcomes. CMS encourages states to seek assistance from the agency as needed. CMS continues to look for ways to reduce overall state reporting burden through the utilization of T-MSIS data for program monitoring and public reporting. In May of last year, CMS issued a letter to states reaffirming the agency's expectations regarding the quality of T-MSIS data and the compliance impact of deviating from T-MSIS reporting requirements. In 2022, CMS introduced an Outcomes Based Assessment (OBA) methodology that includes more than 500 critical and high-priority measures that check for data integrity, accuracy, and completeness issues that may impact the data's usability and usefulness for program monitoring and research purposes. As the states' data quality improves, CMS will continue to add additional measures to ensure timely and accurate T-MSIS submissions. If states' T-MSIS data do not meet reporting requirements for four consecutive months, CMS will initiate the Medicaid Enterprise Systems (MES) Compliance and Reapproval Process, beginning with the issuance of a letter requesting the state to submit a corrective action plan.
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13. Can you share more about what CMS learned from the Crushing Fraud Chili Cook-off last fall? What were some of the proposed analytic and policy solutions participants were able to provide to CMS?

Response:
Last fall, CMS held the Crushing Fraud Chili Cook-Off Competition and invited companies to submit their best tech recipes for crushing fraud. The Cook-Off was a market-based research challenge aimed at harnessing explainable AI, specifically machine learning models, to detect anomalies and trends in Medicare claims data that can be translated into novel indicators of fraud. This challenge sought innovative, scalable technologies that reduce labor-intensive processes while keeping humans meaningfully in the loop to ensure effective oversight and interoperability. CMS invited research proposals from all interested parties and reviewed over 259 applications during the first phase of the competition. For the second and final phase, CMS provided ten finalists with access to CMS's Limited Data Set of Medicare Hospice, Part B, and Durable Medical Equipment (DME) claims data. Participants applied their proposed techniques to the data

and submitted a summary of their findings, as well as proposed scalable analytic and policy solutions. On December 15th, CMS selected Milliman, Inc. as the winner of the Chili Cook-Off Competition. The insights and tools developed through this competition will guide us as we implement new capabilities and technologies to crush fraud and protect taxpayer dollars. More information on the Chili Cook-Off Competition and the solutions that participants developed is in the Crushing Fraud Chili Cook-Off Competition: Summary Report, available at: https://www.cms.gov/files/document/crushing-fraud-chili-cook-white-paper.pdf.

14. In response to a hearing question, you stated that under the "pay and chase" model, which is when the government attempts to recover fraudulent payments after they are made, the recovery rate of taxpayer dollars is very low - probably 10 percent. You also testified that under the caught and stopped approach, which prevents the payments from going out the door in the first place, CMS stopped over $2 billion in suspected fraudulent payments to date. To put this achievement in context with the "pay and chase" model probable recovery rate, what is the probable percentage of stopping suspected fraudulent payments under the "caught and stopped" approach?

    Response:
    CMS has taken decisive action to crush suspected fraud and improper payments by implementing key program integrity initiatives. These initiatives have saved taxpayers billions while protecting beneficiary care. In 2025, CMS suspended $5.7 billion in suspected fraudulent Medicare payments by leveraging advanced analytics, cross-agency coordination, and law enforcement partnerships, and prevented $1.5 billion in suspected fraudulent DMEPOS billing. Total Medicare program integrity savings surged 59%, from $26.3 billion in FY 2024 to a record-shattering $41.9 billion in FY 2025.

    In particular, the Fraud Defense Operations Center (FDOC), also known as the Fraud War Room, which CMS launched in March 2025, integrates cross-functional expertise through a specialized team of data analysts, investigators, health policy experts, legal advisors, and law enforcement. This team leverages rigorous, data-driven analyses to proactively detect, address, and prevent fraud, waste, and abuse in real time.

    Using the FDOC, CMS has shifted its oversight of skin substitutes from a "pay and chase" approach—where Medicare generally paid claims first and attempted to recover improper payments later—to a "stop and caught" approach that uses prepayment analytics, medical review, and targeted fraud prevention tools to identify and stop suspicious or medically unsupported claims before taxpayer dollars are paid. In 2025, the FDOC stopped nearly $106 million in improper payments to suspect providers billing for skin substitutes.

The Honorable Rick W. Allen (R-GA)

1. We have heard instances of some DME suppliers who are billing Medicare supplement companies for amounts that far exceed the Medicare-approved payment - sometimes by as much as 800 percent. One example is an electric scooter company billing Medicare $45,000. Medicare approved $4,700 and the excess charge of $38,000 was then billed to

the Medicare supplement company. This kind of practice is clearly an abuse of the system and has a significant impact on the Medicare system but ultimately on seniors' premiums. Most other Medicare providers who do not accept assignment are subject to a 115 percent cap on what they can charge above Medicare's payment. Unfortunately, this cap does not currently apply to DME suppliers. While a few states have taken the initiative to pass legislation imposing this cap, I wanted to ask if CMS has considered implementing a similar nationwide cap for DME suppliers. Doing so could help prevent further abuse of the system and protect seniors from rising premiums.

Response:
CMS is taking decisive steps to prevent fraudulent Medicare billing by durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) companies. A six-month moratorium on new Medicare enrollment for certain DMEPOS suppliers builds on CMS' stopping more than $1.5 billion in suspected fraudulent billing in this area last year. The DMEPOS supplier enrollment moratorium allows CMS to explore additional safeguards to further mitigate longstanding instances of fraud, waste, and abuse perpetrated by certain DMEPOS companies. This moratorium applies to all applications for initial enrollment and changes in majority ownership for medical supply companies. CMS is also deploying the Fraud Defense Operations Center that leverages data-driven analytics to proactively detect, address, and prevent fraud, waste, and abuse in real time, and other "stop and caught" initiatives, to crush DMEPOS fraud before taxpayer dollars go out the door. Additionally, as of December 2025, CMS is sharing payment suspension information with Medicare supplemental insurance payers to assist in their own program integrity efforts.

The Honorable Earl L. "Buddy" Carter (R-GA)

1. At the March 17, 2026, Energy & Commerce Health Subcommittee hearing titled "Protecting Patients and Safeguarding Taxpayer Dollars: The Role of CMS in Combatting Medicare and Medicaid Fraud," CMS Deputy Administrator and Chief Operating Officer Kim Brandt stated that "under the new [January 1 Physician Fee Schedule] payment rules, we've seen a 99 percent reduction in billing for skin substitutes."

   While I appreciate CMS's efforts to address fraud, waste, and abuse in this space, a 99 percent reduction in billing raises significant concerns that the Agency may have overcorrected in a way that jeopardizes patient access to medically necessary care. Skin substitute products play an important role in treating chronic wounds, particularly for diabetic patients at risk of serious complications, including infection and amputation. A reduction of this magnitude, coupled with reports that 52 percent of surveyed providers have closed or are considering closing their wound care service lines, warrants further scrutiny to ensure that appropriate care is not being inadvertently restricted.

   As you know, I have introduced the bipartisan Skin Substitute Access and Payment Reform Act, which seeks to address inappropriate utilization and pricing concerns while ensuring that patients who need these products are able to access them. This approach reflects the need to strike a more appropriate balance between program integrity and

patient access.

In light of the reported 99 percent reduction in billing, how does CMS define "appropriate utilization" for skin substitute products, and what evidence does the Agency have that current payment levels are not effectively restricting patient access to medically necessary care?

a. Additionally, does CMS believe the current level of utilization—representing roughly a 99 percent reduction—reflects clinically appropriate use, and is the Agency evaluating whether payment policies should be adjusted for 2027 to ensure beneficiary access is maintained?

Response:
CMS believes it is important to maintain patient access to skin substitute products with high quality evidence of effectiveness. Previously, most skin substitutes were paid as if they were biologics under the average sales price-based payment methodology. This led to significant growth in spending under Medicare Part B for skin substitutes. According to Medicare claims data, Part B spending for these products rose from $252 million in 2019 to over $10 billion in 2024, a nearly 40-fold increase.

For CY 2026, CMS finalized paying for skin substitute products as incident-to supplies when they are used as part of a covered application procedure paid under the Physician Fee Schedule (PFS) in the non-facility setting or under the Outpatient Prospective Payment System (OPPS) in the hospital outpatient department setting. CMS also finalized to align skin substitute categorization consistent with their FDA regulatory status. CMS believes that grouping and paying for skin substitute products based on relevant product characteristics, consistent with their FDA regulatory status, recognizes the clinical and resource differences in product types and would incentivize competition to create more innovative products, while also resulting in significant savings to the Medicare Trust Fund. If the Trump Administration had not taken action to address unprecedented spending on skin substitutes, the Part B premium increase would have been about $11 more a month.

The Honorable Diana DeGette (D-CO)

1. Please provide a copy of the memorandum dated June 6, 2025, from Center for Medicaid and CHIP Services Deputy Director Sara Vitolo regarding data or information sharing between the Centers for Medicare & Medicaid Services (CMS) and the Department of Homeland Security (DHS).

2. Please provide a copy of any data or information sharing agreement, active or otherwise, between CMS and DHS or any component thereof entered into after January 19, 2025.

3. What data elements (e.g., name, sex, date of birth, phone number, diagnosis codes) has CMS shared with DHS since January 19, 2025?

4. Has CMS provided the personal information of any United States citizen to DHS since January 19, 2025?

5. Has CMS provided the personal information of any lawful permanent resident to DHS since January 19, 2025?

6. What is the process that CMS uses to verify that any information shared with DHS pertains only to undocumented individuals?

Response (1-6):
HHS does not comment on ongoing litigation.

7. Is it the position of the administration that, under EMTALA, hospitals have a duty to provide stabilizing care to a pregnant patient who is experiencing an emergency medical condition that could result in serious bodily harm or death?
    a. If yes, does that include if the legally required stabilizing treatment is or includes an abortion?

8. In rescinding July 2022 guidances relating to EMTALA on June 3, 2025, CMS stated that the guidances "do not reflect the policy of this Administration." Please describe specifically what elements of the guidances did not reflect the policy of this administration.

9. Please provide copies any outreach from CMS to states and hospitals to clarify its position on hospitals' duties under EMTALA following the rescission of the July 2022 guidances.

10. What protection does EMTALA provide to hospitals and clinicians that provide care that is required under EMTALA if a state law is perceived to or actually conflicts with that requirement?

11. Oklahoma's abortion ban has an exception only for the life—not the health—of the mother. Consider a patient comes in after having broken their water in, for instance, the second trimester, when there is essentially no chance of the baby's survival and significant risk of infection to the mother. In such a scenario, is intervention required under EMTALA? Or would a hospital need to wait for the infection to develop?

Response (7-11):
EMTALA remains a binding federal law and continues to guarantee that pregnant women facing medical emergencies have access to stabilizing care. CMS will continue robust enforcement of EMTALA through established mechanisms, such as expeditious review of complaints and timely action when violations are found.

CMS continues to prioritize its oversight to protect the health and safety of patients and is dedicated to finding innovative methods to streamline and accomplish these goals with greater efficiency. CMS remains committed to educating providers about their EMTALA obligations under federal law. CMS continues to provide the applicable resources, guidance, and support necessary to assist in full compliance with EMTALA requirements. The CMS website contains various EMTALA educational materials and

other resources to help the public, healthcare providers, and hospitals understand their rights and obligations under federal law.

12. Please provide a copy of any agreement entered into between CMS and a pharmaceutical manufacturer relating to "most favored nation" pricing.

13. Have you participated in any meeting, discussion, or negotiation with any pharmaceutical manufacturer regarding "most favored nation" pricing?
    a. If yes, with which manufacturer(s)?
    b. On what date(s) did such discussion(s) take place?
    c. For each date on which such discussion(s) took place, who were the other participants in such discussion(s)? Please list governmental participants, external participants, and any other party that may have been involved.

14. Will manufacturers that have entered into a "most favored nation" agreement with the administration be exempt from CMS' GLOBE and/or GUARD models?

15. Are you involved with any ongoing discussions with pharmaceutical manufacturers with the goal of reaching agreements regarding "most favored nation" pricing? If so, with which manufacturers?

Response (12-15):
Consumers in the U.S. pay more for prescription drugs than any other developed nation. CMS is aligned with President Trump's focus on lowering the cost of prescription drugs for Americans and supporting continued pharmaceutical innovation.

Seventeen leading companies have come to the table to work with CMS and President Trump to reduce prices on drugs that treat numerous costly and chronic conditions. These deals build upon several others we made last fall, including one aimed at lowering the cost of GLP-1 medications for those who simply cannot afford the cost of using GLP-1s and millions of seniors can now access these drugs for just $50 per month. Further, TrumpRx.gov clearly and transparently displays the prices negotiated by President Trump and connects patients to those prices for their drugs.
The ultimate aim of the Trump Administration and E.O. 14297, "Delivering Most-Favored-Nation (MFN) Prescription Drug Pricing to American Patients," is to protect access to innovative drugs for all Americans. The Administration, Secretary and CMS continue to explore every tool under our available authorities to achieve this goal.

Addendum: At the time of the hearing, there were deals with 16 companies; as of May 5, 2026, there are deals with 17 companies.

16. In developing the final rule titled *Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider*

Enrollment; and Other Medicare and Medicaid Policies, CMS added continuous glucose monitors (CGM) and insulin pumps to the durable medical equipment competitive bidding program.

a. What are the specific fraud concerns that CMS is seeking to address by including CGMs and insulin pumps in the durable medical equipment competitive bidding program?
b. Which suppliers, patient advocacy groups, clinicians, and other stakeholders did CMS consult in advance of proposing including CGMs and insulin pumps in the competitive bidding program?
    i. What feedback did CMS receive from such stakeholders?
c. In the final rule referenced above, CMS disagreed with the bulk of comments received relating to CGMs and insulin pumps. How will CMS build trust among those stakeholders as the rule is implemented?
d. How will CMS work to ensure a smooth transition to adding CGMs and pumps to the competitive bidding program and other associated changes, and what outreach with CMS conduct to beneficiaries to educate them as to forthcoming changes?
e. How will CMS ensure beneficiaries do not face difficulties obtaining their prescribed CGM or insulin pump if the technology is not carried by a contract supplier?
f. How will CMS ensure that only qualified suppliers are awarded contracts?
    i. What are the specific criteria CMS will use when assessing suppliers?
g. What steps will CMS take to ensure there are sufficient support services like education and training for when beneficiaries choose to change their CGM or insulin pump?

Response:
CMS is taking significant actions to crush fraud conducted by DMEPOS suppliers. In FY 2024, CGMs had the highest projected improper payments of all DMEPOS items, approximately $278 million. Some suppliers have billed Medicare for CGMs that were never provided to the patients, often without the beneficiary's knowledge or consent. Suppliers have also received kickbacks to bill for CGMs when the beneficiary had no history of diabetes, and the device was, therefore, not medically necessary.

Under the DMEPOS Competitive Bidding Program, CMS will begin paying for all continuous glucose monitors (CGMs) and insulin infusion pumps on a monthly rental basis, giving beneficiaries access to current, fully supported technology that meets evolving safety and performance standards. To ease the transition, beneficiaries who own their own CGM or insulin pump prior to the start of the contract period can continue to use their equipment until it needs to be replaced or they elect to switch to a rented device. DMEPOS Competitive Bidding program resources and educational fact sheets are also available to the public at https://dmeposcompetitivebid.cms.gov. Contract suppliers must furnish replacement supplies and accessories for the beneficiary-owned CGM or insulin pump.

CMS believes it is vital that patients are using equipment with the latest features and technology to ensure that the measuring and displaying of glucose levels is as accurate as possible.

Post-hearing update: As an example, on July 21, 2026, a federal jury in the Middle District of Florida convicted an Oklahoma business owner and chiropractor for his role in a yearslong scheme that attempted to bilk Medicare, TRICARE, and the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) out of over $30 million by purchasing patient information, medical practitioners' signatures, and doctors' orders for orthotic braces and glucose monitors that patients did not want or need.

17. Did Center for Clinical Standards and Quality (CCSQ) employees participate in the development or clearance of the ACCESS model?
    a. If so, please list each the job title and organizational unit (e.g. Coverage and Analysis Group) of each CCSQ employee that participated in the development or clearance of the ACCESS Model.
    b. If so, did any CCSQ employee register an objection to any component of the ACCESS model? Please describe any objection.

18. How will CMS ensure the appropriateness of a medical device for which FDA is exercising enforcement discretion under the TEMPO model with regard to any regulatory requirement (including but not limited to premarket authorization or investigational device requirements) which is furnished under the ACCESS model?

19. Since the passage of the Medical Device Amendments of 1976, has CMS ever provided for Medicare payment for a medical device that has not been approved, cleared, authorized, or exempted?

Response (17-19):
The CMS Innovation Center actively designs and implements new payment and delivery service models deliberately, taking into account data, stakeholder feedback, real-world constraints, and long-term impact to ensure they are both effective and sustainable. This includes thorough review by colleagues across the agency. In addition, the CMS Innovation Center uses independent evaluators to routinely and rigorously assess the impact of each model. Importantly, participating in ACCESS does not change Medicare beneficiaries' benefits, coverage, or rights.

The voluntary ACCESS model tests Outcome-Aligned Payments — recurring payments for managing a patient's qualifying condition, with payment tied to achieving measurable health outcomes. This approach rewards results, not activities or specific technologies, and enables flexible, technology-supported care that improves patients' health.

Under the TEMPO pilot, FDA may exercise enforcement discretion and waive certain requirements, such as premarket authorization, for devices used by ACCESS participants to improve their patients' outcomes. In general, ACCESS participants may use medical devices, including digital health tools, when use is consistent with manufacturer plans discussed with FDA. These plans address mitigating risks to patients and collecting, monitoring, analyzing, and reporting real-world performance data. Providers and suppliers participating in ACCESS that choose to provide beneficiaries with the use of a

device in the TEMPO pilot must obtain enhanced consent, including disclosure that the device is part of an FDA pilot and that certain data will be shared with FDA, consistent with all applicable federal privacy and security requirements.

This pilot will help the FDA and CMS better understand how digital health technologies perform in real-life settings and how they may support efforts to improve care for people living with chronic diseases. Insights from this collaboration will support our efforts to build models that expand access to high-quality, technology-enabled care.