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September 13, 2021

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 Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2022 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 50% of the nation's acute care providers, which includes 95% 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 $100 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 proposal. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the calendar year (CY) 2022 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule.

Payment Amounts

In the Proposed Rule, CMS estimates a conversion factor of $33.58, which is a 3.75% reduction from 2021. Notably, this estimate does not include forthcoming cuts related to sequestration and the statutory Pay-As-You-Go Act of 2010 being triggered as it relates to spending associated with the American Rescue Plan Act. Collectively, these cuts would total 9.75%, which is detrimental to providers. Vizient urges CMS to reiterate this concerning information to Congress as advocacy efforts

to limit such cuts are underway. Also, Vizient encourages CMS to consider whether any regulatory flexibilities can be utilized to minimize harm to providers in CY 2022, given these declining payment amounts.

Determinations of Practice Expense Relative Value Units

The Practice Expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses. Direct expense categories include clinical labor, medical supplies and medical equipment. Indirect expenses include administrative labor, office expenses and all other expenses. PE Relative Value Units (RVUs) are developed considering the direct and indirect practice resources involved in furnishing a service.

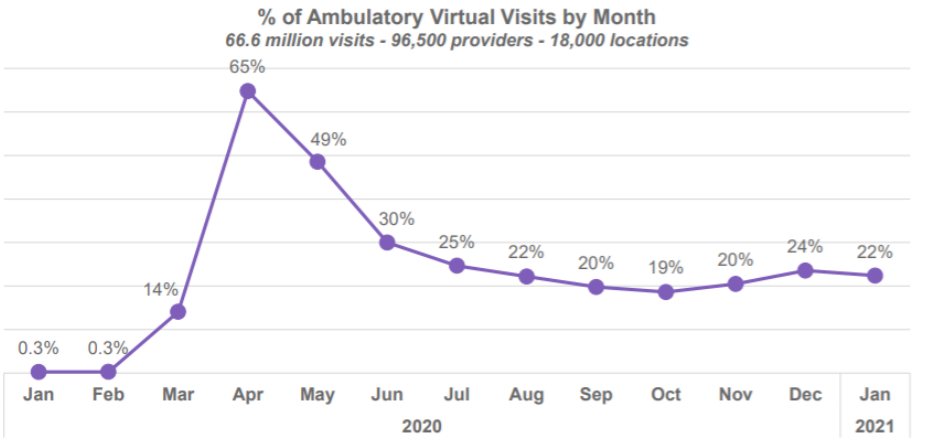
For CY 2022, CMS proposes to update clinical labor pricing, as clinical labor rates were last updated in 2002. CMS proposes to continue to rely on a methodology outlined in the CY 2002 PFS final rule to calculate updated labor pricing. While Vizient appreciates CMS's efforts to update the PE input database, we are concerned about the financial consequences of the update due to budget neutrality requirements. Any increase in clinical labor prices would lead to other decreases, which may negatively impact certain specialties more than others, leading to broader disruptions. Vizient recommends CMS work with Congress to advance more flexible payment policies that are not limited by budget neutrality requirements.

Regarding the clinical labor pricing update, Vizient recommends CMS take a slower, phased approach to implementation of this clinical labor pricing update. CMS notes it considered a four-year phase-in period, which Vizient believes would cause less disruption than a single update. Vizient also encourages the agency to work with stakeholders to consider a potentially longer phase-in period should legislative approaches not advance.

Telehealth and other Services involving Communications Technology

In the Proposed Rule, the agency provides various policies related to telehealth and the flexibilities the agency provided during the COVID-19 Public Health Emergency (PHE). To better understand telehealth utilization during the pandemic, we highlight for the agency an analysis[1] that is derived from the Clinical Practice Solutions Center (CPSC) which was developed by the Association of American Medical Colleges (AAMC) and Vizient. The analysis provides insights regarding the effects of the COVID-19 PHE on telehealth. For example, as shown in the following graph, although telehealth visits spiked in March 2020, the share of all ambulatory visits conducted virtually level off and range between 19-25 percent through January 2021. Thus, telehealth remains a consistent and critical means of delivering care, even after initial spikes in utilization.

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



Includes all visits with Site of Service: Telehealth, Office, On Campus Outpatient Hospital and Off Campus Outpatient Hospital. Standard visit codes (e.g. 99211-99215) are categorized as online visits if billed with telehealth service site or modifier.

Adding Services to the Medicare Telehealth Services List for CY 2022

CMS maintains a Medicare telehealth services list and has a long-standing process for adding or deleting services from the list on either a Category 1 or Category 2 basis.[2] In the CY 2021 PFS Final Rule, CMS created Category 3, to temporarily add services to the telehealth list following the end of the COVID-19 PHE. For CY 2022, the agency indicates it received several requests to permanently add various services to the Medicare telehealth services list. However, CMS indicates none of the requests were received by the February 10 submission deadline for Category 1 or Category 2 criteria for permanent addition. Given the attention telehealth has received during the pandemic and that requests 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.

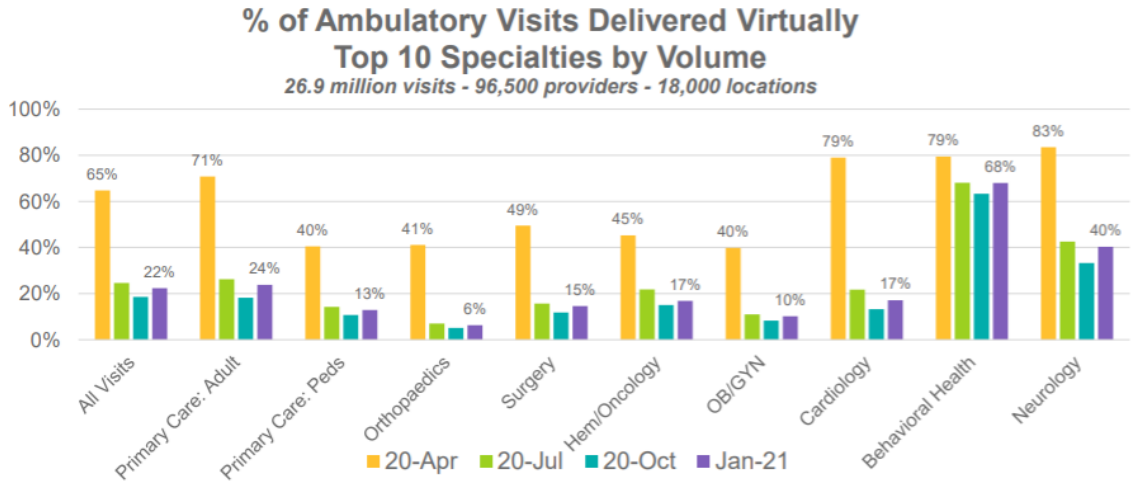
As noted in previous comments, Vizient appreciates the flexibility CMS has provided to enable patient access to an array of telehealth services during the PHE. While CMS has agreed to add several services permanently or temporarily to the telehealth list, Vizient encourages the agency to regularly seek information regarding new services that should be added on a permanent or temporary basis.

Also, in the Proposed Rule, CMS lists many services that are on the expanded telehealth services list for the PHE, but are not proposed to be added to Category 3. Vizient encourages the agency to be mindful of the access implications of abrupt changes in coverage, which collectively, could have significant implications for patient care. Given Category 3 lists services that are temporarily covered and will be studied by CMS, Vizient suggests CMS be liberal in adding services to Category 3, particularly those services which are available during the PHE but not listed in Category 3. To the extent CMS believes there is a safety or quality concern associated with providing certain services via telehealth, Vizient encourages the agency to share that information with stakeholders and also seek their input.

[2] 1834(m)(4)(F)(ii) of the Social Security Act

Revised Timeframe for Consideration for Services Added to the Telehealth List on a Temporary Basis
In the CY 2021 PFS Final Rule, CMS indicated any services added on a temporary basis under Category 3 would remain on the Medicare telehealth services list through the end of the calendar year in which the PHE for COVID-19 ends. To respond to stakeholder concerns regarding the uncertainty of the duration of the COVID-19 PHE, CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. Vizient appreciates CMS's decision to extend this temporary period of coverage as the agency learns more about the need to make these services permanently available. Given there could be instances after 2023 in which the agency may still believe it has insufficient data regarding certain telehealth services, Vizient encourages the agency to extend coverage until such information can be ascertained.

Notably, not all telehealth services available during the PHE will be available until the end of CY 2023, such as certain cardiac rehabilitation services which were added to the Medicare telehealth list temporarily in October 2020. As demonstrated in the below table, Vizient is aware of many different specialties providing care via telehealth and encourages broader extension of the availability of telehealth services, including those that are not currently listed as Category 3. Since CMS's current policy would end the availability of these services when the PHE for COVID-19 ends, Vizient is concerned patients will be harmed or care interrupted should coverage abruptly end. To help address these concerns, Vizient suggests that the agency add these services to Category 3.



Includes all visits with CMS Site of Service: Telehealth, Office, On Campus Outpatient Hospital and Off Campus Outpatient Hospital.

Implementation of Provisions of the Consolidated Appropriations Act, 2021 Pertaining to Medicare Telehealth Services

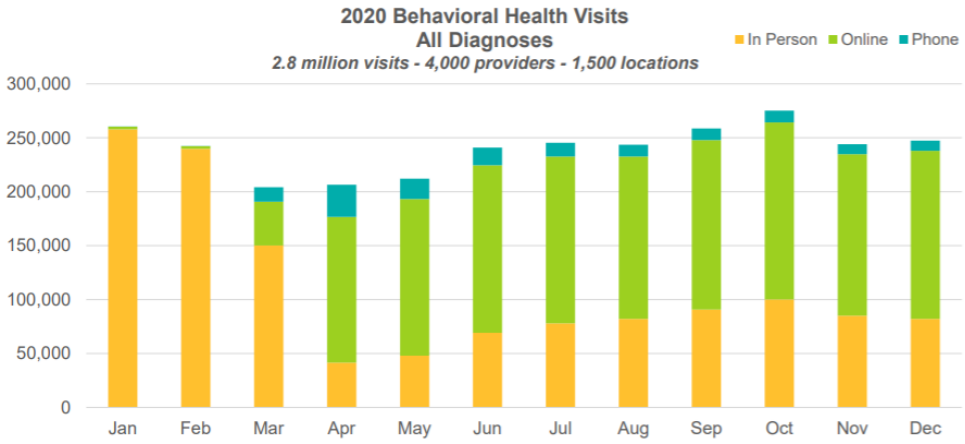
The Consolidated Appropriations Act, 2021 (CAA) modified the Medicare statute to allow the patient's home to be a permissible originating site for mental health services under certain circumstances. Vizient appreciates Congress's efforts to expand access to mental health services provided via telehealth in the patient's home, but we provide various recommendations to better support patient access to the mental health services provided in the CAA. Also, we note our continued support of additional legislative solutions to enhance access to access to telehealth services with fewer restrictions.

Per the CAA, the scope of telehealth services now includes services furnished for the purpose of diagnosis, evaluation or treatment of a mental health disorder, effective for services furnished on or

after the end of the COVID-19 PHE. While the CAA did expand access to mental health services, the law prohibits payment for such mental health services (other than for the treatment of a diagnosed substance use disorder (SUD) or co-occurring mental health disorder) unless the physician or practitioner first furnishes an item or service in-person, without the use of telehealth. As a result, CMS proposes that the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period[3] before the date of the telehealth service and the medical record documentation must distinguish between the telehealth and non-telehealth mental health services.

While Vizient does not believe the in-person requirement is necessary for all patients, we recognize that Congress has required CMS to implement this element of the law. We encourage CMS to be flexible in its interpretation of the in-person requirement, For example, as an alternative to the billing provider furnishing the in-person service, as considered by CMS, we recommend the agency allow the in-person visit to be furnished by another physician or practitioner in the same specialty/subspecialty within the same group as the physician or practitioner who furnishes the telehealth service.

Related to this point, to the extent possible, Vizient recommends CMS broaden their interpretation of the in-person requirement so that it does not unnecessarily limit access to care for patients who may be unable to see a provider in-person every six months. As noted in the below table, a significant proportion of patients receive behavioral health services via telehealth. Vizient is concerned that patients may be unable or unwilling to see a provider in-person and that this requirement will limit access to care. Further, for patients who have grown accustomed to receiving only virtual services in 2020 and 2021, a requirement for an in-person visit every six months could lead to gaps in care, patients paying out-of-pocket due to adverse coverage decisions or patients foregoing care. Vizient encourages CMS to consider potential exceptions to the in-person requirement or circumstances in which no subsequent in-person visits would be required.



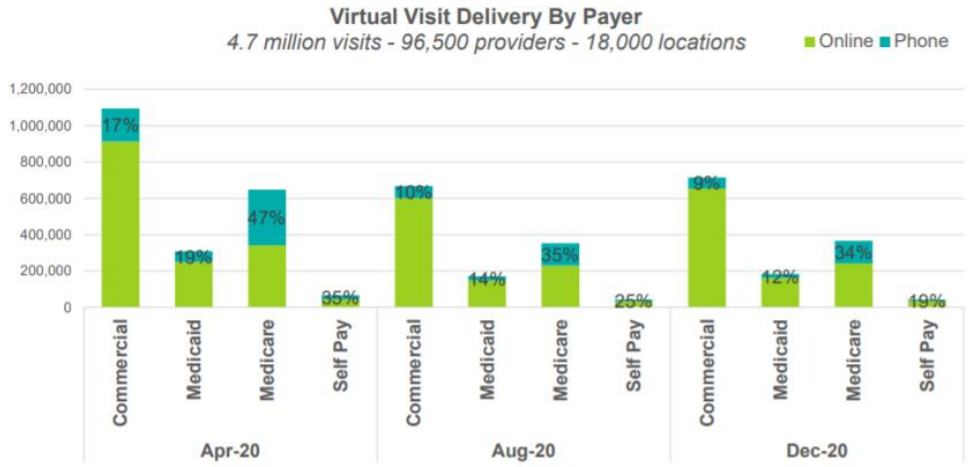
Includes visits with behavioral health providers, including psychologists, psychiatrists and social workers and CMS Site of Service: Telehealth, Office, On Campus Outpatient Hospital and Off Campus Outpatient Hospital.

[3] Given mental health services may be furnished on or after the first day of the end of the PHE, it is important to note that CMS clarifies payment will not be made for these mental health telehealth services unless the physician or practitioner has furnished an item or service in person, without the use of telehealth for which Medicare payment was made (or would have been made) within 6 months of the telehealth service.

In addition, in the Proposed Rule, the agency seeks comment on whether it should adopt a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not. Vizient believes that any new mechanisms CMS adopts should impose little to no burden on providers. Further, CMS should provide additional training and resources to help providers adjust to such a change and work to ensure that claims are not improperly denied as providers adjust to any changes.

Lastly, Vizient recommends that CMS permit more complex services (e.g., level 4 and 5 E/M codes) to be provided via telehealth.

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communications
During the PHE, CMS used waiver authority to permit audio-only telehealth services for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits. CMS clarifies that since emergency waiver authority will not be available after the PHE ends, telehealth services will again be subject to all statutory and regulatory requirements. Vizient's analysis of CPSC data, as shown in the below table, demonstrates that Medicare patients were more likely than patients with commercial insurance or Medicaid to use phone visits for their virtual visits. As such, Vizient encourages CMS to ensure that a range of audio-only visits remain accessible to Medicare beneficiaries.



Includes all visits with CMS Site of Service: Telehealth, Office, On Campus Outpatient Hospital and Off Campus Outpatient Hospital.

In the Proposed Rule, CMS reconsiders its interpretation of "interactive telecommunications system" and proposes to amend the definition to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. Vizient agrees with the need to include audio-only communications technology for telehealth purposes, along with allowing the patient's home to serve as the originating site. Vizient believes these steps will be critical in improving access to services for mental health disorders. However, like CMS's requirements for other telehealth services, for these audio-only services, the agency proposes to require that an in-person item or service be furnished within 6 months of such mental health telehealth services. As noted above, Vizient is concerned that the proposed in-person requirement is too restrictive and will deter patients from initiating or continuing care, particularly those patients who have greater challenges traveling. Again, we recommend the agency consider whether any other flexibilities or exceptions could be provided.

CMS also proposes to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only services because the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. In response the agency's request regarding the need for documentation in the medical record regarding the audio-only services, Vizient does not believe clinicians should be required to note the reason why an audio-only service is provided, as it could lead to unnecessary claim denials and increase administrative burden. Should such documentation be required, we encourage CMS to work with providers to minimize burdens.

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

Expiration of the PHE Flexibilities for Direct Supervision Requirements
Under Medicare statute and regulations, certain types of services, including certain diagnostic tests, must be furnished under a specific level of supervision by a physician or practitioner.[4] During the PHE, CMS changed the definition of "direct supervision" as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through a virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule, CMS finalized the continuation of this policy through the end of the calendar year in which the PHE for COVID-19 ends or December 31, 2021, whichever comes later. Vizient recommends CMS make permanent this flexible supervision policy, particularly because it can help limit disease transmission and clinicians have gained a better awareness of circumstances in which virtual supervision is appropriate. To the extent CMS permits such direct supervision for only a subset of services, we encourage the agency to work closely with providers in identifying such services and to regularly update the types of permitted services.

Lastly, to the extent direct supervision requirements change immediately or shortly after the PHE expires, Vizient encourages CMS to provide communication and education to providers to ensure a smooth transition.

Brief Communication Technology-Based Services
In the CY 2021 PFS final rule, CMS finalized the establishment of HCPCS code G2252 (*Brief communication technology-based service*[5]) on an interim basis. Given the need for additional time to assess the necessity of an in-person service, for CY 2022, CMS proposes to permanently adopt coding and payment HCPCS code G2252 as described in the CY 2021 PFS final rule. Vizient agrees with CMS's decision to permanently adopt coding and payment for more virtual services, but believes the agency should reconsider restrictions related G2252, such as providing more flexible circumstances in which it may be billed, and work with stakeholders to identify other coding needs for virtual services, particularly for various durations and levels of medical decision making. Vizient also

[4] For professional services furnished incident to the services of a billing physician or practitioner and many diagnostic tests, direct supervision is required. Additionally, for pulmonary rehabilitation services and for cardiac rehabilitation and intensive cardiac rehabilitation services, requirements for immediate availability and accessibility of a physician are considered to be satisfied if the physician meets the requirements for direct supervision for physician office services and for hospital outpatient services.
[5] Brief communication technology-based service for HCPCS code 2252 is a virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.

encourages the agency to work with stakeholders to ensure adequate reimbursement is provided for virtual services, like brief communication technology-based services.

New Remote Therapeutic Monitoring Codes
In the Proposed Rule, CMS provides five new remote therapeutic monitoring (RTM) codes. CMS indicates that by providing the new codes, the agency aims to expand the types of patient data that can be captured for care management (e.g., pain levels, medication adherence, therapy adherence) and broaden the types of practitioners who can order and bill for remote monitoring and associated care services. Vizient applauds CMS for advancing policies to support virtual health. However, we encourage the agency to clarify which practitioners may bill for such services and under which circumstances given the agency's concerns noted in the Proposed Rule regarding incident-to rules.

Beneficiary Consent Under General Supervision

During the PHE for COVID-19, CMS allowed stakeholders to obtain beneficiary consent for certain services under general supervision. Vizient encourages CMS to consider retaining this flexibility beyond the PHE.

Evaluation and Management: Split (or Shared) Visits

A split (or shared) visit refers to an E/M visit that is performed ("split" or "shared") by both a physician and a non-physician practitioner (NPP) who are in the same group. In the Proposed Rule, CMS indicates that because the Medicare statute provides a higher PFS payment rate for services furnished by physicians than services furnished by NPPs, it needs to address whether and when the physician can bill for split (or shared) visits. Vizient understands the importance of providing such clarity but is concerned the agency's proposals are too rigid, would impose excessive burden and ignore the need to provide practitioners options for billing when split or shared visits are provided, as described below.

"Substantive Portion"
Notably, only the physician or NPP who performs the substantive portion of the split (or shared) visit is permitted to bill for the visit. Now, CMS proposes to define "substantive portion" as more than half of the total time (not Medical Decision Making (MDM)) spent by the physician and NPP performing the visit. Also, CMS proposes that the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine total time and who provided the substantive portion (and therefore bills for the visit). Vizient urges CMS to revise this policy such that the "substantive portion" is dependent upon which practitioner provides the most complex elements of care. Should CMS adopt this interpretation of "substantive portion", the agency should clarify that the practitioner providing the "substantive portion" may bill for the service considering either MDM or time, as opposed to only time. Vizient suggests this alternative interpretation and approach as we are concerned the proposed shift to only time is confusing in the context of other E/M policies which permit either time or MDM to be used for purposes of code selection. In addition, we are concerned CMS significantly underestimates the burden associated with tracking time between practitioners. Vizient is also concerned this policy will discourage optimal use of various practitioners' time relative to patient needs and each practitioners' skills and expertise. In addition, CMS does not provide reasonable justification to support the substantive portion being more than half of the total time, as this framework does not consider the impact on the patient of different types of activities and that certain providers must ultimately make more complex or critical decisions. As such, Vizient urges CMS to permit MDM to be an option for practitioners to consider, rather than time-only, for split or shared visits.

Also, in the Proposed Rule, CMS provides a list of activities (e.g., preparing to see the patient, obtaining or reviewing separately obtained history, ordering medications, tests or procedures, counseling the family) that could count towards total time for purposes of determining the "substantive portion". Again, Vizient urges CMS to rescind this narrow time-based approach for billing split or shared visits and allow MDM to be used as an alternative. Not only will providing more options ease potential burdens associated with tracking time, but it will also help maintain current care processes and better recognize variable levels of expertise and training between providers. Also, as noted above, Vizient calls into serious question CMS's presumption that practitioners will easily be able to list time spent on each activity and coordinate billing seamlessly. Rather, finalizing this proposal will, without clear justification, be disruptive, increase administrative burden and take additional resources to operationalize.

New and Established Patients and Same Group
CMS proposes to permit the physician or NPP to bill for split or shared visits for both new and established patients. In addition, CMS proposes to allow permit split or shared visit billing when provided in the facility setting by a physician and an NPP in the same group. Vizient has heard from some members 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. 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 raises this concern with CMS as billing for split or shared visits could further exacerbate current billing issues associated with NPP billing for new patient visits should more NPPs bill CMS directly. Vizient recommends CMS work closely with providers to better understand unique billing issues and develop solutions for streamlined billing processes.

Settings
CMS proposes to allow split or shared visits only when provided in the facility setting by a physician and an NPP in the same group. The agency notes that given the availability of incident-to billing in other settings, split or shared visits would not be necessary. Vizient recommends CMS reconsider this notion and allow the provision of split or shared visits in more settings as there are different requirements for incident-to and split or shared billing.

Critical Care Services

Consistent with CMS's efforts to refine payment for office/outpatient E/M visits, CMS proposes refinements to other E/M code sets, including critical care services. Critical care visits are for evaluation and management of the critically ill or critically injured patients. Generally, CMS indicates it aims to update the critical care E/M visit policies to improve transparency and better align payment policy with the 2021 CPT Codebook (E/M Services Guidelines). Vizient appreciates the agency's proposed changes regarding critical care services but recommends the agency halt finalizing these policies and work more closely with stakeholders to better understand potential impacts on patient care.

CMS proposes to allow split (or shared) billing for critical care services in generally the same manner as done for E/M visits, including using a time-based billing threshold. Vizient encourages CMS to adopt our recommendations as noted above, particularly as related to identifying the billing practitioner and allowing time or MDM to be used for code selection.

Also, CMS proposes to bundle critical care services into global surgery packages. Vizient is concerned the bundling proposal overlooks circumstances in which a critical care visit is required but

not directly connected to the surgery. Vizient recommends CMS refrain from finalizing this policy and work with stakeholders to refine policies for critical care services.

Similarly, Vizient is concerned that not allowing an E/M visit to be billed on the same day as a critical care visit is an unnecessary constraint that makes improper presumptions. For example, a patient may be seen for an E/M visit in the morning, but should their condition worsen, it may warrant a critical care visit later in the day. Coverage policies should be structured to provide reimbursement for these types of circumstances.

Payment for the services of Teaching Physicians

As part of the E/M visit coding framework CMS finalized for CY 2021, practitioners can select the office/outpatient E/M visit level to bill based either on the total time personally spent by the reporting practitioner or MDM. In response to stakeholder questions, CMS proposes that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. CMS also notes that the teaching physician presence requirement can be met through audio/video real-time communications technology, only in residency training sites that are located outside of a metropolitan statistical area (MSA). Given the various telehealth advancements during the PHE and that teaching physicians may take measures to reduce exposure, among other reasons, Vizient encourages the agency to allow the teaching physician presence requirement to be met through audio-video real-time communications technology in all residency training sites.

Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management

In the Proposed Rule, CMS notes that there are no existing codes that specifically describe the work of the clinician involved in performing the tasks necessary for pain management care. As such, CMS solicits comment on whether it should consider creating a separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment. Vizient appreciates the agency's ongoing efforts to address chronic pain management and encourages the agency to consider Vizient's comprehensive pain management guide[6], which provides insights regarding the development of a comprehensive pain program and various metrics for evaluating such a program for hospitals and health systems, among other information.

Vaccine Administration Services

In the Proposed Rule, CMS seeks feedback on how the agency should update the payment rate for administration of preventive vaccines (i.e., influenza, pneumococcal, HPV and COVID-19) under Medicare Part B. CMS notes that over the past several years, stakeholders have expressed concerns about the reduction in Medicare Part B payment rates for the services to administer preventive vaccines. Vizient agrees with the need to update the payment rate of preventive vaccines. Should alternative sites of care be set up, like drive-through vaccination sites, or other locations within a hospital be repurposed for vaccine administration, these changes can increase costs, including for planning, set-up, and take-down and demand staff time, among other types of costs. We also note

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

that certain vaccines may be more costly and time intensive to administer based on factors like storage needs, documentation requirements, additional time for patient education and the cost of personal protective equipment.

Also, like other aspects of the pandemic, there is an ongoing need to consider health equity in the context of vaccine administration rates. As CMS considers vaccine administration services broadly, we encourage the agency to also review the flexibilities and rates, such as at-home vaccination rates[7], provided during the pandemic. Vizient believes this information may be helpful in identifying strategies to increase patient access to preventive vaccines and opportunities for improvement. Alternatively, to the extent that rates of vaccination for other diseases has declined during the pandemic, Vizient encourages CMS to also consider mechanisms to increase utilization of these preventive vaccines.

Monoclonal Antibodies Used to Treat COVID-19

During the PHE, CMS began to cover and pay for certain COVID-19 treatments under the COVID-19 vaccine benefit, meaning beneficiaries are not responsible for cost-sharing. When a treatment is provided, CMS makes a separate payment for the products (when not given to the provider or supplier free by the government) and for the service to administer them. Vizient appreciates the agency's efforts to support access to monoclonal antibodies used to treat COVID-19 and encourages the agency to continue to minimize patient's cost-sharing burdens.

In the Proposed Rule, the agency indicates it is considering aligning payment and coverage for these products with the agency's approach for other monoclonal antibody products following the end of the PHE. Vizient appreciates CMS is gaining feedback on policies to implement after the PHE. Currently, given that much remains to be seen regarding the progression of COVID-19 and the broader impacts on the health care landscape, Vizient recommends the agency take a cautious approach to payment and coverage changes for COVID-19 related products and services, as such changes may cause harm to hospitals and other providers. For example, Vizient is aware of members who have significantly increased spending on COVID-19 products, such as remdesivir. Vizient's July 2021 Pharmacy Market Outlook[8] indicates that remdesivir has the highest overall spend among Vizient members. While there are different tools and mechanisms in place to help hospitals and providers deal with these increased expenses, members have continued to voice concerns. Therefore, as the agency considers future payment and coverage policies for monoclonal antibody products, we urge the agency to ensure excessive financial burdens are not placed on hospitals and other providers purchasing such products after the PHE. Until the implications of new payment and coverage policies can be better understood, Vizient believes it is important CMS works closely with hospitals and providers in developing payment and coverage policies for these products.

[7] https://www.cms.gov/newsroom/press-releases/cms-expands-medicare-payments-home-covid-19-vaccinations
[8] https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/PMO221_PharmacyMarketOutlook_Highlights?sc_camp=4445B2CDCE4428B3DF70CC63717F92

Medicare Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act

According to CMS, for a subset of drugs approved by FDA under the 505(b)(2) pathway ("505(b)(2) drugs"), the distinction between multiple source drugs and single source drugs is less straightforward due to the different regulatory needs for approvals (e.g., generic 505(b)(2) applications may rely on studies or published literature that do not come from the applicant). However, unlike a generic drug product, 505(b)(2) drug products are not required to use the same FDA-approved labeling as the products relied upon for approval. In the Proposed Rule, CMS seeks feedback regarding a potential framework to identify whether products should be treated as a sole source drug or multiple source drug. Vizient encourages the agency to provide examples of how it would apply the framework to help stakeholders better understand the agency's approach.

Vizient appreciates the agency's concerns regarding the price of drugs approved under the 505(b)(2) pathway. Similarly, Vizient has raised concerns regarding the price of legacy drugs approved through the 505(b)(2) pathway, including those used largely on an inpatient basis. As CMS identifies policies to address these pricing concerns for Part B covered drugs, we encourage the agency to, in separate rulemaking or in stakeholder communications, consider the options to ease the financial consequences of price increases for 505(b)(2) approved products that were previously marketed as unapproved drug products and used primarily in inpatient settings. Vizient would appreciate working with CMS to help identify solutions to increase access to affordable medications.

Appropriate Use Criteria for Advanced Diagnostic Imaging

The Protecting Access to Medicare Act (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services (e.g., computed tomography, positron emission tomography, nuclear medicine and magnetic resonance imaging). In response to the PHE and stakeholder feedback, CMS proposes the effective date for penalties to be the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19. Vizient appreciates CMS's decisions to delay the effective date for penalties, as this additional time will help providers learn, test, prepare and, as a result, more effectively implement changes associated with AUC.

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

In the CY 2021 PFS final rule, CMS provided a January 1, 2022 compliance date for electronic prescribing of controlled substance (EPCS) for a covered Part D drug under a prescription drug plan or an MA-PD plan. In the Proposed Rule, CMS provides various reasons why implementation has been challenging and proposes to change the EPCS compliance date from January 1, 2022 to January 1, 2023. Vizient appreciates CMS's decision to delay the EPCS compliance date by one year. We encourage the agency to continue to monitor readiness for future compliance, as such information may be relevant to consider so that future enforcement can be structured to better encourage compliance. In addition, we encourage the agency to provide education to providers, particularly regarding exceptions.

CY 2022 Updates to the Quality Payment Program

MIPS Value Pathways (MVPs)
In the CY 2020 PFS final rule, CMS establishes MVPs, which are a subset of measures and activities that are relevant to a specialty, medical condition or specific population, and can be used to meet

MIPS reporting requirements. Consistent between MVPs is a foundation of Promoting Interoperability performance requirements and population health claims-based measures. In the Proposed Rule, CMS provides the first seven MVPs to help advance MVPs more broadly. Given many more MVPs will need to be in place for the broad participation CMS envisions, Vizient recommends CMS provides more information regarding the MVP development process to stakeholders to support the development of additional MVPs.

In the Proposed Rule, CMS seeks to clarify who can participate in MIPS through MVPs. Specifically, CMS proposes that the term MVP Participant means: an individual MIPS-eligible clinician, multispecialty group, single specialty group, subgroup, or APM Entity that is assessed on an MVP for all MIPS performance categories. Although enrollment in MVPs has yet to begin, Vizient encourages CMS to consider opportunities to increase clarity and reduce burdens, such as those that may occur when and MVP Participant participates in more than one MVP. In addition, Vizient appreciates that at least initially, MVP participation would be voluntary and we encourage CMS to consider a longer or indefinite voluntary period and provide multiple participation options.

In the Proposed Rule, based on stakeholder requests for gradual implementation, CMS proposes delaying the implementation and availability of the proposed MVPs by one year, that is, until the CY 2023 MIPS performance period/2025 MIPS payment year. In addition, CMS notes it is considering sunsetting traditional MIPS at the end of the CY 2027 performance period and mandating MVP reporting for the CY 2028 performance period. Vizient is concerned this implementation timeline is too rapid, particularly as much remains to be seen with regard to the transition to voluntary MVP reporting. Vizient appreciates CMS's efforts to notify stakeholders about this potential implementation timeline and encourages the agency to continue to gain stakeholder feedback regularly and take a cautious approach to transitioning away from traditional MIPS.

Medicare Shared Savings Program

The Medicare Shared Savings Program (MSSP) serves as a mechanism for eligible groups of providers and suppliers that participate in an Accountable Care Organization (ACO) to continue to receive traditional Medicare FFS payments and a shared savings payment if the ACO meets specified quality and savings requirements. In the CY 2021 PFS Final Rule, CMS finalized the Alternative Payment Model Performance Pathway (APP) where ACOs would report clinical quality measures using all-payer data rather than the CMS Web Interface starting in performance year (PY) 2022. CMS proposes for PY 2022, that ACOs would have the option to report either CMS Web Interface measures or the three all-payer eCQMs/MIPS CQMs. Vizient appreciates CMS's decision to extend the Web Interface collection type and encourages the agency to consider further extensions. Vizient also notes that the shift towards eCQMs may take more time than CMS envisions and encourages the agency to work with providers to better understand such challenges.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information

As part of CMS's efforts to modernize its quality measurement enterprise, the agency included a request for information (RFI) in the Proposed Rule to inform the agency as it transitions to digital quality measurement. Vizient encourages CMS to consider our responses previously provided to CMS in our comments regarding the inpatient prospective payment system (IPPS) proposed rule. We also note our interest in collaborating with CMS to provide our expertise and insights to inform future agency efforts. We encourage CMS to carefully implement policies related to this RFI, as data reliability should be prioritized over rapid implementation.

Closing the Health Equity Gap in CMS Clinician Quality Programs – Request for Information

Vizient commends CMS in its efforts to provide more transparency regarding health inequities and disparities, either in resources provided or outcomes by healthcare organizations. Vizient encourages the agency to review our recommendations regarding future potential stratification of quality measure result by race and ethnicity and improving demographic data collection, as provided in our comments in response to the IPPS proposed rule.

Conclusion

Vizient welcomes CMS's efforts to update the PFS and other payment policies impacting providers. We appreciate the agency's various requests for comments, which provides 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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