October 5, 2023

Secretary Becerra:

We write to request information about current authorities and planned efforts by the Department of Health and Human Services and its sub-agencies, the Centers for Medicare & Medicaid Services (CMS), Office of Inspector General (OIG), and Administration for Children and Families (ACF), related to artificial intelligence (AI) tools, including predictive algorithms, rules-based automated systems, and more advanced AI systems, such as generative AI. Department agencies can employ these tools to enhance efforts related to federal health and human services programs, and ongoing innovations may provide new opportunities and challenges. Moreover, health care providers, state agencies, and insurers administering or participating in these programs have signaled increased interest in leveraging AI tools.

AI tools, when appropriately designed and deployed, have the capacity to filter through or synthesize vast amounts of data to support government program management, health care and insurance administration, and clinical care. Developers have pointed to numerous viable use cases for AI technology in health care, from augmenting patient care quality by predicting health outcome trajectories to reducing administrative burden and optimizing health care operations.[1] As agencies, providers, manufacturers, and insurers scale up their adoption of these types of tools across diverse health care settings, the Senate Finance Committee seeks to strengthen our understanding of the relevant regulatory and statutory landscape, as well as engage on plans for adapting as the technology evolves.[2]

As with any advancement in health care, AI tools introduce both opportunities and challenges. These technologies can advance governmental efforts to combat fraud and abuse, and clinicians can turn to AI-enhanced systems to identify the early symptoms of disease, as well as streamline

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[1] Government Accountability Office and National Academy of Medicine, "Artificial Intelligence in Health Care Benefits and Challenges of Technologies to Augment Patient Care" GAO 21-7SP; November 2020. Retrieved from: https://www.gao.gov/assets/gao-21-7sp.pdf.

[2] Government Accountability Office and National Academy of Medicine, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics" GAO 22-104629; September 2022. Retrieved from: https://www.gao.gov/assets/gao-22-104629.pdf; Matheny M, Israni ST, Ahmed M, Whicher D. Artificial intelligence in health care: The hope, the hype, the promise, the peril. Washington, DC: National Academy of Medicine. 2019 Dec;10. Retrieved at: https://nam.edu/wp-content/uploads/2019/12/AI-in-Health-Care-PREPUB-FINAL.pdf

care delivery.[3] However, some recent examples of tools intended to enhance patient care have under-performed or offered biased results, raising serious questions and concerns.[4] In its 2022 report on the benefits and challenges posed by the use of machine learning technology for medical diagnostics, the Government Accountability Office (GAO) noted that "poor data quality and prevalent biases in health care can jeopardize progress towards achieving health equity and fuel ongoing uncertainties and hesitancies about adopting these [AI-assisted diagnostic decision support] tools."[5] GAO also concluded that "many available technologies have not been adequately tested or validated across generalizable data sets and settings and, as a result, may not transfer from development to adoption in clinical environments."[6]

As the Senate Committee with jurisdiction over Medicare, Medicaid, the Children's Health Insurance Program, and federal child welfare programs that together cover over half of the U.S. population, we have a responsibility to ensure access to quality health care and services for beneficiaries, particularly given the vital role that federal health care policies play in supporting the adoption and reimbursement of safe and effective new private sector technologies.

To further our understanding of how the Department and its sub-agencies employ AI-enhanced tools, as well as how our federal government programs approach coverage, reimbursement, and regulation of these tools and the services they facilitate, we request one or more staff briefings, beginning no later than November 2, 2023, with appropriate Department officials to receive and discuss the information identified in the attached questions.

Thank you for your attention to this important matter. If you have any questions, please contact Eva DuGoff and Conor Sheehey with the Senate Finance Committee at (202) 224-4515.
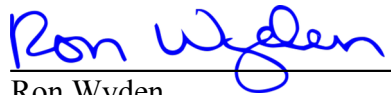
Sincerely,

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[3] Krishan N, "HHS CIO Mathias says tree-based AI models helping to combat Medicare fraud," FEDSCOOP, January 18, 2023. Retrieved from: https://fedscoop.com/hhs-cio-mathias-says-tree-based-ai-models-helping-to-combat-medicare-fraud/; Government Accountability Office and National Academy of Medicine, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics" GAO 22-104629; September 2022. Retrieved from: https://www.gao.gov/assets/gao-22-104629.pdf;

[4] Ross C. "Epic's AI algorithms, shielded from scrutiny by a corporate firewall, are delivering inaccurate information on seriously ill patients, StatNews, July 26, 2021. Retrieved at: https://www.statnews.com/2021/07/26/epic-hospital-algorithms-sepsis-investigation/; Wong A, Otles E, Donnelly JP, et al. External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients. JAMA Intern Med. 2021;181(8):1065–1070. doi:10.1001/jamainternmed.2021.2626; Ziad Obermeyer et al. ,Dissecting racial bias in an algorithm used to manage the health of populations.Science366,447-453(2019). DOI:10.1126/science.aax2342.

[5] Government Accountability Office and National Academy of Medicine, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics" GAO 22-104629. Retrieved from: https://www.gao.gov/assets/gao-22-104629.pdf.

[6] Government Accountability Office and National Academy of Medicine, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics" GAO 22-104629. Retrieved from: https://www.gao.gov/assets/gao-22-104629.pdf.

Ron Wyden
United States Senator
Chairman, Committee on
Finance

Michael D. Crapo
United States Senator
Ranking Member, United
States Senate Committee on
Finance

CC: Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
Jeff Hild, Acting Assistant Secretary/Principal Deputy Assistant Secretary, Administration for
Children & Families
Christi A. Grimm, Inspector General, Office of Inspector General
Greg Singleton, Chief Artificial Intelligence Officer, Office of the Chief Artificial Intelligence
Officer

Senate Finance Committee Chair and Ranking Member Questions on AI Tools

<u>Clinically Appropriate Adoption and Deployment of AI Tools:</u>

1. As CMS evaluates items or services that rely on or otherwise employ AI-enhanced technologies for Medicare coverage and determines appropriate payment methodologies for these tools, what additional information would further assist the agency? What gaps or barriers has the agency identified in its current statutory authorities related to these tools? What questions or plans does the agency have regarding the data used to develop these tools, the transparency and workforce expertise around their development and use, and the health provider and organizational governance of the application and maintenance? What steps, if any, could Congress consider taking to address these hurdles?

2. What types of AI-enhanced tools used in clinical care, if any, would qualify for eligibility under existing or proposed reimbursement and coverage pathways, such as the proposed Transitional Coverage for Emerging Technologies coverage pathway? How does CMS plan to address Medicare payment to practices that use varied models to purchase AI tools, such as per-use or subscription models?

3. While AI tools can, when deployed appropriately, accelerate and improve access to care, recent reports have raised concerns around the deployment of certain AI-enhanced technologies to constrain, delay, or deny reasonable and necessary medical care. How does CMS currently monitor potentially problematic applications of AI tools with respect to the Medicare program, what information does CMS currently collect that could be used to monitor potentially problematic applications of AI tools, and what additional information, if any, would assist the agency in identifying and addressing any such systems or practices?

<u>Deploying AI to Ensure Program Integrity:</u>

4. How has the Department's evolving understanding of AI technologies, along with the ever-changing landscape of AI tools, informed strategic planning efforts for current activities and future efforts with respect to program integrity?

5. What gaps or barriers, if any, continue to inhibit or impede the Department's initiatives to integrate AI technologies into its program integrity efforts?

6. As AI technology rapidly evolves and the exchange of information between providers and patients increases, how does the Department plan to ensure the protection of sensitive patient data?

AI as a Tool to Improve Outcomes for Families:

7. What steps has the Department taken to ensure that child welfare agencies are promoting the ethical and responsible use of predictive algorithms and AI tools in their decision-making processes, including addressing bias, appropriate training and oversight, and ensuring privacy protections for the collection and use of the personal data of children and families?

8. What measures are in place to prioritize transparency and accountability in the decision-making processes driven by AI in the child welfare field?

9. In 2016, the HHS Office of the Assistant Secretary for Planning and Evaluation launched an effort to inform HHS and child welfare stakeholders about predictive analytics and its potential to improve outcomes for families.[7] As new data becomes available, how is the Department continuing its engagement with relevant parties, including policymakers, to address the benefits and challenges of utilizing predictive analytics and AI tools?

Utilization of AI by State Medicaid Agencies:

10. Does CMS review or maintain a database of state Medicaid or Medicaid Managed Care Organization (MCO) uses of predictive algorithms or AI tools?

11. Has CMS communicated with states about AI-enabled resources that improve care or case management? If so, would CMS provide specific examples that could be predictive replicated or shared?

12. At what federal medical assistance percentage are AI-enhanced technologies or systems eligible for purchase or use?

13. Can state Medicaid agencies leverage predictive algorithms and AI tools for their program integrity efforts, and to what extent are such tools required by CMS?

Utilization of AI by Medicare Advantage plans:

14. Does CMS review or maintain a database of Medicare Advantage plan uses of predictive algorithms or AI tools?

15. What, if anything, has CMS communicated to Medicare Advantage plans regarding the ethics, guardrails, or best practices around the use of these tools in the administration of Medicare benefits?

16. Can Medicare Advantage plans leverage predictive algorithms and AI tools for fraud, waste, and abuse prevention efforts, and to what extent are such tools required by CMS?

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[7] Predictive Analytics in Child Welfare | ASPE (hhs.gov).

Cross-Agency Collaboration and Leveraging Private-Public Partnerships:

17. The CMS Artificial Intelligence Health Outcomes Challenge enabled CMMI to engage with private-sector innovators, as well as internal subject-matter experts, to identify potential applications for future models, "including tools to help support clinicians."[8] How does CMMI plan to leverage the lessons learned from this prize competition in the context of both current and future models?

18. Through the establishment of the Office of the Chief Artificial Intelligence Officer (OCAIO) and efforts to move forward with an AI Community of Practice (CoP) and an AI Council, HHS has the opportunity to pool expertise, resources, and insights from across agencies and sub-agencies with respect to responsible AI adoption and deployment.[9] How does HHS, along with its sub-agencies, plan to update Congress, stakeholders, and the general public on progress toward achieving its priorities and goals with respect to AI, both through these initiatives and through other complementary efforts?

19. What opportunities does the Department plan to create for routine and formalized, as well as informal and context-specific, engagement among sub-agencies, such as CMS and FDA, in order to ensure an efficient, effective, and adaptive approach to AI-enabled technologies? What statutory or regulatory barriers, if any, hinder cross-agency collaborations of this type?

20. The HHS AI Strategy cites "collaborating with external partners…to enhance programs and services through the potential of AI" as a key component of the Department's strategic approach.[10] What is the Department's and CMS's vision for leveraging public-private partnerships in this area moving forward?

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[8] https://www.cms.gov/blog/lessons-learned-cms-artificial-intelligence-health-outcomes-challenge.
[9] https://www.hhs.gov/about/agencies/asa/ocio/ai/ocaio/index.html.
[10] https://www.hhs.gov/about/agencies/asa/ocio/ai/strategy/index.html.