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Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (CMS-1770-P)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2023 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule, as many of the proposed policies have a significant impact on our members and the patients they serve.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to the various issues raised in the Proposed Rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS's proposals. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the calendar year (CY) 2023 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule.

Changes to the Physician Fee Schedule and Other Changes to Part B Payment Policies

Calculation of the Proposed CY 2023 PFS Conversion Factor

In the Proposed Rule, CMS estimates a conversion factor (CF) of $33.0075, which is approximately a 4.72 percent reduction from 2022. Notably, this estimate does not include forthcoming cuts related to

the statutory Pay-As-You-Go Act of 2010 being triggered as it relates to spending associated with the American Rescue Plan Act but does reflect the one-time 3 percent CF increase that will expire at the end of 2022. Further, the as a result of these reductions and anticipated cuts, Vizient is concerned about the harm that providers will endure during CY 2023 absent changes by CMS or Congress to better support providers, especially as the effects of the pandemic and inflationary pressures persist. Vizient urges CMS to advance policies that reduce financial strain on providers and to support any legislative efforts that may address these harmful payment reductions.

Clinical Labor Update to the Practice Expense

In the CY 2022 PFS final rule, CMS finalized a four-year, phased-in policy to update clinical labor pricing for CYs 2022 – 2025. For CY 2023, CMS proposes to advance to year two of its four-year plan to update clinical labor pricing and welcomes additional data to improve the accuracy of the agency's final pricing. As CMS is aware, clinical labor costs have drastically increased during the COVID-19 pandemic. The Vizient Operational Data Base (ODB), which provides hospitals with insights in support of performance improvement, includes data that is submitted by 75 percent of academic medical centers, and represents more than $370 billion in operating expenses, showed an increase of 66 percent in licensed nursing staffing turnover in the 4th Quarter of 2021. That turnover and other staffing shortages have also led to a dramatic increase in hours paid for contract nursing (+250 percent) and an increase in overtime as a percent of worked hours (+33.5 percent), compared with the 4th Quarter of 2020. Higher use of contract nursing and greater utilization of overtime has resulted in the average hourly wage range (area wage index adjusted) increasing by 19.7 percent. Despite these pressures, nurses have also been spending less time at the bedside, with a reduction of 5.4 percent in registered nurse working hours per patient day. Combined, these issues have led to median labor cost increases of $114, or 16.4 percent per patient day. As such, Vizient emphasizes to CMS that clinical labor prices have increased drastically, and we encourage CMS to consider this additional information and broader trend. Vizient also notes our willingness to leverage our data sources to help the agency in making this determination should CMS provide additional clarity regarding specific data needs.

Vizient appreciates the importance of updating the clinical labor pricing and the agency's decision to implement the update over a four-year period, however, reductions in payment to specific specialties may ultimately impact access to care. As such, Vizient suggests CMS consider strategies to mitigate risk to these specialties as they face reductions during this transitional period. In addition, Vizient suggests CMS clarify whether it is monitoring for unintended consequences of this policy, particularly regarding the impact on specialties and access.

Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

To prepare for future rulemaking, CMS seeks comments on strategies to improve the accuracy of payment for the global surgical packages under the PFS. Global packages (i.e., 0-day, 10-day and 90-day) include the surgical procedure and any services typically provided during the pre- and post-operative periods (including evaluation and management (E/M) services and hospital discharge services). CMS continues to have concerns regarding the current valuations of the global packages reflecting certain E/M visits that are not typically furnished in the global period, and as a result, CMS believes the visits are not occurring. Vizient recommends CMS work closely with providers to determine potential coding and documentation issues before revising the valuation approach. Vizient also encourages the agency to work with providers to better understand their concerns with reports on global surgical packages, including the RAND reports CMS references in the Proposed Rule. Further, providers' input should be reflected in any future approach the agency considers.

Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1 and GYYY2)

In the CY 2022 PFS proposed rule, CMS requested stakeholder input regarding refinements to the PFS to appropriately value chronic pain management and treatment (CPM) and in the final rule, indicated it would consider feedback in future rulemaking. In the Proposed Rule, CMS agrees with prior stakeholders who indicated that E/M codes may not reflect all the services and resources required to furnish comprehensive CPM to beneficiaries living with pain. CMS now proposes to create separate coding and payment policies for CPM services beginning January 1, 2023. Vizient supports the need for separate coding and payment for CPM services.

Related to the agency's point that current E/M codes may not reflect all the resources and services associated with CPM, a pain management guide developed by Vizient[1] highlights several potential interdisciplinary team members, such as a pain medicine specialist, social worker, dietician, pharmacist and clinical nurse specialist, who provide a range of services related to CPM. Further, there are a range of chronic pain management strategies, including pharmacologic therapies, interventional pain management, and nonpharmacological therapies (e.g., behavioral health, dietary and nutrition therapy). Vizient believes it is important that CPM bundles, including related coding, be flexible enough to ensure that a range of different treatment approaches are covered. Also, Vizient agrees with the need to include ongoing communication and coordination between relevant practitioners furnishing care within the treatment bundle.

As CMS considers how the initial and subsequent visits should be conducted for CPM services, Vizient encourages CMS to also consider components of the proposed bundles that do not require a face-to-face interaction, such as behavioral health services

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

The COVID-19 Public Health Emergency (PHE) has had a substantial impact on the utilization of telehealth services. Telehealth visits remain a critical means of delivering care, allowing access in high need areas while also reducing the need for patients to travel to different healthcare settings. Vizient appreciates CMS's efforts to maintain access to telehealth services and offers several recommendations for the agency's consideration.

Medicare Telehealth Service List
CMS maintains a Medicare telehealth services list and has a process for adding or deleting services from the list. CMS notes that it received several requests to add various services to the Medicare Telehealth Services List effective for CY 2023. However, none of the requests that were received by the February 10, 2022, submission deadline met the agency's Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. CMS proposes instead to add several services to Category 3 of the telehealth list, which would make these services temporarily available through December 31, 2023, as CMS considers making them permanent. According to data from the Clinical Practice Solutions Center© (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, Category 3 codes represented less than 1 percent of services, but these services represented several specialties and service lines, including speech and hearing therapy, behavioral assessments, and other therapeutic activities. Vizient encourages CMS to consider opportunities to extend access to these services, even if applications are not provided on a timely

[1] https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/comprehensivepainmanagementreport.pdf

basis, to minimize disruption to care. Also, given this is the second year that requests to add services to Categories 1 and 2 of the telehealth list were not received by the submission deadline, Vizient encourages CMS to provide additional education regarding the process and information needed to request permanently adding services to the telehealth list. Vizient also suggests CMS consider whether modifications to the process are needed given the lack of timely requests received.

Roadmap for the End of the COVID-19 Public Health Emergency
As noted, Vizient appreciates the flexibility CMS has provided to enable patient access to an array of telehealth services during the COVID-19 PHE. As CMS advances its roadmap for the end of the PHE,[2] we encourage the agency to provide additional information regarding the impact to telehealth services alongside final regulatory policy, such as PFS regulations to provide stakeholders with a more complete picture of upcoming changes. For example, once the waivers[3] are no longer in place, it may be challenging for providers to determine which requirements will be in place given the significant regulatory changes that have also occurred during the PHE. Therefore, as CMS finalizes the Proposed Rule and other annual rules, we suggest CMS provide topic-specific educational resources, such as timelines, to help clarify when waivers will expire, and which specific regulations will be in place.

Vizient agrees with CMS that there are Congressional challenges to expanding telehealth, and we are supportive of Congress making permanent several telehealth flexibilities provided during the pandemic. However, as the flexibilities from the PHE unwind, we emphasize that providers will need time, resources, education, and outreach to prepare for this shift. Further, during this unwinding period, it will be important that patient care remains a priority. Vizient suggests CMS consider approaches to monitor the unwinding process to ensure there are no unintended consequences.

Implementation of Provisions of the Consolidated Appropriations Act (CAA), 2022 Pertaining to Medicare Telehealth Services

Geographic and Originating Site Restrictions
The CAA, 2022, continued to ease geographic and originating restrictions that typically limit access to telehealth services. The CAA, 2022, authorized telehealth services to continue to be provided at different sites, including the individual's home, for 151 days after the end of the COVID-19 PHE. In addition, the CAA, 2022, also eased geographic requirements such that beneficiaries may access telehealth services regardless of their geographic location (e.g., outside of a rural area). As a result, for 151-days after the PHE, Medicare will continue to broadly cover telehealth services, even if the patient is located at home in an area that is not rural. Vizient appreciates this additional flexibility, but we are concerned that patients will again risk losing coverage after this 151-day period.

While Vizient understands the statutory limitations associated with telehealth services, we encourage the agency to consider whether any exceptions or additional flexibility can be provided to support patient access to care or better facilitate this transition. Vizient also encourages patient and provider communications to ensure key stakeholders are aware of, and plan for, anticipated changes.

Telehealth for Mental Health Services
In addition, the CAA, 2022, delayed for the same 151-day period the in-person visit requirement for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health

[2] https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency
[3] https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

disorder and to individuals with a substance use disorder (SUD) diagnosis for purposes of treatment of the SUD or a co-occurring mental health disorder. This extension is critical for mental health telehealth services because the Consolidated Appropriation Act, 2021 (CAA, 2021), which permanently expanded access to telehealth for mental health services by easing geographic and originating site restrictions, also requires that in-person (non-telehealth) visits be furnished to the beneficiary six months before the initial telehealth service. The CAA, 2021, while still a significant improvement to support access to telehealth services, is stricter than policies provided during the PHE. However, as a result of the CAA, 2022's 151-day extension, stakeholders have more time to prepare for the in-person visit requirement to go into effect. Vizient encourages CMS to work with providers to identify challenges that patients may be facing when attempting to meet this in-person requirement. To the extent those challenges can be addressed through more flexible regulations, we encourage the agency to take such steps to prevent care disruption.

As CMS is aware, a significant number of patients receive behavioral health services via telehealth. For example, data from the CPSC, developed by the AAMC and Vizient showed that more than half of behavioral health services were provided via telehealth in 2022.[4] Further, data shows that the COVID-19 pandemic has caused higher rates of mental health concerns, including depression, anxiety, and substance use.[5,6] Also, the CY 2022 PFS final rule provides exceptions to the subsequent visit requirement that CMS does not propose to expand upon in the Proposed Rule.[7] Vizient is concerned that patients may be lost to follow-up because they are unable to see a provider in-person, and that the six-month and twelve-month in-person visit requirements will lead to fewer patients receiving needed care. Also, Vizient notes our concern that patients with limited transportation options, those residing in rural settings or those with limited work flexibility, among other circumstances, may be more likely to be unable to meet in-person. Vizient encourages CMS to consider other potential exceptions and that the agency provide additional information to providers to improve their awareness of the exceptions policy.

Audio-only services

The CAA, 2022, also extends temporary coverage of audio-only telehealth services included on the Medicare Telehealth Services List as of March 15, 2022. CMS reiterates that only those telehealth services that are designated as eligible to be furnished via audio-only technology as of March 15, 2022, will continue to be covered during the 151-day period after the PHE ends.

Audio-only services provide another avenue for patients to access care. As shown in Image 1, a 2022 analysis of data from the CPSC,[8] demonstrated that Medicare patients were more likely than patients with commercial insurance or Medicaid to use the phone for their telehealth visits. Further, video technology is not accessible to patients in all areas of the country for a range of reasons including broadband limitation or lacking access to devices for audio-visual communications. Audio-only services open the door to care for many patients who would otherwise struggle to access audio-video telehealth services, among other means of accessing care.

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[4] According to CPSC data, telehealth utilization rates peaked in the second quarter of 2020 and are beginning to stabilize at a lower rate. Telehealth services for behavioral health, however, remain high despite a decline since the second quarter of 2020 (Q2 2020). For example, rates of utilization for behavioral health telehealth services peaked at 77% in Q2 2020 and is at 54% in the second quarter of 2022. Alternatively, other service lines, such as cardiovascular, cancer and neurosciences, have smaller proportions (i.e., 5-17%) of services being provided via telehealth. Overall, telehealth utilization has been decreasing throughout the pandemic. While it is decreasing somewhat, there is still very high usage for behavioral health compared to all other specialties.

[5] https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm

[6] https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm

[7] https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf

[8] https://newsroom.vizientinc.com/content/1221/files/Documents/EffectsOfCovid19PandemicOnTelehealth.pdf

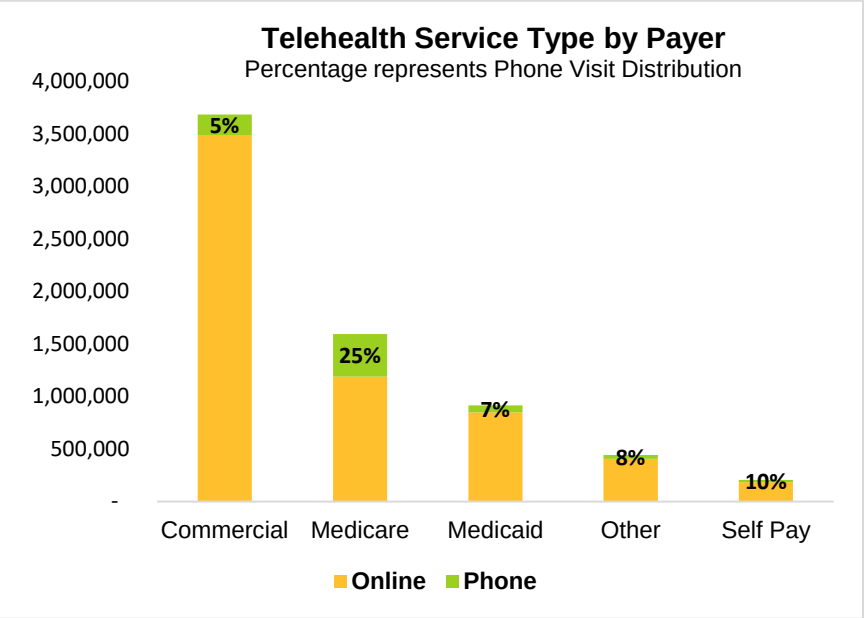

Image 1. Vizient Inc-AAMC Clinical Practice Solutions Center ©. Analysis of data showing telehealth service type by payer.

Also, it is foreseeable that audio-only services can also be improved. For example, while initially there was limited data on audio-only services, additional research is underway, particularly on how the quality of care delivered through audio-only services compares to services delivered through video or in-person care. Early in the pandemic, telehealth utilization spiked so practitioners had to be nimble to transition patients to telehealth. Not surprisingly, the training and infrastructure to more effectively track such services and patient outcomes was relatively limited. For example, a 2020 survey of Medicare beneficiaries asked patients if they had attended an audio-only visit since July 2020 and beneficiaries' answers were compared with their Medicare claims. Of those that reported they had attended an audio-only visit, only 20 percent had a claim for an audio-only visit.[9] The researchers who completed this study considered that this variability is likely related to how visits were coded at the time they were scheduled versus how they were delivered at the time of the visit, a lack of awareness about different codes, and a general confusion regarding different coding and documentation options.[10] While significant strides have been made since 2020 regarding audio-only services, there is more research to do and more work underway. As such, Vizient encourages CMS to continue to consider opportunities to maintain access to a broader range of audio-only services, or at a minimum to provide additional time for research and to maintain patient access. Also, as the end of the PHE approaches, we encourage the agency to consider opportunities to clarify coding and documentation requirements related to both telehealth visits and audio-only visits should the agency limit access to audio-only services.

Use of Modifiers for Medicare Telehealth Services Following the End of the PHE
In the Proposed Rule, CMS proposes to clarify and update modifiers and their use, particularly as related to the provision of telehealth services. For example, CMS proposes that Medicare telehealth services furnished within 151 days after the end of the PHE will continue to be processed for payment

[9] https://www.healthaffairs.org/content/forefront/audio-only-telemedicine-visits-flaws-underlying-data-make-hard-assess-their-use-and
[10] https://www.healthaffairs.org/content/forefront/audio-only-telemedicine-visits-flaws-underlying-data-make-hard-assess-their-use-and

as Medicare telehealth claims when accompanied with the modifier "95," along with the POS code that would have been reported had the service been furnished in-person. On the 152nd day after the PHE, CMS will no longer require the modifier "95" and will instead require the use of either the POS "02" or the POS "10" code.[11] Vizient notes these are just some of the changes anticipated as the PHE flexibilities unwind that may be administratively challenging for providers and pose subsequent coverage issues.

Lastly, although CMS has proposed a policy related to modifiers that is expected to affect nonfacility-based payments, Vizient encourages CMS to reconsider this approach. More detail regarding Vizient's concerns related to nonfacility-based practice expenses is provided in the following section.

Proposed Changes to the Nonfacility-Based Practice Expense
In the Proposed Rule, CMS clarifies that on the 152nd day following the end of the PHE, providers will be unable to bill the nonfacility-based practice expense when providing telehealth services in the office setting. During the PHE, CMS permitted providers to include the nonfacility-based practice expense on claims for telehealth services if the telehealth service would have been provided in the office. Vizient notes that this shift from pre-PHE policy has been critical to ensuring providers can help maintain access to care, including access to telehealth services. However, Vizient is concerned that CMS's proposal to revert to pre-PHE policy where providers were unable to bill the nonfacility-based practice expense could negatively impact patient access to telehealth services. Vizient believes this proposal overlooks the numerous costs and components that should be in place before telehealth visits are offered, making it more challenging for providers to maintain access. For example, providers must identify an appropriate HIPAA compliant video platform, ensure sufficient bandwidth is available, modify workflows, train staff and ensure a private location is available during the telehealth service.[12] Vizient urges CMS to continue to pay providers for telehealth services at the nonfacility rate.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Expiration of the PHE Flexibilities for Direct Supervision Requirements
During the PHE, CMS temporarily changed the definition of "direct supervision" for diagnostic tests, physician's services, and some hospital outpatient services to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology. This flexibility will end after December 31 of the year in which the PHE ends and revert to the pre-PHE rules for direct supervision. In the Proposed Rule, CMS seeks comments on whether to make the flexibility permanent and how best to structure the supervision requirement for the future.

Vizient recommends CMS permanently ease the definition of direct supervision for diagnostic tests in a manner consistent with the flexibilities provided during the PHE. The flexible supervision policy can help limit disease transmission and clinicians have gained experience identifying which services are best for virtual supervision. To the extent CMS permits such direct supervision for only a subset of diagnostic

[11] POS "02" – the rule proposes to redefine this code as "Telehealth Provided Other than in Patient's Home" (descriptor: the location where health services and health-related services are provided or received through telecommunication technology. Patient is not located in their home when receiving health services or health-related services through telecommunication technology). POS "10" – Telehealth Provided in Patient's Home (descriptor: the location where health services and health-related services are provided or received through telecommunication technology. Patient is in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health-related services through telecommunication technology).
[12] Association of American Medical Colleges, Understanding a Video Visit at the Health System Level, available at: https://www.aamc.org/media/58731/download.

tests and hospital outpatient services, we encourage the agency to work closely with providers and stakeholders in identifying such services and providing education regarding such flexibilities.

Remote Therapeutic Monitoring Services

In the Proposed Rule, CMS proposes to develop four new codes, including two HCPCS G codes, that allow certain qualified nonphysician healthcare professionals to furnish Remote Therapeutic Monitoring (RTM) services.[13] CMS also proposes two new G codes to allow general supervision of auxiliary personnel. In addition, CMS provides an overview of the new, permanent remote therapeutic monitoring (RTM) device code for cognitive behavioral therapy (CBT) monitoring.[14] Vizient encourages CMS to continue to gather information on the implementation of RTM for different purposes, especially as it may help fill gaps in care or better connect patient to provider.

Evaluation and Management (E/M) Visits

Over the past several years, CMS has engaged with the American Medical Association (AMA) and other stakeholders in a process to update coding and payment for office/outpatient (O/O) evaluation and management (E/M) visits. For CY 2023, the AMA CPT Editorial Panel has revised the rest of the E/M visit code families (except critical care services) to match the general framework of the O/O E/M. For purposes of the Proposed Rule, CMS refers to these other E/M visit code families as "Other E/M" visits (e.g., hospital inpatient or observation care, Hospital or Observation Discharge Day Management, Emergency Department Visits). For CY 2023, CMS proposes to generally adopt the AMA's revised CPT E/M Guidelines for Other E/M visits and general CPT framework (except for prolonged services). Like the CPT E/M Guidelines for Other E/M visits, CMS proposes practitioner time or medical decision making (MDM) may be used to select the E/M level. Vizient appreciates the agency's decision to generally align Other E/M policy proposal with the CPT E/M Guidelines, particularly regarding the use of practitioner time or MDM to select the E/M level.

Also, related to E/M services, CMS indicates that, for payment purposes, physician and NPPs are not classified as having the same specialty, and the PFS does not recognize subspecialties. However, CMS indicates it is continuing to consider whether it could better align this payment taxonomy with clinical practice (i.e., where CMS may consider NPPs as working in the same specialty as the physicians with whom they work or recognize subspecialties). Vizient continues to hear concerns that NPPs, such as nurse practitioners, billing for an E/M service for a new patient may result in the claim being denied because NPPs generally are not identified as being in the same group for billing purposes. As a result, claims for new patient visits may be denied or additional time is spent rework

[13] The two proposed G codes are: GRTM3 (Remote therapeutic monitoring treatment assessment services, first 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the month); and GRTM4 (Remote therapeutic monitoring treatment assessment services, additional 20 minutes furnished personally/directly by a nonphysician qualified health care professional over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month (List separately in addition to code for primary procedure)). The two other proposed G codes are: GRTM1 (Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes of evaluation and management services); and GRTM2 (Remote therapeutic monitoring treatment management services, physician or NPP professional time over a calendar month requiring at least one interactive communication with the patient/caregiver over a calendar month; each additional 20 minutes of evaluation and management services during the calendar month (List separately in additional to code for primary procedure)).

[14] This CBT monitoring code is 989X6. If finalized, it will be anticipatory and will be contractor priced until more information is learned.

such claims. This can add significant administrative burden and cost to providers[15] and in some cases lead to NPPs limiting their care to established patients. Vizient encourages CMS to ensure claims are not improperly denied by including NPPs in the "same group" as other members of the care team that they work alongside. Vizient recommends CMS work closely with providers to better understand unique billing issues and develop solutions for streamlined billing processes.

Split (or Shared) Visits
CMS notes that it continued to hear concerns from stakeholders regarding implementation of the split (or shared) visit policy which was established in the CY 2022 PFS Final Rule.[16] After consideration, CMS proposes to delay implementation of the updated substantive portion definition until January 1, 2024. However, CMS reiterates its belief that it is appropriate to define the substantive portion of a split (or shared) service as more than half of the total time. Vizient applauds CMS for delaying the split (or shared) policy. We heard and continue to hear concerns from members regarding the operational challenges associated with this transition and unintended consequences related to compensation agreements. Further, Vizient emphasizes the importance of MDM and believes a more flexible approach to split (or shared) visits is critical to ongoing support of team-based care. Vizient recommends CMS rescind the CY 2022 PFS policy regarding the substantive portion of split (or shared) visits and opt for a more flexible approach that is significantly less burdensome and more effectively considers the different types of contributions from the care team.

Critical Care Services

In the Proposed Rule, CMS provides clarification regarding billing for critical care services. Specifically, the agency indicates that CPT code 99292, which is used for subsequent critical care services, may only be reported if there is an additional 30 minutes of service provided to the patient. For example, CPT code 99291 would be used to report the first 30-74 minutes of critical care and CPT code 99292 could only be billed if the patient receives at least 104 minutes of care. Vizient is concerned this interpretation deviates from prior guidance and encourages that CMS reconsider this approach to better recognize additional critical care services.

Geographic Price Cost Indices

By statute, CMS must develop separate Geographic Practice Cost Indices (GPCIs) to measure the relative cost difference among localities compared to the national average for the work, practice expense (PE) and malpractice (MP) fee schedule components. In the Proposed Rule, CMS aims to update the physician work GPCIs using 2017-2020 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data. Vizient appreciates the need to update the GPCIs using more recent wage data but encourages the agency to consider the potential effects of the pandemic on GPCIs given the BLS data is pre-pandemic and wages have increased drastically since the start of the pandemic.

In addition, CMS seeks comment on potentially incorporating the rebased and revised Medicare Economic Index (MEI) cost share weights into the CY 2024 GPCIs, including whether CMS should

[15] Based on CPSC analysis of 2020 data, in a twelve-month period, 14 percent of new patient visit codes billed by APPs were denied which equaled 11,000 claims. It cost on average $25 to rework a claim totaling $275,000.
[16] https://www.federalregister.gov/documents/2021/11/19/2021-23972/medicare-program-cy-2022-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part

phase in this adjustment over a two-year period. However, as noted below regarding the MEI, we urge CMS to not incorporate the rebased and revised MEI into the CY 2024 GPCIs as we believe there is a need to reconsider the approach CMS proposes related to the MEI.

Rebasing and Revising the Medicare Economic Index (MEI)

The MEI reflects the weighted-average annual price change for various inputs involved in furnishing physicians' services. For CY 2023, CMS proposes to rebase and revise the MEI. However, since CMS anticipates that full implementation of the MEI could have significant impacts if done over a single year, the agency does not propose fully implementing the updated MEI for CY 2023. CMS seeks comment on implementation, including a potential four-year transition. Vizient appreciates the agency's efforts to seek stakeholder input before implementing the MEI given the agency's concerns that a single year implementation plan would have significant impacts. Generally, Vizient agrees with the concept of a longer-term implementation plan to provide greater stability, however, we urge the agency to instead rely on the American Medical Association's effort to collect practice cost data from physician practices and to delay the rebasing and revising of the MEI until such information is available. As CMS provides, updating the MEI would cause significant disruption, and, as a result, we believe it is of the utmost importance that CMS take a cautious approach in rebasing and revising the MEI, including working closely with the provider community.

Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

The Infrastructure Investment and Jobs Act, which was signed into law on November 15, 2021, requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. In the Proposed Rule, CMS outlines the circumstances in which providers would have to use different modifiers (e.g., JW, JZ) on claims forms to track discarded amounts. For example, CMS proposes that for all claims for single use vials or single use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. Vizient questions the need to include a modifier on every claim form. Also, Vizient is concerned this policy may have unintended consequences, such as claims being denied when a modifier is not included and that it adds unnecessary provider burden.

Medicare Part B Payment for Preventive Vaccine Administration Services

In the Proposed Rule, CMS proposes a geographic adjustment policy that would apply to preventive vaccine administration services for CY 2023 and subsequent years. CMS proposes to use the Geographic Adjustment Factor (GAF) to adjust the payment to reflect the costs of administering preventing vaccines in each of the PFS fee schedule areas. Under this proposal, beginning January 1, 2023, CMS would apply the GAF to the $40 payment amount for COVID-19 vaccine administration services, so long as the emergency use authorization is still in place.[17] Adequate reimbursement is imperative to help physicians and other providers effectively administer these critical vaccines. Vizient

[17] CMS explains in the proposed rule that the EUA declaration and the PHE declaration are not tied together. Therefore, even though there are vaccines that are fully authorized under the FDA, these rates would still apply as long as the EUA declaration is still in place. (Proposed rule, p. 1008).

agrees with CMS regarding the importance of clarifying these geographic adjustments and supports implementing the GAF for administration of the COVID-19 vaccine.

CMS also proposes an annual adjustment, based on the annual increase to the MEI, to the payment amount for administration of preventive vaccines to reflect changes in cost. Vizient supports ensuring that payments for services are adequate. However, given our concerns regarding the MEI, we do not recommend the agency rely on the on the proposed rebased and revised MEI for this adjustment.

During the PHE, CMS has provided additional payment for vaccinations administered in the home. This allows CMS to track utilization and trends associated with its use to inform policy for CY 2024. In CY 2023, CMS proposes to continue the additional payment of $35.50 when a COVID-19 vaccine is administered in a beneficiary's home under certain circumstances. CMS also proposes to adjust this payment amount for geographic cost difference as done for the preventive vaccine administration services beginning CY 2023. Because the severe cases of COVID-19 disproportionately impact elderly and immune-compromised individuals, connecting homebound persons with the vaccine in a safe space has been a vital part of the overall vaccine strategy.[18] Vizient applauds CMS for providing additional reimbursement to support vaccine administration at the patient's home and hopes a continued focus on vaccinating this vulnerable population helps drive utilization of this and future doses of the vaccine. Further, Vizient encourages CMS to expand this policy to apply to all preventive vaccines covered under Part B to expand access and uptake of these vaccines.

Increased Communication Regarding CY 2023 Changes
As CMS unwinds the PHE, providers will see a multitude of changes and deadlines that will impact the way they bill, code, and deliver healthcare. The Proposed Rule puts forward several changes that are temporary, tied to the PHE or another emergency procedure, and some that will shift as time moves forward. Vizient strongly urges CMS to provide significant communication to stakeholders and providers to avoid mistakes that would result in a payment issue. Vizient remains committed to helping providers navigate the changing landscape of healthcare and hopes to work with CMS and others to ensure a seamless transition for providers and patients.

Requirement for Electronic Prescribing for Controlled Substances for Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan

In the Proposed Rule, related to the electronic prescribing of controlled substances (EPCS) requirement, CMS proposes to extend the existing non-compliance action of sending letters to non-compliant prescribers until December 31, 2024. Vizient supports the agency's proposed one-year extension such that it would send letters to non-compliant prescribers for EPCS program implementation. In addition, given prescribers may be unfamiliar with exceptions, including those to be finalized, Vizient encourages CMS to also provide additional information to prescribers regarding exceptions and how providers can easily determine whether they are eligible for an exception, such as cases where the prescriber issues only a small number of Part D prescriptions. To the extent any exceptions may overlap, we also encourage the agency to provide education regarding application of multiple exceptions.

[18] https://www.cdc.gov/aging/covid19/covid19-older-adults.html#increased-risk

Medicare Shared Savings Program

Smoothing the Transition of the Performance-Based Track

In 2018, CMS redesigned Medicare Shared Savings Program (SSP) participation options so that Accountable Care Organizations (ACOs) would transition more rapidly to two-sided models. However, some ACOs indicated this shift towards greater down-side risk deterred participation. As a result, CMS proposes to allow ACOs to join under one-sided risk and remain in two-sided risk models with lower levels of risk. Related to this transition, CMS proposes a new 5-year agreement period under a one-sided model for certain ACOs which would apply for agreement periods beginning on or after January 1, 2024. While CMS provides additional options for ACOs, we encourage the agency to also consider additional incentives for ACOs that have made the transition to the performance-based track and those with agreement periods starting before January 1, 2024.

Financial Methodology

In the Proposed Rule, CMS proposes a combination of modifications to the SSP financial methodology to encourage sustained participation by ACOs in the program and remove barriers to serving medically complex and low-income populations. Among other changes, the agency proposes to expand the eligibility criteria to qualify for shared savings such that certain low revenue ACOs participating in the BASIC track may share in savings, even if the ACO does not meet the minimum saving rate (MSR). Vizient supports additional opportunities for ACOs to earn shared savings distributions as it may foster the shift towards value-based care. For example, such additional opportunities may help increase engagement and support reinvestment into ongoing strategies around care coordination, chronic diseases education and management, and other strategic investments.

CMS proposes that this opportunity would not be available to all ACOs, as high revenue ACOs are excluded. Vizient encourages CMS to consider whether additional incentives can be provided to high revenue ACOs to encourage their ongoing participation or whether to update the eligibility criteria to include high revenue ACOs.

Seeking Comment on Incorporating an Administrative Benchmarking Approach into the Shared Savings Program

CMS provides an overview of various policies in the Proposed Rule that aim to address certain issues with the existing benchmarking methodology (i.e., ratchet effects[19]) that results in selective participation. CMS seeks comment on broader changes to the benchmarking methodology to further strengthen incentives for providers and suppliers to participate in the SSP and generate savings while preserving a mechanism for convergence to a consistent regional benchmarking approach. CMS also outlines a potential administratively established benchmarking approach. Under this approach, benchmarks would be allowed to rise above realized FFS expenditure growth as ACOs generate savings, allowing ACOs to retain more of their savings and thus strengthening incentives to

[19] In the Proposed Rule, CMS identifies two concerning ways in which ACO spending reductions can lead lower benchmarks and refers to these two ways as “ratchet” effects. The ratchet effects are: (1) downward pressure on an individual ACO’s benchmark resulting from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor; and (2) downward pressure on benchmarks due to program-wide spending reductions across all ACOs. CMS provides that as more Medicare FFS beneficiaries are assigned to ACOs, this program level ratcheting effect diminishes incentives to participate in the SSP.

participate and achieve savings. Vizient supports the need for a revised benchmarking methodology that addresses the "ratchet effect" and provides ongoing financial incentives for providers to continue participating in VBP models. However, as CMS considers benchmarking revisions, Vizient suggests CMS provide additional protections against volatility or a drop in benchmark price. Also, Vizient would be concerned if the administrative growth factor results in even lower benchmarks.

Proposal to Modify Methodology for Determining Scaled Shared Losses for the ENHANCED Track Based on Quality Performance

Currently, an ACO in the ENHANCED track must meet the quality performance standard to have its shared losses scaled and avoid automatically facing the maximum shared loss rate of 75 percent. CMS proposes that for performance year (PY) 2023, and subsequent PYs, CMS would determine the ACO's shared loss rate using a sliding scale approach when an ACO has losses that exceed its minimum loss rate and either meets the existing quality performance standard applicable for the PY or achieves a certain quality performance score. Vizient appreciates the agency's proposal as it would provide more opportunities for shared losses to be scaled, thereby easing risk concerns. Similarly, Vizient suggests CMS explore whether a scaled approach could also be applied considering upside savings, such as for ACOs participating in Basic D or E, as this may help encourage ACOs to take on more risk.

Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

In the Proposed Rule, CMS indicates it is interested in increasing participation in the SSP by easing up-front costs for inexperienced, low-revenue ACOs and supporting those ACOs in providing accountable care for underserved beneficiaries. Vizient appreciates CMS's efforts to support ACOs and believe an initial upfront payment will help inexperienced, low-revenue ACOs. We also encourage CMS to make this payment available to other ACOs that may benefit, such as those that recently joined the SSP. However, we offer various recommendations and insights related to planning, payment amounts, scoring framework, recoupment, and future considerations.

Planning
In the Proposed Rule, CMS notes that more information regarding eligibility and participation as related to the upfront payment will be shared through subregulatory guidance and that the initial cycle to apply for advance incentive payments (AIPs) will be for a January 1, 2024, start date. As CMS is aware, the decision to participate in an ACO takes significant time and planning. Vizient encourages the agency to include potential participants and other stakeholders as it develops subregulatory guidance so that it reflects their input and meaningfully supports their participation. Also, related to the subregulatory guidance, Vizient recommends CMS release this information with adequate time for potential participants to make an informed decision, which may take several months.

AIP Amounts
Regarding the payment amounts to support inexperienced, low-revenue ACOs, CMS provides that it would be comprised of a one-time payment of $250,000 and eight quarterly payments based on the number of assigned beneficiaries (up to 10,000 beneficiaries). While Vizient believes advance payments are critical to fostering participation in the SSP, we question the adequacy of the initial and quarterly payments as it may not be enough to meaningfully encourage participation while meeting the various resource needs of beneficiaries. For example, the quarterly payments may cover an additional staff member, however, when splitting this time over thousands of beneficiaries, the overall benefit may be limited. Vizient encourages CMS to reconsider the AIP amounts including options to increase payments.

Scoring Framework
CMS indicates the AIP amounts would be based on a factors-based score that uses the Area Deprivation Index (ADI) and dual eligibility status. Vizient is concerned this scoring approach could misalign CMS resources by not identifying communities with the greatest need. As shown in Appendix 1, the ADI has several gaps that lead Vizient to recommend that the agency consider an alternative approach, such as the Vizient Vulnerability Index™. For CMS's consideration, Vizient also compared application of the ADI and VVI, to better understand gaps within the ADI that weaken the agency's AIP proposal if not corrected.[20]

To illustrate the impact of selecting an index of neighborhood vulnerability for the purpose of identifying beneficiaries with social needs, we calculated two sets of potential AIP payments. More specifically, using our members' data from 2019-2021, we calculated each hospital's Medicare patients' neighborhood vulnerability using the ADI and the VVI, to compare how the AIP structure would be affected by each index. We assigned ranges of VVI values to the AIP values based on national percentiles, to match the total expenditure and relative payment ranges to that of the ADI-based AIP proposal. As a result of this analysis, we identified significant differences, both potential over-payments and under-payments, in the proposed total payments to a hospital based on the index that is used to calculate the neighborhood vulnerability. Although the ADI includes 17 components, two components (i.e., income and housing) account for almost all of the variation. Alternatively, the VVI has 19 components in 8 social determinants of health (SDOH) domains. Generally, these differences are highly regional, and more pronounced in rural areas.

Vizient believes the following images further illustrate these differences and should prompt CMS to question whether the ADI is the best option for purposes of identifying neighborhoods that are more vulnerable. Generally, based on this information, the potential for underestimating neighborhood vulnerability in those parts of the country with the lowest life expectancy, highest rates of chronic disease and greatest obstacles to care leads to Vizient's reluctance to fully supporting an otherwise commendable effort.

[20] Vizient's analysis was not based on low revenue ACO data, rather, it was based on member hospital data to demonstrate variation between the ADI and VVI and how such variation would impact projected AIP payments.

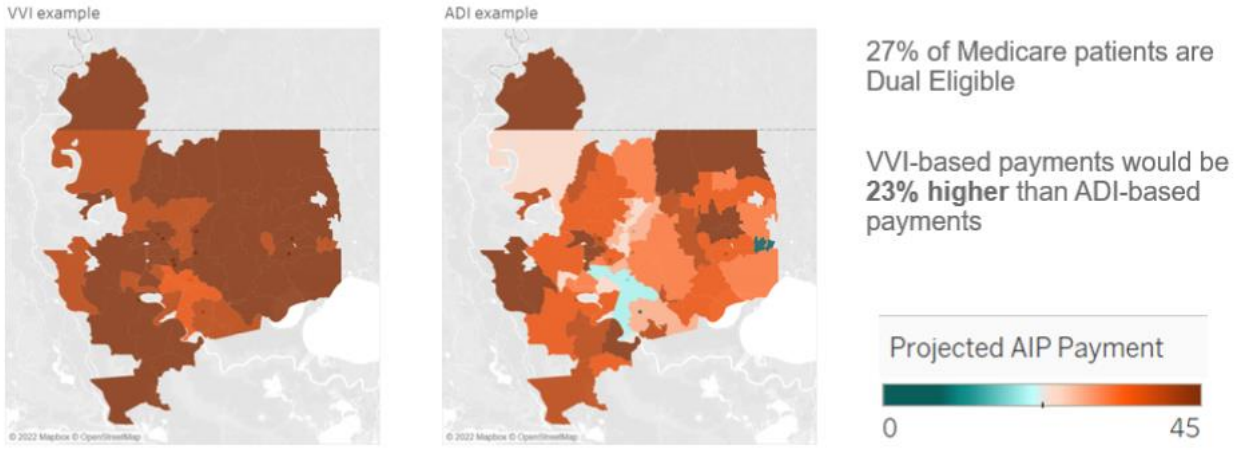

Image 2. In areas of the country that have extremely short life expectancy, high rates of chronic disease and multiple obstacles to care, including the South and Appalachia, the ADI greatly underestimates the neighborhood vulnerability compared with a VVI-based calculation. For example, the above image is a comparison of one hospitals' patients where the hospital is located in a metropolitan area. In areas with extremely short life expectancy, such as the South and Appalachia, member hospitals would have projected payments 20-30% higher with a neighborhood vulnerability calculated using the VVI, rather than the ADI.

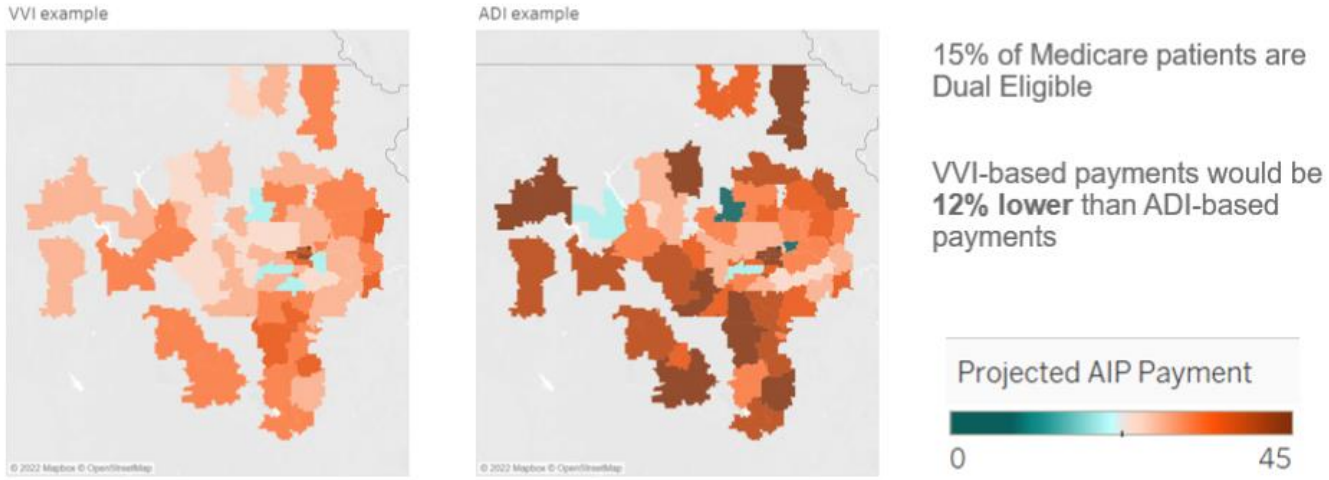

Image 3. Vizient found that areas of New England, the Midwest and Plains states show much lower vulnerability with a VVI-based calculation. The above images provide a comparison within a single state. These are areas with higher life expectancy and lower rates of chronic disease in our member data. A member hospital in one of these locations might have a projected payment more than 10% lower with a VVI-based calculation than with an ADI-based calculation. In other words, based on Vizient's analysis the ADI would result in certain locations receiving additional payments despite being less vulnerable when compared to the VVI which calls into question the use of the ADI for resource allocation purposes given this variability.

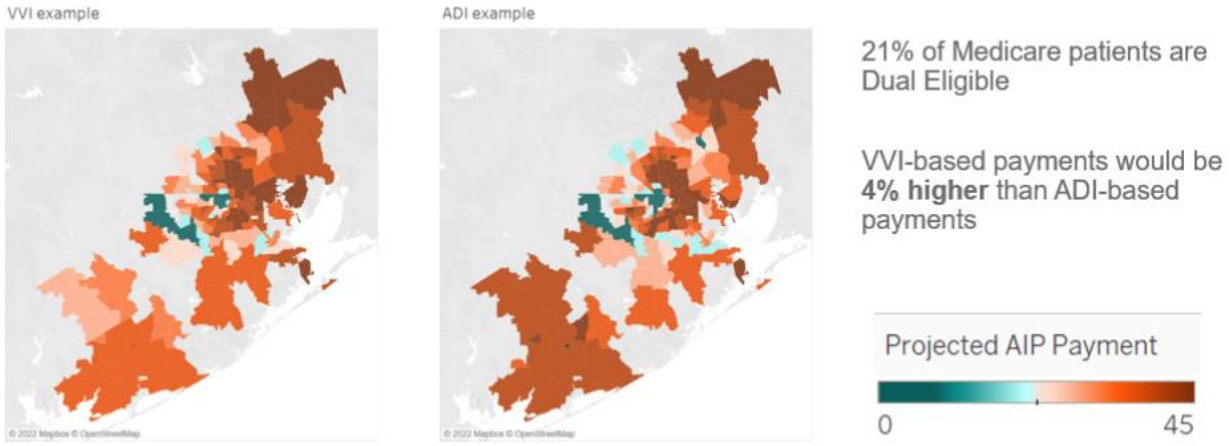

Image 4. In many urban areas, the vulnerability of a neighborhood is only affected in small ways by differences in index weighting. The above image is from a metropolitan area. The heavy reliance of the ADI on income and home values reflects correlations between those two variables and other social risk factors. However, t the strength of this correlation tends to vary geographically, particularly considering cities compared to rural areas. For example, in a densely populated city, neighborhoods with lower income and lower home values are the same neighborhoods with food deserts, lack of broadband, and transportation obstacles, but in a rural area, this correlation would be weaker, making it more difficult to identify social risk factors for rural beneficiaries.

Therefore, based on Vizient's analysis, Vizient urges CMS to, at a minimum, reconsider use of the ADI given its demonstrated limitations. As an alternative, Vizient encourages CMS to use the VVI, which was developed specifically for health equity and when applied, can provide more accurate insights to inform a broader health equity strategy.

Recoupment

In addition, regarding recoupment, CMS proposes to recoup AIPs from any shared savings earned by the ACO in any PY until CMS has recouped all AIPs. If the shared savings are insufficient to recoup the AIPs made to an ACO for a PY, CMS would carry forward the balance owed to the subsequent PY(s) in which the ACO achieves shared savings. If an ACO terminates its participation agreement during the participation period, the ACO must repay all AIPs it received. Vizient is concerned this recoupment process may discourage participation as it would be difficult for the ACO to terminate or change its participation agreement or transition smoothly out of the ACO as balances would carry forward or need to be repaid. Vizient encourages CMS to consider whether AIPs could have more flexible recoupment terms or opportunities to receive shared savings while AIPs are being recouped, such as issuing the AIP interest free, or extending the payment time for recoupment.

Future Considerations

More generally, given CMS's focus appears to be including health equity, in addition to shared savings, Vizient suggests CMS develop a longer-term strategy that more prominently demonstrates this shift. While Vizient appreciates the additional lower risk options CMS has proposed and AIPs we suggest the agency more carefully consider policies to support health equity in the context of the SSP, such as data standardization, measurement, infrastructure and support, and incentives. For example, while CMS may be providing an AIP and providing guidance regarding use, measurement is still lacking. Additionally, there are not assurances that the health information technology (HIT) infrastructure is developed. This will only exacerbate barriers providers face, particularly as patients, communities, and care systems more broadly rely on a baseline HIT infrastructure.

Also, Vizient encourages CMS to work with different government agencies to identify ways to further support hospital's equity efforts in the context of other requirements, such as the Internal Revenue Service to better align Community Health Needs Assessments with the administration's broader health equity strategy. These types of efforts will help reduce both provider burden through improved information sharing and streamline hospital's strategies.

Health Equity Bonus Points for ACOs that Report All-Payer eCQMs/MIPS CQMs, and are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries

In the Proposed Rule, CMS proposes to create a health equity adjustment (through the form of bonus points) designed to support those ACOs serving a high proportion of underserved individuals while also mitigating disparities in health care by encouraging all ACOs to treat underserved populations. Vizient agrees with the need to consider adjustment options, particularly those that function as a bonus, to support ACOs serving a high proportion of individuals who are underserved. Vizient offers various recommendations for CMS's consideration regarding the health equity bonus points.

Generally, Vizient recommends that CMS modify programs so that they better address different aspects of health equity, rather than only encouraging ACOs to serve underserved populations without further guidance. There are a range of complex issues at various levels (i.e., intrapersonal, interpersonal, institutional, community and systemic) that impact a patient's health care journey. As such, efforts are needed to address each level, but for CMS's purposes, it is important that the agency consider which aspects are within the ACO's locus of control and tailor policies accordingly. Vizient welcomes the opportunity to discuss future longer-term approaches with the agency.

Underserved Multiplier Considerations
CMS clarifies the level of adjustment would be determined based on both the ACO's performance on quality measures and the population served by the ACOs (e.g., higher proportion of beneficiaries who are from underserved neighborhoods) or dually eligible for Medicare and Medicaid. Also, CMS proposes to use an "underserved multiplier" for each ACO that would be determined using the higher value of either the proportion of an ACO's assigned beneficiary population that is considered underserved based on beneficiaries who are from underserved neighborhoods; using ADI data; or using the proportion of an ACO's assigned beneficiary population that are dually eligible for Medicare and Medicaid. CMS would then multiply this underserved multiplier by a measure performance scaler to determine the ACO's health equity adjustment bonus points.

As noted above, Vizient has significant concerns regarding the ADI and recommends that CMS reconsider its use. Although the ADI includes seventeen different factors related to education, income, employment, housing, and household characteristics, the relationships among the specific variables chosen result in an index that is heavily weighted toward income and home values with very little contribution from the other variables. Also, as noted above, this weighting provides a poor fit to life expectancy, especially in rural areas of the South and Appalachia. Therefore, there are opportunities to improve the ADI, particularly in the South and Appalachia regions.

In an analysis of Vizient members' data where we considered dual-eligibility, the ADI and the VVI identified the following key insights regarding the underserved multiplier:

- When assessing neighborhoods as vulnerable using the VVI and ADI, both at the 85th percentile of each index,[21] just over one third of hospitals would have a higher neighborhood-based assessment of underserved population than their dual-eligible proportion, so Vizient agrees, there is a significant need to identify beneficiaries living in highly vulnerable locations using a method other than dual eligibility status given such a large proportion would be identified by an index.
- Although the total number of hospitals eligible to receive additional points would be similar, the specific hospitals and the scale of their projected bonus points are quite different based on the use of the ADI or the VVI.
- The ADI particularly underestimates neighborhood vulnerability compared with the VVI for hospitals in Louisiana, Tennessee, Mississippi, Georgia, and South Carolina.

As we noted above, the use of the ADI risks underestimating the vulnerabilities of neighborhoods where we see the lowest life expectancies and highest burden of chronic disease.

Future Considerations
More generally, Vizient suggests that CMS develop a longer-term equity-specific plan that also includes incentives to care for beneficiaries with more social needs. Further, we encourage CMS to explore how community organizations can also be included within broadened ACOs. Vizient believes such a shift in the scope of ACOs participating would help share resources and broaden the scope of social risks that that may be within the control of a more holistic ACO that includes community organizations.

Request for Information on Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measure and Future Measure Development

In the Proposed Rule, CMS indicates it is considering adopting health equity measures related to screening: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. Consistent with Vizient's comments to the National Quality Forum Measure Application Partnership, we believe both measures can be improved, but are particularly concerned with the Screen Positive Rate for Social Drivers of Health Measure. Vizient also offers recommendations regarding future measure development.

Screening for Social Drivers of Health Measure
Regarding the Screening for Social Drivers of Health measure, Vizient is concerned that the measure lacks a definition of "screening" and "social drivers of health" as related to this measure. Clear and consistent definitions are critical to collecting data that can be meaningfully used by the health care system to improve outcomes for patients. In addition, defining such terms also supports identification and use of validated screening tools. Without consistency, it will be difficult for ACOs to address patient needs and risks identified during the screen, and potentially harm patients by impairing their ability to efficiently access needed services, creating confusion if communication between health

[21] As proposed by CMS, an 85 risk-factor based score would reflect a beneficiary not dually eligible residing in a census block group with an ADI in the 85th percentile. The per beneficiary payment amount would be $45, which is equivalent to the payment amount for dually eligible beneficiaries.

systems is inconsistent. We recommend that CMS defines these terms clearly prior to advancing use of the measure.

In addition, Vizient is concerned that including the Screening for Social measure before there is a standard approach for collecting screening data related to social drivers of health will limit the utility and comparability of collected data. Standardization is critical for ensuring that patient data collected by health systems can be effectively utilized to address community needs and ensure that future measures promote community-wide improvements in social drivers of health. A risk of approving this measure without standards is that inconsistent data collection will yield incomplete or unusable data sets, which could make any future analysis for development of new measures to addressing social drivers difficult. We encourage CMS to work with stakeholders to define and set the standard for data collection to ensure the patient data collected will be used to promote health equity.

Screen Positive Rate for Social Drivers of Health
While Vizient agrees that it is important measure the impact of social drivers of health for patients, Vizient does not believe the Screen Positive Rate for Social Drivers of Health measure achieves this goal or provides meaningful information. Vizient wholly supports efforts to increase screening all patients for social drivers of health, however this measure lacks standardization for data collection and lacks clarity regarding the denominator (i.e., patients to be screened) or the numerator (i.e., what constitutes a positive screen). Without clear definitions of who to screen or what constitutes a positive screen, it will be difficult to meaningfully interpret the data collected or benchmark. Also, without these definitions, the publicly reported data could be misleading.

In addition, the measure does not account for differences by geography. Vizient's analyses have shown significant variation in community need across large geographic areas as well as within local markets at the zip code level. Similar to the need for definitions, without accommodations for geographic variation, interpretation of these data when reported publicly could be misleading. Vizient notes that accommodations for geographic variation could be achieved through benchmarking using an index of local obstacles to care (e.g., Vizient Vulnerability Index). Vizient has recently reviewed several state and national indices intended to help provide benchmarks for community need and found an opportunity to expand upon these indices to ensure standardization across the country and also tie community need to hospital performance.

Vizient is willing to work with CMS to leverage our analysis or conduct a similar analysis to evaluate current indices and address gaps before selecting a standard. Vizient notes our concern that data lacking such accommodations could potentially disadvantage hospitals or providers with higher levels of community need. Collectively, the aforementioned issues related to data collection standardization and geographic differences also limit the utility of the collected data for future analysis; namely specific measures to promote addressing social drivers of health for patients. Before advancing policies that include this measure, we recommend CMS provide clear standards for defining the populations to screen, as well as clearly defining a positive screen for those populations. These definitions should be grounded in currently available data and tested indices should be leveraged to provide a standard approach, especially for correcting for geographic variation. Without these definitions and corrections, the likelihood of negatively impacting both reporting hospitals and providers as well as patients is high, and Vizient cannot support its use.

Future Measure Development
Vizient encourages CMS to develop a baseline measure that evaluates community characteristics (e.g., life expectancy), in addition to more focused measures that can support longer life expectancies. To support future measurement development, Vizient recommends CMS adopt the

following principles, consistent with our recommendations in our IPPS proposed rule comments, related to measure selection when inclusion of health equity performance is being considered:

- Measures should be within the ACO's locus of control (i.e., a combination of outcome process measures that ACOs have direct influence/control over);
- Measures should be defined and based on clinically meaningful and cohesive patient populations; and
- Identify those measures in which 100% of the patients should receive care or "zero harm" measures for reporting.

Once these measures have been identified and defined, to drive performance improvement, Vizient recommends CMS provide detailed assessments for ACOs to review. These assessments can include meaningful stratification (e.g., race, ethnicity, gender) but must be thoughtful regarding the appropriateness of social risk factors for risk adjustment. It is critical that risk adjustment not be used to mask disparities.

Lastly, Vizient responds to the agency's question on whether measures to drive health equity and health outcomes should be considered in pay-for-reporting measures. Given the various concerns Vizient has outlined regarding currently developed measures, we would not recommend these measures be considered to be pay-for-reporting measures.

Updates to the Quality Payment Program

Transition from Traditional MIPS to MIPS Value Pathways

In the CY 2022 PFS Proposed Rule, the agency provided additional insights regarding the potential sunsetting of traditional MIPS and transition to MIPS Value Pathways (MVPs). While CMS does not provide more information regarding this potential transition in the Proposed Rule, Vizient encourages the agency to work closely with providers before establishing a timeline and ensure that there are a sufficient number of MVPs before the transition occurs.

APM Incentive Payment

Under the Quality Payment Program (QPP), an eligible clinician who is a Qualifying APM Participant (QP) for a performance year earns an APM Incentive Payment, which is made in the corresponding payment year for payment years 2019 through 2024. The APM Incentive Payment is equal to 5 percent of the eligible clinician's estimated aggregate payments for covered professional services in the base period. After performance year 2022 (payment year 2024), there is no further statutory authority for a 5 percent APM Incentive Payment for eligible clinicians who become QPs for a year. CMS recognizes that the lack of financial incentives under the QPP for QPs for the 2023 performance year (2025 payment year) could reduce eligible clinicians' participation in Advanced APMs. Vizient agrees with CMS's concerns that without the financial incentives under the QPP for QPs for the 2023 performance year, eligible clinicians may be less inclined to participate in Advanced APMs. While Vizient understands a legislative change would be required to extend the payments, we encourage the agency to consider whether additional upside opportunities may be available for ACOs participating in Base D and E. For example, offering a sliding scale for upside savings between 50 percent and 75 percent may continue to entice ACOs to enter into or progress along a higher risk glidepath.

Request for Information – Approaches for Health Equity Measurement in Traditional MIPS and MIPS Value Pathways

In the Proposed Rule, CMS indicates it is interested in feedback regarding the approach for health equity measurement in traditional MIPS and MVPs. Vizient applauds CMS for its continued focus on health equity and efforts to gain stakeholder feedback before advancing policy. Vizient responds to various questions posed by CMS, as noted in the following sections.

Generally, as CMS looks towards sunsetting traditional MIPS, Vizient believes it is important that health equity measurement approaches be translatable from traditional MIPS to MVPs, in addition to other Medicare quality reporting and performance programs, such as those included in the Inpatient Prospective Payment System. While Vizient is not commenting on the health equity related measures CMS proposes to include in proposed new MVPs, we do appreciate the agency's efforts to more carefully consider health equity measures in the context of MVPs. To the extent CMS is considering measures to include in the foundational layer, Vizient would need more clarification from CMS regarding such a measure before responding to whether it should be included.

Capturing Health Equity Needs Under MIPS in the Future
In the Proposed Rule, CMS asks "How would a measure best capture health equity needs under MIPS in the future?" In response, Vizient encourages the agency to consider our comments regarding measurement considerations for the SSP. For example, Vizient believes it is critical that there is a common set of working definitions, an understanding of the provider's locus of control, consistent data standards, and clarity and prioritization of health equity needs.

As CMS considers health equity needs, Vizient notes that there is a tremendous amount of publicly available data that can be used to identify health inequities. Vizient recommends leveraging indices that rely on publicly available data, such as the VVI, to help identify these social needs. However, while Vizient understands the importance of asking the patient about their social needs, we recognize the challenges associated with asking a patient about their social needs when the providers are not equipped to address those needs. In turn, Vizient recommends leveraging the VVI to help identify health equity needs as a more supportive ACO structure is developed to help providers address those needs.

As CMS considers feedback from the RFI, we also encourage the agency to clarify whether it is focused on health equity (e.g., health of the community or population) or health care equity (e.g., provider's locus of control). Such information will help inform stakeholders' responses and recommendations to the agency.

Actionable Information
Vizient believes that is possible for a measure's quality action to provide actionable information and link to the quality of care provided to populations with health inequities, however, we recognize the challenges CMS faces in developing such a measure. Based on Vizient's experience, and as noted elsewhere in our comments, we believe that it is critical that the providers' locus of control be considered when developing quality measures as this will also relate to whether the measure provides actionable information.

In addition, Vizient encourages the agency to work with providers to carefully consider what outcomes are within their locus of control and to consider that information in the context of social needs. For example, Vizient suggests CMS consider the domains of the social determinants of health at the community-level and also consider geographic variability when considering when information is truly actionable. To provide actionable insights, a range of factors must be considered. We continue

to recommend the VVI be utilize in this context and welcome the opportunity to discuss how CMS may best leverage it. Also, we urge CMS to be cautious in utilizing indices or measures that are not designed to serve health equity-related purposes or may not provide sufficiently granular or actionable information related to social risk factors.

Limitations in Data Interpretation if a Future Health Equity-Related Measure Would Not Be Risk-Adjusted
In the Proposed Rule, CMS seeks comment on the limitation in data interpretation if a future health-equity related measure would not be risk-adjusted. Vizient appreciates that CMS is seeking feedback on implications of not risk adjusting measures as we have cautioned the agency not to risk adjust away certain factors which could mask disparities. Through Vizient's health equity work, we recognize that SDOH can be categorized into several different layers: systemic, community, institutional, interpersonal, and intrapersonal. While it is challenging for Vizient to opine on issues that may emerge if no risk adjustment is provided given the measure in question is unknown, we would have concerns that the potential insights gleaned would be misleading. For example, a patient located in an area with a shortage of primary care providers may have more difficulty accessing treatment which may lead to poorer outcomes. Yet, providers in such areas may be perceived as providing lower quality care if different SDOH layers are not considered. Therefore, we emphasize the importance of taking a thoughtful approach to risk-adjustment to ensure it does not mask disparities while at the same time, developing a more refined measurement framework for measures that include influences beyond the providers locus of control, such as 30-day readmissions.

Concerns if a Future Health Equity-Related Measure Did Not Specify Requirements for Use of Consistent Tool(s) for Data Collection under such a Measure
In the Proposed Rule, CMS seeks input on potential issues with a future health-equity related measure that does not support flexibility in choice of tools for data collection. In addition, CMS seeks comment on whether such a tool should require standardized coding of responses to support interoperability. Vizient continues to advocate for data standards and standardized approaches to data collection. However, we are also aware of the significant time and work needed to optimally collect data in standardized and interoperable fashion. As such, Vizient encourages CMS to work with stakeholders, including hospitals and the Office of the National Coordinator for Health Information Technology to layout a longer-term plan to achieve this goal.

Further, Vizient understands that the Office for Civil Rights may also be considering data collection requirements for covered entities as part of the proposed rule regarding Section 1557 of the Affordable Care Act.[22] Vizient urges collaboration and would be concerned if multiple, disjointed approaches to data collection were being imposed on providers.

Potential Approaches for Measuring Health Equity in MIPS and MVPs
In the Proposed Rule, CMS indicates that it is seeking to encourage clinicians to collect social risk information. Vizient appreciates the agency's efforts to encourage collection of race data, and suggests that agency build upon this work by creating data standards that better capture a person's culture to more accurately represent the individual, especially when compared to race.

[22] https://www.federalregister.gov/public-inspection/2022-16217/nondiscrimination-in-health-programs-and-activities

Research has demonstrated that race, a social construct, is inadequate in not only capturing a person's cultural or ethnic background, but also holds no clinical relevance or value to clinicians.[23] Vizient recognizes race has been an attribute used to evaluate differences between populations in healthcare for some time; however, Vizient believes focusing data collection efforts on race runs the risk of further perpetuating society's focus on a social construct initially created for the purposes of segregation and suppression. Vizient urges CMS to elevate Federal data capture efforts to focus more on culture, rather than race as it does not adequately capture the cultural elements needed to better understand a person. Vizient recognizes this pivot would be a shift, but an important one.

As CMS is aware, providers have struggled with data completeness, accuracy and how to operationalize rEAL data collection and measuring progress. In response, Vizient developed a data health and health care equity measurement maturity model, as outlined in Image 5, that focuses on the completeness, accuracy and integration of data regarding a patient's culture and ethnic background. As shown in Image 5, Vizient defines maturity based on our focus of aligning data collection that reflect the community, more specifically cultural information (ethnicity, ancestry, and language - rEAL).

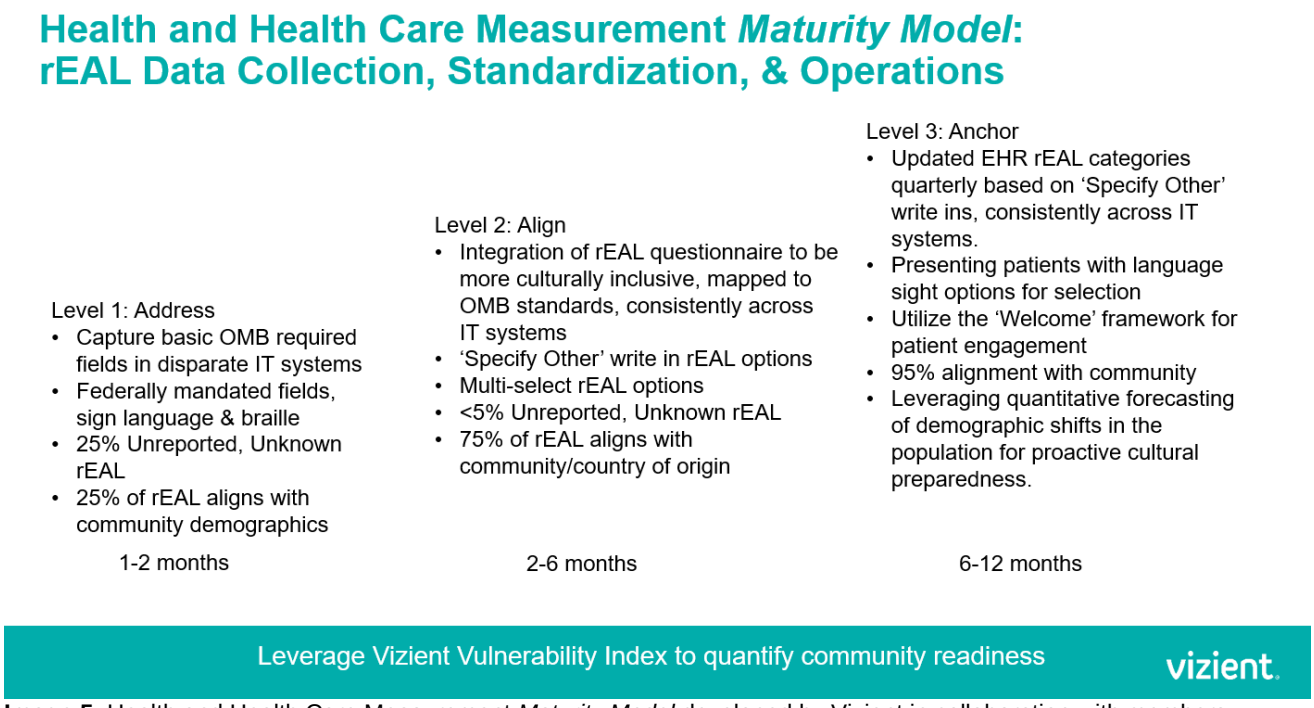

Image 5. Health and Health Care Measurement *Maturity Model* developed by Vizient in collaboration with members.

The outline of the framework described in Image 5 represents providers' organizational goals regarding rEAL data collection and is based on three levels: address, align, and anchor. Vizient and our provider members use the address, align, and anchor framework to describe an organization's scope of impact on health equity, with "address" indicating a scope that includes clinical manifestations of SDOH, "align" indicating a scope that includes patient social needs, and "anchor" indicating a scope that includes social and structural determinants of health for the community. In this

[23] Jones CP. Levels of racism: a theoretic framework and a gardener's tale. Am J Public Health. 2000;90(8):1212-1215

context, “address” focuses on standard data collection efforts that support required reporting. “Align” incorporates more integration within the organization and the community rEAL data collection efforts. “Anchor” deepens the organization’s focus beyond their four walls and considers the changing dynamics of the community. Vizient also recognizes that different communities may have more readiness or willingness to provide and collect cultural information. To better understand communities and inform next steps, Vizient encourages providers to use the VVI for a community readiness assessment. Along those same lines, we recommend CMS consider a similar framework supporting providers to understand their goals and to support CMS in setting the appropriate expectations for rEAL data collection.

Use of a Standardized Tools with Coded Questions and Data Elements to Collect Self-Reported Patient Characteristics Across Clinicians and Practices
Vizient believes a standardized framework would be very meaningful for providers and allow for benchmarking and gap assessments. Otherwise, it is difficult to measure impact and change.

Use of a Consistent Screening Tool(s) to Collect Social Drivers of Health Information
Vizient supports a consistent screening tool but believes it must be designed in a way that supports ‘additional needs’ not listed within the standard format so that those can be captured and incorporated into future iterations of the needs assessment. Vizient recommends standardization be designed with future flexibility in mind. Also, Vizient does have concerns that providers may be required to ask about social needs that the providers are unable to support.

Unless a structure is put in place to support providers and the community they serve, collecting this information will be very challenging, frustrating, and potentially create further divide between the patient, provider, and community support.

In addition, Vizient encourages CMS to consider our comments regarding the health equity related screening measures provided above.

Appropriateness of a Quality Measure to Assess Clinician Referrals to Community-Based Services Upon Screening for a Social Driver of Health
Vizient does not believe it would be appropriate to develop a quality measure that assesses clinician referrals to community-based services upon screening for social drivers of health at this time. There is significant foundational work that needs to be developed based on the country’s current lack of data standardization, limited structural support and funding. It would be very challenging, at this point, to think about assessing clinician referral performance. Vizient encourages CMS to more meaningfully and thoughtfully advance definitions, data collection, and standardization prior to evaluating any provider performance.

Assessing Patient-Clinician Communication and Receipt of Appropriate Language Services
Vizient appreciates the approach CMS is considering regarding receipt of services. However, to develop such a measure, Vizient believes there are fundamental components that would need to be carefully considered. For example, how do you standardize data questions regarding language? Is the focus on written or spoken language? Vizient requests that CMS provide more clarity on what type of language services the agency aims to assess. Vizient recommends CMS consider a ‘Welcome’ packet that each patient receives that asks questions regarding a patient’s culture and ancestry as it pertains to patient care. In addition, as regulations related to Section 1557 of the Affordable Care Act have been proposed, we suggest that CMS and the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) work collaboratively to identify opportunities to support patient access to language services.

Conclusion

Vizient welcomes CMS's efforts to update the PFS and other payment policies impacting providers. We appreciate the agency's various requests for comment, which provide an opportunity for stakeholders to inform the agency on the impact of specific proposals.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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Appendix 1.

Vizient's comparison of different indices considered for health equity applications.

	Area Deprivation Index	Distressed Communities Index	Social Vulnerability Index	Intercity Hardship Index	Child Opportunity Index	AHRQ Socioeconomic Status Index	Vizient Vulnerability Index
Data granularity	× County × Zip Code × Census Tract ✓ Block Group	✓ County ✓ Zip Code × Census Tract × Block Group	✓ County • Zip Code possible ✓ Census Tract • Block Group possible	• County possible • Zip Code possible • Census Tract possible • Block Group possible	× County ✓ Zip Code ✓ Census Tract × Block Group	× County × Zip Code × Census Tract ✓ Block Group	✓ County ✓ Zip Code ✓ Census Tract ✓ Block Group
Timeliness	Updated in 2015 and 2019	Updated annually	Updated every two years	Not provided at the national level; algorithm available	2010 and 2015	Updated in 2015 and 2019	Updated annually
Social Determinants of Health Domains	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Health Systems ✓ Transportation ✓ Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Health Systems × Transportation × Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Health Systems ✓ Transportation ✓ Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Health Systems × Transportation × Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Health Systems × Transportation ✓ Social Environment ✓ Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Health Systems × Transportation × Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing ✓ Health Systems ✓ Transportation ✓ Social Environment ✓ Physical Environment × Public Safety (in development)
Health Care Focus	✓ Life Expectancy / Mortality × Chronic Disease Prevalence ✓ Readmissions × ED utilization × Maternal Health	× Life Expectancy / Mortality × Chronic Disease Prevalence × Readmissions × ED utilization × Maternal Health	× Life Expectancy / Mortality × Chronic Disease Prevalence × Readmissions × ED utilization × Maternal Health	× Life Expectancy / Mortality × Chronic Disease Prevalence × Readmissions × ED utilization × Maternal Health	✓ Life Expectancy / Mortality ✓ Chronic Disease Prevalence × Readmissions × ED utilization × Maternal Health	✓ Life Expectancy / Mortality × Chronic Disease Prevalence ✓ Readmissions × ED utilization × Maternal Health	✓ Life Expectancy / Mortality ✓ Chronic Disease Prevalence ✓ Readmissions ✓ ED utilization ✓ Maternal Health
Measurement Focus	17 components 2 components account for almost all of the variation (income and housing) Intended to predict mortality, but a poor fit to life expectancy (r^2 0.25)	7 components 2 components account for almost all of the variation (income and housing) Intended to describe economic differences; poor fit to life expectancy (r^2 0.31)	14 components in 4 domains, 2 components account for almost all of the variation (income and education) Intended for disaster management planning; poor fit to life expectancy (r^2 0.20)	6 components 2 components account for almost all of the variation (income and education) Intended to describe economic differences; poor fit to life expectancy (r^2 0.14)	29 components in 3 domains no serious issues with partial correlations Reports a moderate relationship to life expectancy (r^2 0.43)	7 components no serious issues with partial correlations Intended to describe economic factors related to health care access; poor fit to life expectancy (r^2 = 0.30)	19 components in 8 domains. All are significant in different locations Intended to describe differences in life expectancy (r^2 0.63)
Geospatial Adjustments	Single index algorithm for the whole country	Single index algorithm for the whole country. Small zip codes excluded	Single index algorithm for the whole country	Single index algorithm for the whole country	Single index algorithm for the whole country, but with state or local standardization options	Single index algorithm for the whole country	Index adapts to local relevance of each domain as it correlates with life expectancy