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December 29, 2023

The Honorable Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator (ONC)
U.S. Department of Health and Human Services (HHS)
Mary Switzer Building, Mail Stop: 7033A
330 C St. SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services (HHS)
500 Security Boulevard
Baltimore, MD 21244-1850

RE: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking [RIN 0955-AA05]

Dear Dr. Tripathi and Administrator Brooks-LaSure:

The AAMC (Association of American Medical Colleges) appreciates the opportunity to comment on the notice of proposed rulemaking to establish disincentives for health care providers that have committed information blocking as required by the 21st Century Cures Act, 88 *Fed. Reg.* 74947 (November 1, 2023).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

The AAMC and our members share the agencies' commitment to improving interoperability and to ensuring that patients and providers can seamlessly access, exchange, and use electronic health information (EHI) to improve clinical care and outcomes while also safeguarding sensitive health data. Conduct that deliberately obstructs the sharing of critical health information contravenes the spirit of collaborative, patient-centered health care, and should be disincentivized. Our members have firsthand knowledge of the benefits of health data exchange to improve patient outcomes and

engagement in their care. To this end, they have been working diligently to understand the ONC's information blocking regulations and are making every feasible effort to comply.

Despite these efforts, there are still significant knowledge gaps and confusion within the provider community with respect to what is, and what is not, appropriate sharing or restricting of EHI under the rules. We respectfully ask the agencies to delay imposition of any monetary disincentive to support this critical real-world educational effort to ensure that health care providers have a fair opportunity to self-correct and ensure their information sharing practices comply. Additionally, we call on the agencies to ensure that the investigative process and the right of appeal is fair and consistent across all actors regulated under the information blocking rules.

Regarding the proposed disincentives through CMS programs, we urge the agencies to adopt alternative approaches to reduce the significant financial impact and the outsized variance across different types of health care providers, where some providers will be penalized for the actions of another while others will see no reduction in Medicare reimbursement regardless of their conduct. An overly punitive approach as proposed could critically impact care delivery and reinvestment in value-based health care delivery for health systems. This would ultimately negatively affect patients and their families.

Feedback in response to specific proposals follows.

Enforcement Process

Health Care Providers Need Greater Clarity on What Is and What Is Not Information Blocking

OIG Should Prioritize Individualized Education and CMS Should Delay Assessment of Disincentives Through its Programs to Allow Providers to Self-Correct Before CMS Begins to Impose Disincentives

Since the ONC finalized the information blocking rules in 2020,[1] it has worked to develop informational materials for regulated actors subject to the rules. These materials include recording webinars,[2] posting frequently asked questions,[3] and sharing (limited) information on the claims it receives through the ONC's information blocking complaints portal.[4] Unfortunately, all together, this information does not clearly tell health care providers when a scenario is or is not information blocking. Instead, the common refrain from the agency is "[w]hether a practice constitutes information blocking depends on the unique facts and circumstances of the practice."[5] Because the

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[1] ONC, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," 85 *Fed. Reg.* 25642 (May 1, 2020), codifying the information blocking definition at 45 CFR § 171.103.
[2] One can find a series of webinars by the ONC posted to YouTube here: https://www.youtube.com/playlist?list=PLo4YwNR8ANzOqu2cNIioE_xxR38aIMkNc
[3] ONC, Information Blocking Frequently Asked Questions
[4] ONC, Information Blocking Claims: By the Numbers (last updated through November 2023)
[5] For example, the quote in full, from the FAQ "How would any claim or report of information blocking be evaluated?" (*supra*, note 4) states "The facts and circumstances of each situation or allegation would need to be evaluated. Whether a practice constitutes information blocking depends on the unique facts and circumstances of the practice. More specifically, information blocking occurs when: an individual or entity engaging in a practice is an actor as defined in 45 CFR 171.102; the practice involves EHI as defined in 45 CFR 171.102; the actor meets the

ONC has not been able to definitively share examples of when conduct is or is not information blocking under the rules, health care providers are left to consider whether they reasonably believe their conduct is not information blocking and hope that, in the event of an investigation under this proposed rule, the Office of the Inspector General (OIG) will concur. The ONC and CMS do propose to publicly share greater specifics of practices found to have been information blocking once determined by the OIG (p. 74953), but this information will not be available to inform health care providers' best practices until such determinations begin to be made. Additionally, the OIG has previously discussed that it has the ability "to conduct individualized education and corrective action plans where an actor has committed information blocking."[6] **The AAMC strongly believes that education, including individualized education and corrective action plans, is the most appropriate first step before imposing financial disincentives for health care providers and would greatly improve broader compliance with information blocking regulations. We urge OIG to focus initially on education-first and CMS to delay the assessment of financial disincentives through CMS programs for a period of at least two years to allow for information on these investigations and findings to provide critically important, nuanced, specific education for providers.**

Health Care Providers Need Additional Transparency from OIG Regarding Investigations of Information Blocking

The proposed rule describes the OIG's "anticipated priorities" for its discretionary approach to choosing which information blocking complaints to investigate. (p. 74951) These four priorities are: (i) resulted in, are causing, or have the potential to cause patient harm; (ii) significantly impacted a provider's ability to care for patients; (iii) were of long duration; and (iv) caused financial loss to Federal health care programs, or other government or private entities." (p. 74951) We recommend that the OIG provide health care providers with greater transparency, beyond these priorities, on how the OIG will approach investigations of information blocking.

OIG should provide a discussion of how it will prioritize information blocking claims potentially made moot by later modifications to ONC's information blocking rules.

The ONC recently issued a final rule that in part modifies the original information blocking rules.[7] And we anticipate that the ONC may modify the information blocking regulations as it deems appropriate in the future. This creates a scenario where conduct that could have been information blocking before a modification to the rule no longer would be considered information blocking under current rules at the time of an investigation. The AAMC asks the OIG to discuss how it would consider such potentially moot conduct within its priorities for investigations.

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requisite knowledge standard applicable to the type of actor; the practice is likely to prevent, materially discourage, or otherwise inhibit the access, exchange, or use of EHI; the practice is not one that is required by law; and the practice is not covered by an exception under 45 CFR Part 171."

[6] OIG, Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules, 88 *Fed. Reg.* 42820 (July 3, 2023), at 42824.

[7] ONC "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing," was released informally on December 13, 2023.

ONC and CMS should set a clear effective date from which to begin investigating claims of information blocking like policies finalized by the OIG for investigations of other regulated actors.

The OIG finalized policies for the other regulated actors under the information blocking rules, establishing Civil Monetary Penalties. In that rule, OIG established an effective date of September 1, 2023, recognizing that "information blocking is newly regulated conduct and that individuals and entities would require time to take steps to achieve compliance with the ONC Final Rule."[8] This proposed rule does not contain such certainty for health care providers. **We urge the ONC and CMS to finalize a date certain, a minimum of 60 days from the final rule, from which health care providers will be subject to investigations of information blocking complaints, as was afforded to other regulated actors by the OIG.**

Health Care Providers Should Have Meaningful Opportunities to Address Allegations of Information Blocking and Have the Same Appeal Rights as Other Regulated Actors

OIG Should Formalize Opportunities for Providers to Engage Before It Makes an Information Blocking Determination

The proposed rule does not include whether OIG's process will include an opportunity for health care providers to respond to an on-going investigation and explain why their conduct did not implicate the information blocking rules. The AAMC believes that it would be in the best interests of the Department and of health care providers to allow providers to respond to allegations of information blocking early in the process. This could resolve allegations sooner and save valuable time and resources for the OIG and the provider.

CMS Should Establish a Meaningful Appeals Process for All Providers

CMS does not propose distinct appeal rights for health care providers when applying a disincentive. Instead, CMS states that the right to appeal an incentive will be based on the underlying CMS program's appeal rights. If the CMS program does not provide for a right of appeal, the providers subject to the disincentive under that program would have no right to appeal. This is in sharp contrast to the other regulated actors, who have the right to appeal the imposition of civil monetary penalties to an administrative law judge under the OIG's rule.[9] **Appeal rights should not vary arbitrarily based on the disincentive being applied. We urge CMS to establish a meaningful appeals process that is available to all providers, regardless of the disincentive's underlying program.**

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[8] *Supra*, note 6 at 42827.
[9] *Id*, at 42826.

DISINCENTIVES

ONC and CMS Should Adopt Alternative Approaches to Disincentives in Consideration of the Grossly Underestimated Economic and Public Health Impacts of the Proposed Disincentives through CMS Programs for Hospitals, Clinicians, and Accountable Care Organizations (ACOs)

ONC and CMS propose disincentives through the following CMS Programs: the Medicare Promoting Interoperability Program (PIP) for Eligible Hospitals and Critical Access Hospitals, the Promoting Interoperability Performance Category of the Merit-based Incentive Payment System (MIPS) for eligible clinicians, and the Medicare Shared Savings Program (SSP), which is the largest Medicare program for ACOs. In reviewing the Costs and Benefits of these proposed disincentives, the agencies state that "[t]he Office of Management and Budget (OMB) has determined that this proposed rule is not a significant regulatory action, as the potential costs associated with this proposed rule would not be greater than $200 million per year and it does not meet any of the other requirements to be a significant regulatory action." (p. 74948) **The AAMC respectfully disagrees.**

CMS greatly simplifies the projected potential financial costs to health care providers in this proposed rule. The agency proposes to reduce a hospital's fiscal year market basket update by 75 percent under the PIP if it has been found by the OIG to have committed information blocking and is referred to CMS. Similarly, CMS proposes to apply a negative annual payment update under MIPS collectively to an entire physician practice where a single clinician within the group is determined by the OIG to have blocked information under the ONC's rules. In addition to these penalties, CMS proposes to ban a hospital or health system from participating in an SSP ACO for at least year if found by the OIG to have committed information blocking. Health care providers not subject to these programs would not have any disincentives applied by CMS. In assessing the potential financial impact of these penalties, CMS relies on median estimates of impact for hospitals and clinicians under the PIP and MIPS for its projected financial costs, while also noting "the actual monetary impact resulting from the application of the disincentives proposed in this section may vary across health care providers subject to the disincentive." (p. 74955) The variance of magnitude of the proposed disincentives is arbitrarily proportional to a provider's Medicare reimbursement, and not to the severity of the information blocking offense. **Altogether, the imposition of disincentives appears to be binary – all purported conduct would have equal weight, regardless of facts and circumstances, and any financial disincentive applied depends on the provider type and participation in a subset of CMS reimbursement programs.**

We urge CMS to consider alternative approaches to creating information blocking disincentives to reduce the significant yet unequal Medicare payment ramifications across providers due to structural differences in existing CMS programs. The substantial variance in proposed financial disincentives across providers and health systems creates outsized financial penalties for some health care providers and no penalties for others. In the case of hospitals, CMS modeled a $394,353 median disincentive amount and that "the value of the reduction in the market basket increase would be larger in dollar terms for hospitals with greater base IPPS payments." (p. 74957) **Using FY 2021 IPPS payments, we estimate an average disincentive amount of roughly $3,400,000 per AAMC member institution, which is nearly 10x greater than the median and**

would be a significantly larger penalty than the maximum $1,000,000 in CMPs that other regulated actors are subject to. Similarly, CMS estimated the per clinician disincentive amount to be $1,798 and for a median-sized six clinician group to be $10,788, and again that "ranges of potential group disincentive amounts vary based on eligible clinician payments and group sizes." (p. 74960) Teaching physicians who work at academic health systems provide care in what are among the largest physician group practices in the country and are typically organized into large multi-specialty group practices under a single tax identification number (TIN), ranging in size from a low of 115 individual providers to a high of 3,694 and a median of 1,088.[10] **Translating to this our member group practices, the median impact is roughly $1,956,224, again more than 10x greater than the agency's estimated median impact for groups and a larger penalty than the maximum for other regulated actors.** CMS does not provide an estimate of the potential cost of applying the disincentives to providers who are prospectively barred from participation in the SSP. The AAMC posits such costs would include the potential loss of net savings to the Medicare Trust Funds, as well as shared savings payments to the ACO and its participating providers. In 2022, ACOs generated $1.8 billion in net savings to Medicare, amounting to $3,734,439 on average per ACO.[11] **All together it is reasonable to view these potential financial impacts together with the ONC's public reporting of claims[12] of potential information blocking against health care providers and see such proposals as a "significant regulatory action" having an annual effect on the economy of $200 million or more.**

The proposed financial disincentives are not the only potential costs of this proposed rule. The harshness of these financial disincentives would create additional financial distress for physicians, hospitals, and health systems, ultimately impacting access to care for Medicare beneficiaries. CMS policies should focus on improving access to high quality care rather than discouraging participation in the Medicare program. Specific to ACOs, the inability to participate in the SSP could result in a significant reduction in Medicare patients in accountable care delivery relationships with their preferred providers and a large-scale disinvestment in the delivery of value-based, accountable care and reduction in clinical and analytic staff supporting the ACO enterprise. Given this impact and the financial challenges that physicians, hospitals and health care systems are currently facing, we strongly urge the agencies to prioritize education and corrective action rather than imposing disincentives.

There are also potentially significant adverse effects of these disincentives on jobs and public health. The proposed all-or-nothing approach to applying disincentives for the PIP and MIPS could create incentives for hospitals and health systems to disinvest and reduce information technology staffing. Significant cuts to Medicare reimbursement in the event of a determination of information blocking will challenge hospitals and health systems to maintain the resources necessary to report the other

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[10] Data derived from the Clinical Practice Solutions Center (CPSC), developed by the AAMC and Vizient.
[11] CMS Press Release, Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care, (August 24, 2023).
[12] *Supra*, note 4, noting that over 700 claims of potential information blocking have been submitted to ONC against health care providers; while the AAMC cannot know if all claims are *actually* information blocking, or if all are against health care providers who would be subject to these proposed disincentives, it suggests the volume of claims could support a significant number of annual OIG determinations.

electronic health record (EHR) interoperability measures included in the PIP and under MIPS, including interoperable public health data reporting and quality outcomes.

Due to these significant financial costs and potential downstream adverse effects on the health information system sector and interoperability of public health data reporting, we strongly urge CMS and ONC to first focus on education and corrective action before imposing disincentives and to adopt the following alternative approaches to disincentives for health care providers:

> **Instead of determining that a hospital is not a meaningful user of EHR technology, CMS should consider deducting points when scoring hospitals on the Provider to Patient Exchange and the Health Information Exchange EHR Objectives under the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals.**

Specifically, CMS proposes to revise the definition of "Meaningful EHR User" to state that a hospital is not a meaningful user under the PIP in a calendar year of the EHR reporting period if the OIG refers a determination that the hospital committed information blocking. As such, under this proposal, even where a hospital reports all measures and meets the scoring threshold under the four EHR objectives for a calendar year EHR reporting period, it would not be a meaningful user if in that same period a determination (likely from a prior year's conduct) from the OIG that it had committed information blocking. The resulting financial disincentive is an inability to receive 75 percent of the annual market basket adjustment to IPPS payments in the fiscal year two years following the calendar year reporting period. It is reasonable to believe that a hospital, upon notice from the OIG that it is being referred to CMS for committing information blocking, will have less incentive to continue reporting any of the measures and objectives under the PIP to CMS, as doing so would not result in any ability to be determined as a meaningful EHR user in the Program.

The AAMC believes this proposed approach is counterproductive due to this disincentive to continue reporting PIP measures and data to CMS, including measures of critical public health importance like electronic prescribing practices, immunization registry reporting, syndromic surveillance reporting, electronic case reporting, public health registry reporting.[13] We urge CMS take an alternative approach where instead of modifying the definition of "Meaningful EHR User" in the Code of Federal Regulation (CFR), it modify PIP scoring by deducting 5 points from the Provider to Patient Exchange and the Health Information Exchange EHR Objectives in a calendar year of the EHR reporting period if the OIG refers a determination of information blocking for the hospital. We believe this approach balances setting an appropriate disincentive for hospitals to not commit information blocking, while not removing the incentives under the PIP to report critical EHR use data to CMS. As hospitals need to meet PIP scoring thresholds on the EHR Objectives to be a meaningful EHR user and receive 75 percent of the market basket update, such a policy *could* (but not necessarily) result in a hospital being a meaningful EHR user and thus not disincentivize a hospital from all EHR reporting under the PIP for the EHR reporting period. Additionally, this would

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[13] CMS, Medicare Promoting Interoperability Program Objectives and Measures for CY2023.

not change the disincentive for hospitals to avoid being reported publicly as an information blocker on a public ONC website.

Instead of giving eligible clinicians a zero score for the MIPS Promoting Interoperability performance category, CMS should consider deducting points when scoring the performance category for eligible clinicians and groups.

CMS proposes to add a requirement to the MIPS Promoting Interoperability performance category that a MIPS eligible clinician must be a meaningful EHR user to receive a score (other than zero) for the Promoting Interoperability performance category, which influences 25 percent of an eligible clinician's total MIPS performance score. The MIPS performance score is then used to determine an eligible clinician's MIPS payment adjustment for a payment year two years following the performance period. Additionally, to be a meaningful EHR user for a given calendar performance period, an eligible clinician cannot have been referred by the OIG for committing information blocking in that performance period. Setting the Promoting Interoperability performance category score to zero as the disincentive for information blocking would effectively ensure that an eligible clinician could not achieve a total MIPS performance score greater than 75 points, if they scored perfectly in the three remaining MIPS performance categories. As CMS sets higher performance thresholds for obtaining a positive or even neutral MIPS payment adjustment, it is unlikely that an eligible clinician found to have information blocking could avoid a negative MIPS payment adjustment.

A clinician might report and be scored as an individual, or as a group identified by a single TIN, where the entire group receives the same MIPS score. Under this proposal, a single clinician participating within a group found to have committed information blocking would impact the MIPS Promoting Interoperability performance score for the entire group. As noted above, faculty physicians at academic health systems typically organize their practice as a large multispecialty and subspeciality group practice under a single TIN, which reports as a group practice under MIPS. Squared with this proposal, on average, 1,087 physicians could receive a negative MIPS adjustments as a penalty for the conduct of one physician within the group. The AAMC struggles to see how penalizing all the physicians in the group practice for the actions of one individual physician is an appropriately sized disincentive.

And, similar to the proposal for establishing disincentives for hospitals, under this proposal, even where an eligible clinician or group reports all measures and meets all requirements for the MIPS Promoting Interoperability performance category for a calendar year performance period, it would not be a meaningful EHR user if in that same period a determination (likely from a prior year's conduct) from the OIG that the eligible clinician or a clinician within the group had committed information blocking. The resulting financial disincentive is thus an inability to receive a positive or even neutral MIPS payment adjustment in the payment year two years following the performance period. It is reasonable to believe that eligible clinician or group, upon notice from the OIG that it is being referred to CMS for committing information blocking, will have less incentive to report any additional EHR measures under MIPS to CMS, as doing so would not result in any ability to be receive a positive MIPS payment adjustment.

The AAMC believes this proposed approach is counterproductive due to its collective penalty structure and due to this disincentive to continue reporting MIPS EHR interoperability measures and data to CMS. Instead of providing a zero score for the Promoting Interoperability performance category, we urge CMS take an alternative approach by deducting 10 points from the category score in a calendar year of the performance period if the OIG refers a determination of information blocking for an eligible clinician or a clinician within a group. We believe this approach balances setting an appropriate disincentive for eligible clinicians to not commit information blocking, while not removing the incentives to report meaningful measures and data to CMS on clinical practice. As clinicians and groups need to score well across all MIPS performance categories to receive a positive or neutral MIPS payment adjustment, such a policy *could* (but not necessarily) result in an eligible clinicians or group meeting the overall MIPS scoring threshold for a positive adjustment and thus not disincentivize a clinician or group from reporting for the performance period. Additionally, this would not change the disincentive for clinicians to avoid being reported publicly as an information blocker on a public ONC website.

CMS should only remove ACOs from participation in the SSP where the ACO entity was found to have committed information blocking and has not otherwise had disincentives applied under the PIP or MIPS.

Finally, CMS proposes that a health care provider that OIG determines to have committed information blocking may not participate in the SSP for a period of at least one year. CMS would apply the disincentive "no sooner than" the first performance year after it receives a referral of an information blocking determination from the OIG. (p. 74965) Under the SSP, ACO participants are identified by TIN, and there is no administrative way to target an individual participating clinician who has been found to have committed information blocking. As proposed, CMS could remove an *entire* multispecialty group practice from participating in an ACO where a single clinician previously erred in committing information blocking. The AAMC believes this approach would stymie CMS's stated goal of having every Medicare beneficiary in an accountable care relationship by 2030[14] and to include more specialist participation in ACOs.[15] Instead, we urge CMS to tailor its approach to applying disincentives through participation bans in the SSP to ACO entities alone, where it is determined that the ACO entity itself committed information blocking and has not otherwise been disincentivized under the Medicare Promoting Interoperability Program or MIPS. Otherwise, removing ACO participants and providers/suppliers is imprecise and self-defeating in consideration of broader care delivery and ACO participation goals.

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[14] CMS Press Release, CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship, highlighting that "growth furthers achieving CMS' goal of having all people with Traditional Medicare in an accountable care relationship with their health care provider by 2030."

[15] *See*, CMS, CY 2024 Physician Fee Schedule Proposed Rule, 88 *Fed. Reg.* 52262 (August 7, 2023), at 52438, in an RFI on specialists in SSP ACOs, CMS notes, "[o]ur overarching intent is to have specialist participation in ACOs in a meaningful way[.]"

CMS should allow for discretion in applying disincentives where a health care provider has already taken significant corrective action in the interim period between the conduct and the OIG determination that such conduct was information blocking.

Consistent across each of the proposed disincentives is the potential for a significant delay between the date of a health care provider's information blocking conduct and the date when OIG makes a referral to CMS, largely due to the time required to investigate a claim. It is not impossible to envision a scenario where a provider commits information blocking and five or more years later has a financial disincentive applied to Medicare payments. In the interim period, the provider could have taken significant corrective action, including termination of a clinician, to address the conduct. CMS should create a policy that would allow a health care provider to demonstrate the significant correction actions it has taken to address information blocking and give the agency discretion in applying disincentives in such cases.

Conclusion

We thank the ONC and CMS for the opportunity to provide input on proposed disincentives for health care providers under the information blocking rules. We would be happy to work with you on any of the issues discussed above or other topics relating to interoperability that involve the academic medicine community and the patients we serve. Please contact my colleague Phoebe Ramsey (pramsey@aamc.org) with any questions about these comments.

Sincerely,

Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO