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Re: ATA Action Questions & Recommendations in Response to CMMI ACCESS Model & FDA TEMPO Program

On behalf of ATA Action, the affiliated policy and legislative advocacy arm of the American Telemedicine Association, we are encouraged by the release of two new innovative models under the Center for Medicare and Medicaid Innovation (CMMI) ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Program: a 10-year pilot program centered on outcome-based payments for chronic care management, and the related Food and Drug Administration (FDA) Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Program. The TEMPO Program will allow a limited number of devices to receive enforcement discretion for use within the ACCESS Program, enabling the collection of real-world data during the model period.

We commend this Administration for its forward-thinking leadership and its commitment to harnessing technology to make care more accessible, affordable, and effective for patients nationwide. These programs signal a meaningful shift toward modern, patient-centered care delivery, and we appreciate the tremendous effort behind their development.

After carefully reviewing the Request for Applications, we convened our membership to discuss participation and identify opportunities to strengthen implementation. While we look forward to additional details, particularly regarding payment structure and outcome targets, we have identified several questions and recommendations that we believe will help ensure the ACCESS and TEMPO Programs achieve full potential.

CMMI ACCESS MODEL

I. Questions

1. Scope of Access Model Organization (AMO) Participation

a. How participation should be structured in light of existing service models and regulatory limitations?
b. What restrictions on AMO structures, relationships, and billing should look like given agency goals (e.g., AMO ownership limitations, FFS billing)?
c. Could you please confirm the initial deadline for AMOs is April 1?

2. Tools Directory

a. What information will be shared on the Tools Directory?
b. Will tools have any deadlines or will it be on a rolling basis?
c. What is the scope of technologies that are eligible for use under this program?
d. If a broad range, how does the agency intend to address the differences in regulatory burden? For example, will payments differ between TEMPO products and products that have already incurred the cost of obtaining FDA authorization? Is there a separate technology payment for the tools and how will that be determined?

3. Model Codes and Valuation Considerations

a. When can we expect payment rates to be released for the ACCESS model?
b. What factors are being considered in developing AMO codes and payments, and what is being considered to ensure model success despite potential drawbacks (e.g., delays in payment and significant downward adjustment)? When can we expect details?
c. What factors are being considered in developing the clinical targets? When can we expect publication?
d. How was the referring provider coordination payment determined and what scope of activities are covered under those payments?
e. Could other arrangements be made between AMOs and providers to allow for increased payment for better patient management?
f. What if a patient self-refers and then their primary care physicians (PCP) gets roped in?
g. Because this PCP will have additional work to do in connection with ACCESS, how will they be compensated?
h. Related to PCP coordination payments and incentives, what should be re-evaluated and what types of arrangements should be allowed between AMOs and physicians?

4. **Data Sharing and Transfer**
    a. Who should be responsible for data collection and sharing and who should have access?
    b. If technology providers are tools not AMOs, what are the applicable requirements for data sharing and how will CMS and provider ensure the data sharing agreements are in compliance?

5. **Other**
    a. Will there be a CMS webinar about ACCESS and if so, when should we expect it?

II. ATA Action Recommendations on the CMMI ACCESS Model

1. **Increase Payment for Co-Management Services:** In the ACCESS Model, the "$30 referral payment" is a new co-management payment that primary care physicians (PCPs) and other referring clinicians can bill for reviewing care updates and participating in care coordination for ACCESS beneficiaries. At approximately $30 per instance, billed once every four months per beneficiary, this payment may be insufficient to justify the time and effort required, particularly if clinicians must forgo Medicare Part B fee-for-service revenue to participate fully. We urge CMS to consider increasing the reimbursement rate to better reflect the administrative and clinical effort involved, ensuring that co-management is both feasible and attractive for participating clinicians.

2. **Reduce Workflow Burden:** Requiring clinicians to submit a post-review EHR note and chart documentation for each service, for only $30, poses a substantial administrative burden. For clinicians managing multiple ACCESS beneficiaries, this could translate into several hours per week spent on paperwork, potentially detracting from direct patient care and discouraging participation. To improve feasibility and promote integration into routine practice, we recommend that documentation requirements be shifted to the front end of care coordination, for example, incorporated into initial care planning or automated through existing EHR workflows, so that documentation aligns naturally with clinical processes rather than adding extra steps after the fact.

3. **Ensure Minimum Payment Supports Sustainability:** While the Clinical Outcome Adjustment's 50% cap on payment reductions provides some protection, the minimum payment must still be sufficient to sustain participating organizations. For many practices, particularly smaller or resource-limited providers, receiving only half of the full Outcome-Aligned Payments (OAPs)in the first performance year may not cover the costs of care coordination, staff time, technology infrastructure, and reporting requirements necessary to participate in the model.

If the threshold does not provide a financially viable floor, there is a real risk that organizations will opt out of participation, undermining the program's reach and effectiveness. Ensuring that the minimum payment supports operational sustainability is therefore critical to securing robust engagement and achieving the model's goals.

4. **Release Payment Rates and Outcome Targets Immediately:** We urge CMS to release the exact payment rates and structures as soon as possible, as the first cohort must submit applications by April 1. These details represent the most critical component of the ACCESS Model, and without clarity on reimbursement levels and the outcome-based targets tied to payment, organizations cannot accurately assess feasibility or plan for participation. We strongly encourage CMS to establish a fair and transparent reimbursement rate along with clearly defined outcome targets. Providing this information promptly is essential to ensure organizations can allocate resources, confidently participate, and support the long-term success and sustainability of the model.

5. **Continue Stakeholder Engagement:** ATA Action thanks the CMS team for already meeting with the ATA Action team to discuss the ACCESS Model. These conversations have been invaluable in helping our members understand the program and provide early feedback. We strongly encourage CMS to continue these engagements through regular webinars, interactive sessions, and other opportunities for stakeholders to ask questions and receive timely responses. Ongoing dialogue will be critical to addressing implementation challenges, clarifying requirements, and ensuring the model's success for both providers and beneficiaries.

6. **Factor Tool Costs and Regulatory Status into Reimbursement:** The ACCESS Tools Directory is a first-of-its-kind resource where digital health companies can list technologies and platforms that support model participation and compliance. This Directory will help ACCESS Model Organizations (AMOs) identify tools that facilitate care management, remote monitoring, and other key program requirements. We offer two key recommendations to strengthen its impact:

   a. Factor cost and regulatory status into reimbursement – Tools vary widely in cost and regulatory status, and these differences should be reflected in reimbursement to ensure fair and sustainable participation.

   b. Consider alternatives to "all-or-nothing" outcome targets – Scaled or proportional payments can reward partial achievement while maintaining accountability, encouraging broader adoption of these technologies.

7. **Support Sustainable G-code Valuation:** Monthly billing using track-specific G-codes through standard claims will streamline reporting and support adoption of aligned payment approaches by other payers, including Medicare Advantage, Medicaid, and commercial plans. When establishing G-code valuation, several key considerations must be addressed: clinician organizations need to sustain costs and generate revenue throughout the year, ensuring the model is financially feasible and operationally sustainable.

FDA TEMPO MODEL

I. Questions

1. Are there deadlines for the TEMPO program?
2. Will priority be given to manufacturers that complete the process early?
3. What type of participation is required in the ACCESS program in order to qualify for TEMPO? AMO? Tool?
4. What are the bounds of enforcement discretion and what are FDA's expectations for waiver of certain requirements?
5. What are the threshold safety requirements?
6. Will guidelines or a matrix be issued explaining when various FDA requirements will be waived?
7. What is the expectation for companies that have started the application process but have not yet obtained authorization from FDA?
    a. Can they withdraw and proceed under TEMPO?
    b. What about devices cleared for one indication but seeking data for another indication?
8. What claims can TEMPO participants make to AMOs and the public?
    a. If they cannot make claims, how can they express their value?
9. Will real world evidence generated under this program be treated as primary evidence for FDA submissions?
10. If a technology provider is not enrolled as an AMO, how is the data sharing supposed to work between the various parties?

II. ATA Action Recommendations on the FDA TEMPO Model

Differentiate FDA-Cleared vs. Non-Cleared Technologies and Align Reimbursement with Evidence: CMS and FDA should ensure that the TEMPO Program explicitly differentiates between FDA-cleared, authorized, or approved medical technologies and tools without FDA clearance, including how each category is evaluated, qualified, and deployed within the ACCESS Model, and reimbursed. This differentiation should be clearly communicated in program materials, selection criteria, reimbursement structures, and any resulting enforcement discretion decisions.

Companies that have invested in rigorous clinical evaluation and secured FDA clearance or authorization may be hesitant to participate if their products are treated the same as those with limited or no evidence of safety and efficacy. Without clear categories or stratified expectations, higher-evidence technologies risk being undervalued relative to lower-evidence tools, which could disincentivize innovators, reduce the overall quality of evidence associated with the program, and undermine trust in clinical and regulatory standards. By explicitly aligning incentives and expectations with regulatory status, TEMPO can reinforce the importance of evidence and promote meaningful participation by validated technologies.

ATA Action is excited to continue collaborating with the CMS and FDA teams as the ACCESS and TEMPO Programs move from concept to reality. We are eager to share insights, help address implementation challenges, and contribute to a program that sets a new standard for patient-centered, evidence-driven care. By working together, we can ensure these initiatives are not only innovative but practical, sustainable, and impactful.

We look forward to being an active partner in making these programs a resounding success. Please reach out to me (aapple@ataaction.org) if you have questions.

Kind regards,

Alexis Apple
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ATA Action