Charles N. Kahn III
President and CEO

September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

RE: CMS-1784-P; Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program; 88 Fed. Reg. 52,262 (August 7, 2023).

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the *CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies* proposed rule (Proposed Rule) and provide our comments on specific proposals below.

CY 2024 PFS Ratesetting and Conversion Factor

CMS proposes to reduce the calendar year (CY) 2024 physician fee schedule (PFS) by 3.36 percent from $33.89 to $32.75, which results in reducing overall payment rates under the PFS by 1.25% in CY 2024 compared to CY 2023. Unfortunately, these cuts coincide with ongoing growth in the cost to practice medicine, which is underscored by the fact that CMS projects a 4.5 percent Medicare Economic Index (MEI) increase for 2024. In addition, due to new policies in the proposed rule that require budget neutrality, such as the evaluation and management (E/M) visit add-on code, these cuts exacerbate even deeper cuts to multiple physician specialties. We are concerned that requiring medical practitioners to absorb these cuts in an environment of steep inflationary medical cost increases will affect patient access to care. **Thus, we urge CMS to support and work with Congress to avert the 1.25 percent PFS payment reduction for CY 2024.**

II.D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
e. Implementation of Provisions of the CAA, 2023

CMS clarifies that certain telehealth flexibilities have been extended through December 31, 2024, under the *Consolidated Appropriations Act* (CAA), 2023, for example the Proposed Rule would:

- Allow telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home;
- Allow certain services to be furnished via audio-only telecommunications systems;
- Expand the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists;
- Delay the requirement for an in-person visit with the physician or practitioner within six months prior to initiating mental health telehealth services, and again at subsequent intervals as the Secretary determines appropriate; and
- Continue coverage and payment of telehealth services included on the Medicare Telehealth Services List (as of March 15, 2020).

We commend CMS for continuing to recognize the value of telehealth beyond the COVID-19 Public Health Emergency (PHE) in the provisions for the payment of Medicare telehealth services and appreciate CMS' initiatives and proposals to continue to advance the use of telehealth in Medicare. **The FAH supports these proposals and implementation of the telehealth provisions in CAA, 2023 and, in particular, we support the proposal to delay the in-person visit requirement for mental health services furnished via telehealth** (although we note our continued support for Congressional action to repeal this in-person requirement prior to its implementation). This extension would provide the flexibility needed to offer many types of telehealth services, which is essential to ensure that patients have access to care in a reasonable timeframe, especially for those in rural and under-served areas.

Moreover, exclusion of mental health audio-only services from the in-person visit requirement would increase access to care, particularly in geographic areas and populations without widespread access to broadband and would help alleviate the persistent shortage of mental health care professionals.

Place of Service for Medicare Telehealth Services

CMS proposes that, beginning in CY 2024, telehealth services furnished to people in their homes would be billed with POS 10 and paid at the non-facility PFS rate. In addition, the Proposed Rule discusses that behavioral health services furnished in a patient's home as an originating site have the same practice expense (PE) as services provided in-person and therefore are more accurately reflected by the non-facility rate. However, claims billed with POS 2 will continue to be paid at the PFS facility rate.

The FAH supports these proposals and agrees that this would protect access to mental health and other telehealth services by aligning with telehealth-related flexibilities that were extended via the CAA, 2023.

Other Non-Face-to-Face Services Involving Communications Technology under the Physician Fee Schedule: Direct Supervision / Virtual

CMS proposes continuing to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through 2024. **The FAH supports this proposal as well as making this method of providing direct supervision permanent.** In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic, or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to admit the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

When the current policy is made permanent, there should not be a requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track whether and to what extent they supervised through telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified.

Thus, the FAH requests that the definition of direct supervision be permanently amended to allow supervision via audio visual technology, without the requirement for a new modifier.

Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy when Furnished by Institutional Staff to Beneficiaries in Their Homes

CMS proposes to continue to allow institutional providers to bill for outpatient therapy, DSMT, and MNT services through CY 2024 when furnished remotely in the same manner they would have during the PHE. **The FAH strongly supports this proposal.**

Throughout the duration of the PHE, the use of telehealth modernized the provision of essential health services. We commend CMS for recognizing the value of telehealth beyond the PHE in these proposed provisions. This extension will provide the flexibility needed to offer these outpatient therapy services to patients, especially those who have difficulty traveling to a hospital and otherwise would not have access to these critical services.

II.C. Potentially Misvalued Services Under the PFS
3. CY 2024 Identification and Review of Potentially Misvalued Services

6) CPT codes 93655 and 93657 (*Cardiac Ablation)*

The FAH is concerned that for the third year in a row, CMS is proposing not to identify certain cardiac ablation services as a potentially misvalued for the 2024 PFS rulemaking cycle, (i.e., CPT code 93655: *Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia;* and 93657: *Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation*), per the nomination of the Heart Rhythm Society (HRS). **While the FAH appreciates that CMS accepted the RUC-recommended work relative value units (RVUs) for CPT codes 93653, 93654 and 93656 in the CY 2023 MPFS final rule, we urge CMS to reconsider the RUC-recommended work RVU of 7.00 for CPT codes 93655 and 93657 during the CY 2024 PFS rulemaking cycle.**

These codes were reviewed at the April 2021 RUC meeting and were included in the RUC comment letter submitted in response to the 2022 PFS proposed rule. Because they were not submitted in time for consideration of the 2022 physician fee schedule proposed rule and instead submitted as comments, CMS would not consider these RUC recommendations for the CY 2022 PFS final rule. Instead, CMS finalized the proposal to reduce the RUC-recommended work RVUs for CPT codes 93655 and 93657 from 7.00 to 5.50. We believe this is based on a flawed crosswalk assumption, which is one of the requirements for nomination of a potentially misvalued service. In addition, the lower 5.50 work RVUs were assigned as interim values for CY 2022 and were not intended to be permanent.

The FAH is concerned that CMS' proposed work RVUs for these services will significantly impact the delivery of these important services. CMS' proposed reductions do not

reflect the intensity and work time required for performing these cardiac ablation services on critically ill patients and are based on a completely inappropriate comparator code, which does not sufficiently capture the high intensity clinical decision making, complexity in the intraoperative skills required for treatment, morbidity/mortality risks to the patient, and work intensity. Our hospital members remain concerned about the impact these lower payments will have on contracts with clinicians, physician staffing firms, and managed care organizations. We urge that CMS work to ensure the appropriate payment levels for these codes so that Medicare patients have access to these life-saving services.

II.F. Evaluation and Management (E/M) Visits

The Office/Outpatient (O/O) E/M visit complexity add-on code G2211 describes intensity and complexity inherent to O/O E/M visits associated with medical care services that serve as the continuing focal point for all needed health care services and/or medical care services that are a part of ongoing care related to a patient's single, serious, or complex condition. CMS proposes to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024.

The FAH understands the intent of this proposal and believes it is important to ensure appropriate payment, especially for those practitioners who provide and manage care for patients on a continuous, longitudinal basis. We are concerned, however, about ensuring clarity around this new policy as there will be great uncertainty about those specific patient encounters that are eligible for billing using HCPCS Code G2211.

We agree that many practitioners delivering care in settings designed to address acute health care needs, without coordination or follow-up, will regularly have patient encounters that are not part of the continuous, longitudinal care that is intended to be addressed by G2211. While we appreciate that CMS provides examples in the Proposed Rule to distinguish services that would not qualify for billing Code G2211 in cases where practitioner encounters with a patient are discrete, routine, or time-limited (e.g., mole removal, counseling related to seasonal allergies, and treatment for a fracture.), there will be countless instances where it is not clear whether use of this new Code is appropriate.

Thus, we urge CMS to actively monitor use of Code G2211 and undertake any needed mid-course corrections to ensure appropriate usage of the Code and that such usage is meeting the intent of the policy without redistributive affects that would affect patient access to care across all specialties.

II.F.3. Split (or Shared) Visits

In the 2022 physician fee schedule final rule, CMS finalized a policy for E/M visits furnished in a facility setting, to allow payment to a physician for a split (or shared) visit (including prolonged visits), where a physician and non-physician practitioner (NPP) provide the service together and the billing physician personally performed a substantive portion of the visit. CMS finalized a phased-in approach to the definition of substantive portion of the visit for 2022 and 2023.

- For 2022, the definition of substantive portion could be one of the following: history, or exam, or medical decision making (MDM), or more than half of the total time.
- For 2023, CMS finalized that the definition of substantive portion would be limited to more than half of total time for the visit.

We appreciate that based on continued concerns about the implementation of this policy and requests to recognize MDM as the substantive portion of the visit, CMS delayed implementation of its definition of the substantive portion to more than half of the total time of the visit until January 1, 2024. CMS now proposes to delay the implementation of its definition of the "substantive portion" of a shared visit as more than half of the total time through at least December 31, 2024.

The FAH strongly supports this proposal and urges CMS to make it permanent. Defining the "billing provider" based on which provider spent more than half of the time with the patient – when an NPP and physician from the same group perform visits to the same patient on the same day – diminishes the role of the physician in a split (or shared) E/M visit. While a physician may ultimately spend less time with the patient, the physician is performing key tasks such as updating a patient's diagnosis and/or treatment plan, reviewing diagnostic testing, and analyzing patient risk. Regardless of time spent with a patient, a physician that personally performs and documents his/her MDM during an encounter is a more accurate reflection of a "substantive portion" of a patient encounter. And, MDM, when performed by a physician and/or NPP, should be documented as part of each independent encounter, thus ensuring that the billing provider has performed the substantive portion of the visit.

II.K. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In the 2023 PFS final rule, CMS identified clinical scenarios where payment is permitted under Medicare Parts A and B for dental services where the services are not considered to be in connection with dental services. In the Proposed Rule, CMS proposes Medicare coverage for dental services that are inextricably linked to other covered medical services for:

- Chemotherapy when used in the treatment of cancer;
- CAR T-Cell therapy, when used in the treatment of cancer; and
- Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

The FAH supports the addition of these dental services for coverage and payment and believes such coverage is critical since they are inextricably linked and substantially related to the clinical success of other covered medical services. This will assist in ensuring that poor oral health in these circumstances does not further complicate the treatment of these covered medical conditions – and will promote greater access to and higher quality care for patients.

III.E. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners

Current law provides conditions of coverage under Medicare Part B for items and services furnished under cardiac rehabilitation (CR) programs, intensive cardiac rehabilitation (ICR) programs, and pulmonary rehabilitation (PR) programs. Initially, the law required these items and services to be furnished under the supervision of a physician. However, under the *Bipartisan Budget Act of 2018* (BBA), beginning January 1, 2024, physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) also are to be included as "nonphysician practitioners" who may supervise PR, CR, and ICR programs. CMS issues a number of proposals to implement this BBA provision, including: (i) adding the new term "nonphysician practitioner" (NPP), which would be defined as a PA, NP, and CNS; (ii) changing the term "supervising physician" to "supervising practitioner," which would mean a physician or NPP; (iii) changing the definition for the programs to specify they are physician or NPP-supervised; (iv) specifying that a physician or NPP must be immediately available and accessible when services are being furnished under the programs; and (v) specifying that the sections include supervising practitioner standards (not just supervising physician standards).

The FAH supports these proposals and believes that allowing NPPs, as respected and valued allied health practitioners, to supervise these services will help promote a team-based approach in providing medical services to patients and help alleviate health care workforce shortages.

III.G. Medicare Shared Savings Program (MSSP)

CMS proposes a number of changes to the MSSP, and indicates these changes are intended to advance Medicare's overall value-based care strategy as well as to respond to concerns raised by Accountable Care Organizations (ACOs) and other interested parties. As of January 1, 2023, almost 11 million people with Medicare receive care from one of the 573,126 health care providers participating in the 456 ACOs in the MSSP. Acknowledging the Center for Medicare and Medicaid Innovation's (CMMI) strategic objective to drive accountable care with the goal of all Medicare fee-for-service beneficiaries being in a care relationship with accountability for quality and total costs by 2030,[1] the FAH recognizes the key role that the MSSP has in that objective and the hand-in-hand importance for health care systems and physicians to be able to successfully participate in the MSSP. We appreciate the opportunity to comment on the MSSP proposals and commend CMS for its continued responsiveness to concerns raised by ACOs and other interested parties.

B. Proposal for Shared Savings Program ACOs to Report Medicare CQMs

CMS proposes for performance year 2024 and subsequent performance years determined by CMS, to establish a temporary collection type option, the Medicare clinical quality measures (CQMs), for ACOs participating in the MSSP to report on the ACO's Medicare Fee-For-Service

[1] https://innovation.cms.gov/strategic-direction.

(FFS) beneficiaries, instead of its all payer / all patient population. The FAH supports this option as a way to assist ACOs in transitioning to the all payer / all patient population CQMs.

We encourage CMS to simplify the reporting requirements and structure, as much as possible. There are many complexities involved in the overall program as well as numerous configurations of health systems involved in ACOs and with participating practitioners. It is important to recognize within that context the difficulties in applying a system that had primarily be structured around primary care to incorporate specialty care. While we recognize that the agency's Medicare CQM proposal is intended to be most useful to ACOs with a higher proportion of specialty practices, we believe it is important to emphasize generally the unwieldy complexities of managing ACOs with multiple specialty providers, that it is often not reasonable to treat specialists in the same manner as primary care providers, and the extreme burden to manage various requirements if the criteria under the Program is tailored to and different among specialties.

Also, with respect to collection type options, the FAH urges CMS to reconsider the movement we have seen to greatly reduce the inventory of electronic clinical quality measures (eCQMs). As the inventory stands today, with CMS' proposals, clinicians will have 44 eCQMs, of which only 30 currently have benchmarks in 2023 and are not currently topped out. Both clinicians and electronic health records (EHRs) have made considerable investments, at the agency's urging, to build and adopt or change workflows that allow these measures to calculate accurately. Continuing to shift away from eCQMs leads to more administrative burden for clinicians and EHRs who have already invested heavily into eCQM reporting over the past decade.

H. Proposals To Align CEHRT Requirements for Shared Savings Program ACOs With MIPS

CMS proposes to sunset at the end of performance year 2023, the requirements that ACOs must certify compliance with CEHRT use thresholds (currently 75 percent for Advanced APMs and 50 percent for other APMs). CMS also proposes to require beginning with performance year 2024 that all MIPS eligible clinicians, qualifying APM participants, and partial qualifying APM participants participating in an ACO (regardless of track) report the MIPS promoting interoperability (PI) performance category measures and requirements to MIPS as an individual, group, virtual group, or the ACO as an APM entity, and earn a MIPS PI performance category score at the respective level.

The FAH appreciates the reasons for aligning the PI category requirements and integrating the MIPS PI reporting requirements under the MSSP, especially for purposes of simplifying requirements. However, ACOs are fundamentally different than individual clinicians or groups. In fact, qualifying practitioners participating in Advanced APMs are per statute exempt from MIPS. In furtherance of CMS' stated goal that all Medicare fee-for-service beneficiaries being in a care relationship with accountability for quality and total costs by 2030, we stress the importance of recognizing that the characteristics of and challenges facing ACOs are not necessarily aligned with those of individual clinicians or groups that are not part of an ACO. These differences must be appreciated and considered.

We continue to stress that the upcoming expiration of the ability to earn an APM bonus incentive payment and the upcoming increase in the thresholds of payments or patients that will be required to reach qualifying participant or partial participant eligibility are looming factors that will affect ACO and MSSP stability. Removing the thresholds and applying a 100 percent requirement to comply with the MIPS PI category requirements across the board, adds burden to an already overburdened and strained clinician population, making it harder to achieve APM eligibility requirements. Our concerns we are raising in our QPP comments regarding the PI category proposals (specifically objecting to the proposed extension of the reporting period and the proposal to require a "yes" attestation on the SAFER GUIDEs measure) would also apply here since under this proposal all the PI category proposals would automatically carry through to the MSSP as well.

CMS specifically seeks comment on an alternative approach that would remove the option for MIPS eligible clinicians, QPs, and partial QPS participating in an ACO to report the MIPS PI performance category at the individual, group, or virtual group level, and instead require ACOs to report at the APM entity level. The FAH would caution against removing the current options for reporting. There is not a one-size-fits-all approach that will work for every APM entity and each APM entity may not have the ability to report for each of its participants what the individual or groups may already have invested resources in structuring.

Proposed Modifications to the Step-Wise Assignment Methodology

CMS proposes to expand the window for beneficiary assignment to an ACO. The expanded window would include the current 12-month assignment window and the previous 12 months. CMS also proposes to add a step 3 to the assignment methodology, which would be used to identify Medicare FFS beneficiaries not identified under the pre-step but who received at least one primary care service with an ACO professional who is an NP, PA, or CNS in the ACO during the 12-month assignment window and received during the expanded window at least one primary care service with an ACO professional who is a primary care physician or physician with a specified specialty designation.

The FAH supports this proposal to revise the step-wise beneficiary assignment methodology to include services rendered by NPs, PAs, and CNSs and we are glad to see that CMS is recognizing the considerable work that these practitioners contribute to the increasing need for primary care services and support the increased insight that CMS would have into the day-to-day treatment of patients furnished by these practitioners participating in ACOs.

Proposal to Add Remote Physiologic Monitoring to Definition of Primary Care Services for Attribution to MSSP

CMS proposes to amend the definition of primary care services that is used in the assignment methodology to include several additional codes to align with the billing and coding under the physician fee schedule. Included among the proposed additional codes are remote physiologic monitoring CPT codes 99457 and 99458.

The FAH supports CMS' inclusion of these remote monitoring codes in the MSSP assignment methodology and agrees that the devices involved in these codes and the clinicians who read the results are important elements in patient care and care management services. However, we urge CMS to reexamine and clarify the assignment methodology to ensure that third party device companies and specialists who use the devices involved in these codes do not inadvertently impact MSSP attribution. When these devices are billed for by clinicians who do not provide a patient's primary care services, it is important that those billing codes are not used to align or remove a patient from their primary care provider's attribution.

III.J. Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS proposes to pause implementation of the appropriate use criteria (AUC) program for reevaluation and related to this pause CMS also would rescind current AUC regulations at §414.94. The Proposed Rule notes that CMS expects "this to be a hard pause to facilitate thorough program reevaluation and, as such" CMS is not proposing a time frame within which implementation efforts may recommence.

The Proposed Rule discusses that the existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that are or are not subject to the AUC program requirement to report AUC consultation information as prescribed by law. This means that the Medicare claims processing system is not able to ensure that claims for services that are not subject to the AUC consultation information reporting requirement will not be improperly denied for failure to append AUC consultation information.

The Proposed Rule further discusses that throughout the course of implementing the AUC program, CMS has "intentionally taken a diligent, stepwise implementation approach to maximize the opportunity for public comment and engagement with interested parties and allow for adequate advance notice to physicians and practitioners, beneficiaries and other AUC interested parties of any programmatic changes or updates."

The FAH acknowledges the significant challenges that CMS as well as providers have faced throughout the implementation process, and we appreciate and commend CMS in its diligent approach and the multiple opportunities to provide our member feedback regarding each phase of implementation of the AUC program. As we have previously stated in comments to CMS, while we support the goals and use of the AUC program and have worked diligently to meet the implementation challenges, we have had ongoing concerns about the ability of providers to implement the changes required (especially due to the unprecedented financial and operational strain placed on providers by the PHE), the continued complexity of AUC implementation, and its potential impact on patient care. **Thus, we agree with CMS that a pause in the AUC program is the best course of action due to the inherent risks in terms of data integrity and accuracy, beneficiary access and on a timely basis, and potential beneficiary financial liability for advanced diagnostic imaging services.**

III.K. Medicare & Medicaid Provider & Supplier Enrollment

The Proposed Rule includes a number of fairly significant changes to CMS' existing Medicare provider enrollment regulations. Although the FAH recognizes the importance of CMS' appropriate efforts to protect the integrity of the Medicare Trust Funds and Medicare beneficiaries, we have concerns that some of the proposals would create undue burdens or unintended consequences.

Expansion of Revocation and Denial Reasons

The Proposed Rule includes a number of amendments to 42 C.F.R. §§ 424.530(a) and 424.535(a), setting forth the reasons for which Medicare enrollment may be revoked or denied. The FAH is concerned that the proposed addition of certain misdemeanors as a basis for revocation or denial under proposed 42 C.F.R. §§ 424.530(a)(16) and 424.535(a)(16) is overly broad and may place providers or suppliers at unnecessary risk of revocation or denial of enrollment and create unintended consequences. First, the misdemeanor offences that could provide the basis for revocation or denial of enrollment are those that "CMS deems detrimental to the best interests of the Medicare program and its beneficiaries," without any clear guardrails or limitations. Although proposed subsection (a)(16)(ii) sets forth examples of the types of misdemeanor offences that could be so deemed, the list is expressly "not limited in scope or severity" to the listed offences, creating Medicare enrollment risks for misdemeanor offences that are not listed and are not similar in severity. The preambular text notes differences in States' classification of misdemeanor and felony offences, suggesting that a State's designation of an offence as a misdemeanor does not lessen the risk that the conduct may pose to Medicare and its beneficiaries. **The FAH would support expressly recognizing this consideration by confining misdemeanors under subsection (a)(16) to those state misdemeanor offenses that would be classified as felony offenses under Federal law or another state's law.**

In addition, proposed subsection (a)(16) does not acknowledge that some misdemeanors may endanger the Medicare Trust Funds' integrity or Medicare beneficiaries' health and safety when committed by a provider or supplier but may not pose such risks when committed by an owner, managing employee, officer, or director. In short, because the same conduct may have different consequences in terms of risks to the Medicare program and its beneficiaries depending on the role of the convicted individual, any revocation or denial under proposed subsection (a)(16) should be limited to conduct that, in light of the convicted individual's or entity's role with respect to the provider or supplier, endangers the Medicare Trust Funds' integrity or Medicare beneficiaries' health and safety.

Finally, the FAH is concerned about proposed subsection (a)(16) reaching misdemeanor convictions that consist only of a court's acceptance of a guilty plea or the person's entry into a deferred adjudication program (42 C.F.R. § 1001.2). With this scope, proposed subsection (a)(16) would significantly alter the consequences of accepting a plea deal for providers and suppliers and their owners, managing employees or organizations, officers, and directors as compared to the consequences for other persons. This may make a misdemeanor plea deal far more punitive than intended and necessitate undertaking the expense of defending criminal allegations rather than accepting a plea deal. In addition, the language of proposed subsection

(a)(16) would put providers and suppliers at risk of revocation and denial of enrollment based on plea deals entered in the *last ten years* when the consequences of such a plea deal did not involve potential consequences for a Medicare enrollment. **Such a result is unjust, and at a minimum, the subsection (a)(16) should be limited to certain misdemeanor convictions entered "within the previous 10 years and after January 1, 2024."**

Stay of Enrollment

Although the FAH appreciates CMS' acknowledgment of the importance of ensuring that noncompliance with enrollment requirements is addressed through "appropriate, fair, and reasonable measures," we oppose the proposed addition of a stay of enrollment status and process in proposed 42 C.F.R. § 424.541. The proposed stay of enrollment is expressly designed to address noncompliance that can be readily remedied through the submission of a Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application. This might include technical noncompliance produced by simple clerical errors during the enrollment process, and the Proposed Rule does not suggest that this proposed process could be used in cases where actual misconduct is alleged. **The FAH is concerned that the stay of enrollment process is itself overly punitive and would be deployed in cases where a provider would otherwise act appropriately and expeditiously to remedy the noncompliance upon learning of the issue.**

As noted in the Proposed Rule, the stay of enrollment would result in the provider or supplier being ineligible for payment for services or items furnished during the up to 60-day stay period, even after the provider or supplier remedies the technical noncompliance. Thus, under this process, a provider might be subject to a stay of enrollment based on a minor and/or unknown mistake on its enrollment application relating to one particular practice location, resulting in non-payment for all items and services furnished in each of its practice locations during the stay period. As an example, publicly traded entities are oftentimes not aware of Securities and Exchange Commission (SEC) Section 13 ownership reporting until more than a month after the end of a calendar year. This type of delay would make updating ownership records for all enrolled providers within the 60-day window very difficult, if not impossible. Yet, the non-payment penalty in these instances is a significant and punitive measure, and under the proposal, there would no opportunity to cure the enrollment defect in a manner that would allow the provider to obtain payment for items and services furnished during the stay period. **At a minimum, the submission of a compliant Form CMS–855, Form CMS–20134, or Form CMS–588 change of information or revalidation application during the stay period should be given retroactive effect such that the provider can move expeditiously to correct errors and retroactively restore its eligibility for payment.**

Overall, it does not appear that the proposed stay of enrollment process is necessary to secure provider compliance with enrollment requirements. The Proposed Rule does not indicate any concern that providers, upon learning of such easily remedied issues, do not already engage with their MACs and act to appropriately and expeditiously remedy the noncompliance. The risks of any action on a provider's enrollment are already sufficient to ensure that a provider that might be subject to a stay of enrollment under the Proposed Rule is adequately incentivized to remedy any enrollment issues. Therefore, the introduction of a new, intermediate enforcement

measure is unnecessary to promote compliance and will instead lead to an expansion of burdensome enforcement activities. **For these reasons, the FAH believes that the stay of enrollment under proposed 42 C.F.R. § 424.541 does not constitute an appropriate, fair, or reasonable measure to address the types of noncompliance described in the Proposed Rule.**

Reporting Changes in Practice Location

The FAH also is concerned that the proposal to amend 42 C.F.R. § 424.516, significantly shortening the time for reporting a change, addition, or deletion of a practice location for hospitals and certain other suppliers and providers, would create unnecessary administrative burdens and jeopardize otherwise proper payments for services furnished at new practice locations. Under current rules, providers and suppliers other than DMEPOS suppliers, IDTFs, and physicians and nonphysician practitioner organizations have 90 days within which to report practice location changes. This long-standing timeline for reporting changes provides a reasonable window within which a hospital, that adds or relocates a provider-based department or other practice location, may report the change and update its Medicare enrollment. The FAH is concerned that shortening the timeframe to just one-third of the existing timeframe will result in payment uncertainty for new provider-based departments that are appropriately licensed under State law and fully comply with the detailed requirements of 42 C.F.R. § 413.65 based solely on technical noncompliance with an artificially urgent reporting requirement.

Timeframes for Reversing a Revocation

Lastly, the FAH opposes the proposed amendment to 424.535(e) that would provide only 15 days within which a provider or supplier may obtain a reversal of revocation by terminating a business relationship with an owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program following a revocation notification. The current regulatory timeframe of 30 days provides an appropriate window within which to evaluate the revocation notification and terminate the business relationship with the party whose adverse activity resulted in the revocation. Although providers and suppliers are generally responsible for addressing program integrity risks posed by owners and managers, a provider or supplier may first become aware of a reason for revocation or of a CMS determination that a revocation is warranted upon receipt of the revocation notification. **A 30-day window provides an appropriate outer limit for the time a provider or supplier will need to evaluate the revocation notification, understand the nature of the adverse activity, and terminate the business relationship with the individual or entity, and the FAH therefore supports retaining this 30-day timeframe.**

IV. Updates to the Quality Payment Program (QPP)

D. Request for Feedback

CMS seeks comments on how they can modify their policies under the QPP to foster clinicians' continuous performance improvement and positively impact care outcomes for

Medicare beneficiaries. Such modifications for MIPS may include requiring more rigorous performance standards, emphasizing year-to-year improvement in the performance categories, or requiring that MIPS eligible clinicians report on different measures or activities once they have demonstrated consistently high performance on certain measures and activities.

The FAH appreciates the opportunity to provide feedback on how the QPP could be modified to encourage continuous improvement with the goal of further advancing patient outcomes. We urge CMS to focus on ensuring program stability and increasing the meaningfulness of existing requirements. Since the inception of this program, QPP participants have had to adapt to a new reporting program with four complex categories, balance internal quality improvement activities against the competing, and often conflicting, program reporting requirements, invest in EHRs, and incorporate eCQMs – all while providing the highest quality care to their patients during the COVID-19 public health emergency.

The degree of burden in reporting for MIPS and associated costs cannot be understated. For example, a qualitative study published in 2021[2] found that practices spend over 200 hours for each physician annually to participate in this program and the average cost per physician was more than $12,000 each year. These estimates are from 2019 and do not reflect any of the recent changes to the program, including the shift to MIPS Value Pathways (MVPs), which CMS believes will create connections across measures and activities that are more meaningful and reduce complexity and burden.

The FAH does not believe that the current design of MVPs achieves these goals since each combines the four performance categories without any changes in requirements and the only "burden reduction" that we are able to identify would be the requirement in the quality category that only four measures must be reported. This decrease by two measures with all other category requirements remaining the same is insufficient, particularly due to the possible future additions of new measures to the foundational layer and the continued process of combining several quality measures into one. The proposed addition of the Preventive Care and Wellness composite is a good example where seven existing measures have been combined to create a single composite. This composite is proposed for inclusion in MIPS beginning this year and is proposed for at least one MVP. While this measure will be listed as one metric, in reality practices will now need to implement those seven metrics along with an additional three in order to meet the quality category requirements. In addition, any detailed information around a practice's performance on each individual metric is lost and the ability to drive improvements through this measure will be negatively impacted. This approach is the exact opposite of what we understood to be some of the goals for moving to MVPs.

We continue to urge CMS to determine whether MVPs will serve as the "glidepath" toward alternative payment models and demonstrate value as envisioned. For example, CMS must still:

[2] Khullar D, Bond AM, O'Donnell EM, Qian Y, Gans DN, Casalino LP. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. *JAMA Health Forum.* 2021;2(5):e210527. doi:10.1001/jamahealthforum.2021.0527

- Move beyond the current conceptual model and validate how MVPs will be scored and how those differences may or may not impact an eligible clinician or practice's ability to achieve the performance threshold;
- Model using existing data how the resulting scores from quality, cost and the population health measures in the foundational layer represent value-based care;
- Determine what the additional reporting burdens will be with the addition of subgroup reporting and for multi-specialty practices or health systems if CMS requires one group to report multiple MVPs;
- Explore how it can minimize any negative unintended consequences such as a practice earning a penalty based on MVP reporting when the same group would have earned an incentive through traditional MIPS; and
- Balance MVP implementation with other competing priorities such as the anticipated shift to digital quality measures.

CMS must streamline the processes and reporting requirements so that providers can focus on patient care. To date, we believe that the recent and proposed changes continue to miss the mark and further decrease any meaningfulness that the program might have.

CMS should shift to a greater focus on leveraging the work that has already been completed by the groups and organizations on approaches that incentivize improvement (and not just reporting) and reduce burden. Each of these achievements are costly for health care providers in terms of time and money – and require significant additional annual investments to continually update their EHRs and other systems to accommodate new government programs and requirements. In addition to technology resources, these changes also require clinician time and participation to be successful, including continual education and adaptation to workflow changes. CMS continues to finalize revisions to each of the performance categories every year in a timeframe that allows little time for practices to dedicate additional resources to understand and then implement the updates. This process contributes to a seemingly constant state of change and it creates fatigue and frustration for clinicians.

The FAH also encourages CMS to explore how they can continue to provide timely feedback on current performance to practices and incentivize reporting for new metrics. As we have noted in the past, MIPS is also not currently structured to encourage reporting on new measures, and clinicians and organizations may elect not to report on a new measure for a time while they determine how to incorporate the measure into their practices, including assessing the burden and utility of collecting the measure and enabling the requisite analytic capability. As a result, measures for which reporting is initially low may be due to slow uptake and not necessarily indicative that the measure is not meaningful. As we move toward measures that are more complex, such as composites or patient-reported outcomes, these measures could experience slower uptake due to data collection burdens and limitations of analytic capacity. As a result, CMS must find ways in which reporting these measures can be incentivized.

In addition, we recommend CMS reevaluate the data completeness requirement to reflect actual patterns of practice and further improve the benchmarking approaches. Specifically, the current benchmarking approach for the quality and cost measures does not provide meaningful information for tracking improvement internally or across MIPS participants. It is not clear that

either is representative of many or few reporters and based on the current design, the distributions are typically not stable year over year. If true improvement is the priority, then the benchmarking approach must be more sophisticated and allow benchmarks to be set not only on the data submitted but also incorporate clinical knowledge, consider the impact of random fluctuation, and be adjusted for practical considerations of comparison and relative performance.

Specific to cost, the FAH does not support the current approach for benchmarks where higher cost is associated with lower deciles and points. Lower cost should not automatically achieve higher scores, and for several of the measures, the variation in costs is limited, which could lead to determinations on costs being made based on small differences in spending. These assumptions are inherently flawed and could lead to negative unintended consequences such as misleading clinicians and the public on what constitutes reasonable costs.

F. MIPS Performance Category Measures and Activities

(II) Data Submission Criteria for the CAHPS for MIPS Survey Measure

CMS proposes to require the administration of the CAHPS for MIPS Survey in the Spanish translation; more specifically, they propose to require groups, virtual groups, subgroups, and APM Entities to contract with a CMS-approved survey vendor that, in addition to administering the survey in English, would administer the Spanish translation to Spanish-preferring patients using the procedures detailed in the CAHPS for MIPS Quality Assurance Guidelines. Also, they recommend that groups, virtual groups, subgroups, and APM Entities administer the survey in the other available translations (Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese) based on the language preferences of their patients.

The FAH supports the proposed requirement to administer the Spanish translation of the survey based on patient preference as it will enable patients to better respond to the survey items in their preferred language and reflect patients' perspectives on the care received.

(D.II.) Data Completeness Criteria for Quality Measures

CMS proposes to increase the data completeness criteria threshold from 75 percent to 80 percent for the CY 2027 performance period/2029 MIPS payment year. This increase would apply to all reporting options.

The FAH does not believe that CMS has adequately addressed the concern raised by multiple commenters regarding the difficulty, and potential impossibility, for some practices to report higher numbers of patients due to challenges with data collection and aggregation across sites, particularly if the EHR systems are not interoperable. In addition, there may be challenges if a clinician or practice participates with a specific registry for MIPS reporting but one of the sites of service at which they provide care is not a participant of that same registry. Lastly, providers and practices continue to face environmental and financial challenges that require mid-year EHR transitions and other impacts to their ability to meet the increased data completeness threshold.

The FAH encourages CMS to explore other alternatives to establish adequate sample sizes, such as minimum sample sizes for each measure, to ensure that the performance scores produce reliable and valid results, particularly for small or rural providers. If CMS continues to use the current approach for data completeness, we believe that CMS must validate its assumptions it is possible to continually increase the percentage when interoperability and seamless transfer of data are not yet universally available.

For example, CMS could compare the patients and data that are reported by practices to registries against which patients can be identified for the practice via administrative claims. This type of analysis would need to be completed across multiple specialties such as gastroenterology, radiology, internal medicine, and family practice. Determinations of data completeness thresholds should be data driven and this review would provide additional information on the extent to which challenges such as data interoperability or site of service differences impact the feasibility of practices, registries, and others to meet this requirement.

(E.) Selection of MIPS Quality Measures

The FAH strongly encourages CMS to reconsider the movement they have made over the past few years that has greatly reduced the inventory of eCQMs. As the inventory stands today, with CMS' proposals clinicians will have 44 eCQMs, of which only 30 currently have benchmarks in 2023 and are not currently topped out. Both clinicians and EHRs have made considerable investments at CMS' urging to build and adopt or change workflows that allow these measures to calculate accurately. Continuing to shift away from eCQMs leads to more administrative burden for clinicians and EHRs who have invested heavily into eCQM reporting over the past decade.

Connection to Community Service Provider

CMS proposes to add this measure to the MIPS Quality Measures as well as multiple specialty measure sets, beginning in CY 2024. The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, we cannot support the inclusion of this process measure in MIPS. Measures must be evidence-based and facilitate improvements in patient care.

Unfortunately, the developer does not provide any evidence in support of the five social needs, nor did they sufficiently justify the requirement to collect a patient with a community services provider on at least one need within 60 days. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). It also assumes that the practice has been equipped with the necessary resources and tools to address the individual's needs for any one of the selected factors. Any implementation of this measure is premature until these resources and tools are widely available.

In addition, the measure itself is not yet tested to demonstrate reliability and validity since only data for two screening tools (which are not required) were provided and most of the

information outlined is based on CMMI's Accountable Health Communities project, which involved community health centers/health systems and therefore does not provide sufficient information on how this measure would perform at the individual clinician level. It has also not been endorsed by the Consensus-Based Entity. Furthermore, we believe that is imperative that this process measure has demonstrated links to directly improving patient outcome without any unintended consequence of creating patient harm. Because we do not believe that this measure will result in effective change, we do not support its inclusion in MIPS.

(4) Promoting Interoperability Performance Category

(B) Promoting Interoperability Performance Category Performance Period

CMS proposes that for the CY 2026 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of any continuous 180-day period within CY 2024, up to and including the full CY 2024 (January 1, 2024, through December 31, 2024). CMS believes that this proposal would minimally increase the information collection burden on data submitters.

The FAH agrees that lengthening the EHR reporting period may yield more comprehensive and reliable data for required measures but stresses the importance of flexibility prior to and during the reporting period. Extending the reporting period past 180 days may potentially create converse results and greatly reduces the flexibility that practices need to choose a reporting period that allows them to have fully certified system. Additionally, it further strains practices that are working with the required Public Health registries to improve data quality to ensure a move to production can be accomplished with the CMS required timeframe. Flexible reporting periods still provide the opportunity for valid data submissions and attestations, which aid hospitals in demonstrating meaningful use of health IT.

The FAH strongly urges CMS to consider an alternative approach that produces accurate and reliable data for qualified facilities without extending the reporting period past 180 days.

III. Changes to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) Measure

CMS proposes to amend the SAFER Guides measure to require MIPS eligible clinicians to conduct this self-assessment annually, and attest a "yes" response, accounting for completion of the self-assessment for the High Priority Practices SAFER Guide. Under this proposal, an attestation of "no" would result in the MIPS eligible clinician not meeting the measure and not satisfying the definition of a meaningful EHR user.

The FAH appreciates the value that CMS places on developing a "culture of safety" within healthcare organizations, as well as encouraging greater information technology (IT) use. However, we recommend CMS reconsider its requirement of attesting "yes" for the SAFER Guides measure starting in 2024. While we recognize that the SAFER Guides measure is intended to promote safety and effectiveness across EHR implementations, the proposed process requires extensive resources to complete. Smaller practices and health systems are at a

disadvantage in gathering the required documentation from various staff, partner organizations, and other vendors.

The SAFER Guides are redundant to the required annual Security Risk Assessment (SRA) in this same category. Additionally, the SAFER Guides have not been updated since CY 2016. The FAH questions their place in this category altogether. The EHR landscape, as well as these requirements, have significantly evolved since 2016. Instead, we propose that CMS reevaluate its stance on incentive payments and apply its Meaningful Measures 2.0 framework when deciding how best to promote optimal patient safety outcomes and progress IT use. The SAFER Guides require a significant undertaking in comparison to other aspects of this category; attributing funds to their completion would be more plausible and less burdensome than including it as another prerequisite to compliance with the Promoting Interoperability Category.

The FAH disagrees with the SAFER Guides incorporation to the program and believe this places an undue burden on MIPS eligible clinicians. Should CMS finalize this proposal to require a "yes" attestation, they would be doing so without true merit to the category and the MIPS program.

G. MIPS Final Score Methodology

(I) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

CMS proposes two modifications to the criteria by which we assess the impacts of ICD-10 coding changes. The first proposal is to eliminate the 10 percent ICD-10 coding change factor established in the CY 2018 Quality Payment Program final rule, since it does not reflect a meaningful impact to clinicians' ability to report and be fairly scored on a quality measure. Instead, CMS proposes to assess how the coding changes affect the measure numerator, denominator, exclusions, and exceptions in ways that could lead to misleading or harmful results. The second modification would allow CMS to assess the impacts of coding changes and our associated course of action (suppression, truncation, or standard 12-month reporting) by measure collection type.

The FAH supports removing the 10 percent ICD-10 coding change factor since to our knowledge that cut-off was not based on any empirical analyses. We also support making these decisions based on the effect on the various data collection types. While we support these changes, we remain concerned that the current approach to truncate the performance period to 9 months may not yield sufficient data to establish reliable measure scores and/or benchmarks, which is critical.

CMS should evaluate the potential impact on the measure score reliability due to any substantive change and/or the resulting truncation of data as well as whether a coding update should be considered a substantive change if it based on whether changes in performance scores are due to the modifications to the changes in the measure construct or coding rather than actual performance.

(I) Cost Improvement Scoring Methodology

CMS proposes to determine each MIPS eligible clinician's cost improvement score at the category level and remove the requirement that they compare measures with a "statistically significant change (improvement or decline) in performance" as determined based on application of a t-test, beginning with the CY 2023 performance period/2025 MIPS payment year, to address the operational feasibility issues identified with the previous approach. They also propose that the maximum cost improvement score beginning with the CY 2025 MIPS payment year is 1 percentage point.

The FAH supports this shift to calculating the improvement score at the category level and without statistical significance. We also encourage CMS to consider incremental increases to the maximum score beyond the proposed one point.

(F.2.) MIPS Performance Threshold

CMS proposes to specify that, beginning with CY 2024 performance period/2026 MIPS payment year, a "prior period" for purposes of establishing a performance threshold is a time span of 3 performance periods. Subsequently, they also propose to redesignate language, which states that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period. If this proposal is finalized, then CMS proposes to use the CY 2017 through CY 2019 performance periods/2019 through 2021 MIPS payment years (mean of 82 points, rounded down from 82.06 points) as the prior period for the purpose of establishing the performance threshold for the CY 2024 performance period/2026 MIPS payment year.

The FAH supports changing how a performance threshold is defined and agrees that using three performance periods will reduce variability based on year-to-year fluctuations and increase the predictability of the threshold for future years. While this change will prove useful in the future, we request clarification on whether CMS intends to apply this change retrospectively. Specifically, CMS refers to "2024, 2025, and 2026 MIPS payment years" where we believe they intended to refer to 2024, 2025, and 2026 MIPS *program* years or *performance* years or performance periods:

- IV.A.4.H(b)
    - Paragraph 3, in the public inspection version of the rule Page 1078, in the federal register version of the proposed rule page 52597.
- VIII.J. List of subjects, in the public inspection version of the rule Page 1464, in the federal register version of the proposed rule page 52748.
    - § 414.1405 Payment

We do not support retrospective changes to the thresholds and do not believe that the current wording reflects CMS' intent.

In addition, we do not support the proposal to increase the performance threshold to 82 points in 2024. As we have stated in previous letters around this issue, we question whether

clinicians will be able to meet the proposed increase, particularly as performance categories continue to be reweighted (e.g., the cost category was zeroed out in 2019, 2020, and 2021) and it is nearly impossible for clinicians to successfully participate given the structure of some of the performance categories and the many changes that continue to be finalized year over year. In addition, the three years (2017, 2018 and 2019) that would be used to create this threshold include the first two years where requirements were less stringent and 2019 where the EUC hardship exception was applied. The FAH does not believe that the scores from those years reflect the reality of the MIPS program now.

For example, requirements to comply with each category have increased, some key high-performance measures were removed across many performance categories, the cost performance category constitutes 30 percent of the overall score and yet no data on the 25 cost measures were made available until recently, and many bonus points have been retired. At a minimum, CMS should maintain the same threshold of 75 points for the 2024 performance period and not move forward with any increases until the MIPS program demonstrates more predictability and stability in the category requirements and resulting scores.

K. MIPS Targeted Reviews

CMS proposes to permit submission of a request for targeted review beginning on the day they make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the MIPS payment year.

The FAH does not support the proposed halving of the time practices and clinicians have to submit a Targeted Review and respond to a demand for more information in a Targeted Review case. This shortened timeframe severely strains already overworked staff and can be made more difficult when responses from an EHR are needed.

We support the inclusion of subgroups for MVPs to the list of entities able to submit a Targeted Review and would strongly urge CMS to permit them to 60 days to receive analyze and submit a Targeted Review request and 30 days to respond to demands for additional information on those Targeted Reviews. If a clinician participates in a novel QPP pathway, then we believe they should be permitted the opportunity to understand a novel set of data and potential issues for their participation.

L. Public Reporting on Compare Tools

CMS proposes to modify the existing policy for public reporting on individual clinicians and group profile pages regarding the telehealth indicator and utilization data.

The FAH supports CMS' initiative to provide more data on the public facing websites of the Compare Tools. We urge CMS to provide additional nuance to patients by providing context for the star ratings and other performance indicators when there is not clearly labeled TIN versus clinician performance.

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The FAH appreciates the opportunity to submit these comments on these important issues to providers and patients. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,