

December 28, 2020

Submitted electronically via: www.regulations.gov

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Regulatory Relief to Support Economic Recovery; Request for Information (RFI) (HHS-OS-2020-0016)

Dear Secretary Azar,

Vizient, Inc. appreciates the significant flexibility the Department of Health and Human Services (HHS) has provided in response to the COVID-19 public health emergency (PHE) as many of the policy changes continue to have a significant impact on our members and the patients they serve. In response to the request for information, “Regulatory Relief to Support Economic Recovery” (Docket No. HHS-OS-2020-0016) (hereinafter, “RFI”), Vizient offers the following recommendations for HHS’s consideration.

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

Vizient is deeply appreciative of the effort HHS has made to identify opportunities to better support our nation’s health care providers during the COVID-19 pandemic. Given the significant transformation our health care system has undergone due to COVID-19, it is clear that retaining some of the vital flexibilities and other positive changes provided

during the COVID-19 PHE could have positive long-term benefits for the U.S. health care delivery system.

In addition, while we offer several recommendations below, we recognize that as the pandemic evolves, we will learn more about the impact – both positive and potentially negative – that the new flexibilities have provided. In addition, as HHS remains continuously active in responding to the pandemic, we anticipate additional flexibilities may be needed. As such, Vizient encourages HHS to continue to regularly seek feedback from stakeholders regarding those evolving needs and potential policy changes.

Telehealth & Other Virtual Health Services

During the PHE, telehealth and other virtual health services have been an important mechanism for healthcare providers to provide care. Vizient recognizes that HHS sub-agencies' flexibilities, such as policies provided by the Centers for Medicare and Medicaid Services (CMS), have been critical in supporting patient and provider uptake of telehealth and virtual health services. For example, CMS has, among other efforts, taken steps to expand the number of these services, the methods by which they can be provided and the locations in and from which they can be provided – thus drastically increasing access to care. As such, great consideration is needed when modifying these flexibilities, particularly as patients have grown accustomed to receiving care in this way.

To support longer-term telehealth expansion and ensure gaps in care do not emerge after the PHE, Vizient encourages HHS to consider further extending the several actions from Attachment A of the RFI list below. Vizient also notes that while CMS has extended several flexibilities through the CY 2021 Physician Fee Schedule final rule, we believe additional opportunities remain to more firmly support telehealth and virtual health access by offering formal rulemaking to allow the continuation or expansion of telehealth services related to the actions below.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 4: Notification of Enforcement Discretion for Telehealth Remote Communications
- 111: Communication Technology-Based Services (CTBS)
- 112: Direct Supervision by Interactive Telecommunications Technology
- 113: Telephone Evaluation and Management (E/M) Services Codes

- 119: Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement¹
- 123: Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) Telehealth
- 125: Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
- 143: Payment for Remote Physiologic Monitoring (RPM) Services
- 149: Updating the Medicare Telehealth List on a Sub-regulatory Basis
- 189: Allow use of audio-only equipment to furnish audio-only telephone E/M, counseling and educational services
- 201: Practitioner locations
- 210: Remote Patient Monitoring Reporting
- 215: Eligibility for Telehealth
- 281: Telehealth

Rural Health

Vizient strongly believes that it is essential for our country to support a vibrant and quality health care system that ensures access to care for patients in rural and underserved areas. This goal could be accomplished through: 1) adequate reimbursement to ensure hospitals and other providers in rural and underserved areas have the means to serve their communities and provide access to appropriate and high-quality care; 2) incentives to ensure that rural and underserved communities have the ability to recruit and retain the highly-skilled workforce needed to provide care; 3) regulatory modifications to ease unnecessary restrictions and provide new flexibility for providers to implement alternate payment and care delivery models to better serve their communities; and, 4) expanded access to broadband and necessary funding to support adoption and scaling of telemedicine services to ensure access to both primary care services and specialists who may otherwise be unavailable in rural and underserved communities. During the PHE, several flexibilities have been provided to support patients in rural and underserved communities.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 123: Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) Telehealth

¹ Vizient suggests HHS consider opportunities to further study this action item. The continuation of virtual options for the three provider visits each week could create clinical efficiencies for providers in shortage areas after the PHE. But it is unclear if safety and outcomes would be affected. A short study or evaluation of metrics during the waiver period should look at any differences in the improvement of Functional Independence Measure scores and other quality outcome measures. Additionally, IRF length-of-stay and readmission to acute hospital rates should be reviewed. If operational and quality outcomes are not impacted, virtual options for physician (and APP) visits should be allowed to continue.

- 144: Rural Health Clinics (RHC)
- 166: Hospitals Classified as Sole Community Hospitals (SCH)
- 167: RHC and FQHC Temporary Expansion Locations
- 178: CAH Bed Count and Length of Stay
- 179: Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDH)
- 192: Responsibilities of Physicians in Critical Access Hospitals (CAHs)
- 194: Physician Supervision of NPs in RHCs and FQHCs
- 195: Staffing Requirements for RCHs and FQHCs
- 196: CAH Staff Licensure
- 197: CAH Personnel Qualifications

Site of Care Flexibility

During the PHE, hospitals and other health care providers have needed to adapt quickly to different care demands while continuing to protect patients from the spread of COVID-19. Hospitals have utilized flexibilities, such as those advanced through the “Hospitals Without Walls” initiative, to optimize space and provide care to patients in unique settings, including their homes. Vizient encourages HHS to consider further extending the below policies after the PHE. Vizient also notes that as HHS considers these flexibilities, we recognize that these policies were quickly implemented in the context of the pandemic. As extensions and other modifications are made to these policies, additional improvements could be provided to support patient safety and access. As such, we believe additional rulemaking could provide an effective regulatory framework to support providing care in different settings. Vizient notes our support for continuing needed flexibility to economically support such expansions through adequate provider-based reimbursement.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 118: Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital
- 119: Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement
- 141: Furnishing Hospital Outpatient Services Remotely
- 142: Treatment of New and Certain Relocating Provider-Based Departments
- 164: Physical Environment
- 201: Practitioner locations

Medical Education

As HHS is aware, to prepare for COVID-19 surges, hospitals have added beds to increase their treatment capacity and utilized other flexibilities provided to allow for medical residents to be effectively deployed as caregivers while continuing to complete medical education requirements. Vizient believes these changes help support medical education while also increasing hospitals’ abilities to prepare for surges and care for

patients. Since it is foreseeable that hospitals may need to have additional capacity after the PHE or may be unable to immediately revert to prior ratios, Vizient recommends CMS clarify that academic medical centers and other facilities who are eligible for teaching status adjustments will not have their indirect medical education (IME) payments reduced after the PHE. In addition, CMS could provide a transition policy to support hospitals' as they prepare for future potential surges or adapt to more regular practices.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 137: Indirect Medical Education
- 138: Medical Education: Time Spent by Residents at Another Hospital during the COVID-19 PHE
- 148: Additional Flexibility under the Teaching Physician Regulations

Streamlining Care and Reducing Burden

During the PHE, HHS provided numerous flexibilities to help reduce burdens on providers so that they can better focus their time on caring for patients. In addition, policies have advanced to more quickly ensure patients receive care that will be covered by payers. Vizient appreciates these efforts which have streamlined care and reduced burden in various circumstances. While several of the policies noted below were drafted specifically in response to COVID-19, we encourage HHS to consider extending these policies beyond the PHE, and to ensure these flexibilities do not rely on the PHE being in effect.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 120: Removal of the IRF Post-Admission Physician Evaluation Requirement
- 133: Care Planning for Medicare Home Health Services
- 136: Laboratory Tests: Payment for COVID-19 Specimen Collection to Physicians, Non-Physician Practitioners and Hospitals
- 147: COVID-19 Serology Testing
- 160: Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission
- 226: Prior Authorization

Quality Payment Programs

Vizient appreciates CMS's efforts to improve elements of various quality reporting programs, such the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy (i.e., Action 107), so that CMS could grant broader exceptions to hospitals beyond the PHE. While the modifications to the ECE policies were developed and made permanent in the context of the COVID-19 pandemic, there may be other circumstances that warrant different approaches to ECEs or modifications to the application of ECEs. For example, CMS could share more

information publicly regarding the analysis it performs to determine whether data can be adequately relied upon when calculating performance scores or imposing payment adjustments. Therefore, Vizient encourages HHS to consider whether other changes to the ECE policies may be needed.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 107: Update to the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy
- 108: Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID-19, and Update to the Performance Period for the FY 2022 SNF VBP Program

Advanced and Accelerated Payments

In response to the PHE, health care providers were able to utilize the Advanced and Accelerated Payments (AAP) program to help alleviate financial burdens. The PHE also highlighted existing issues regarding the AAP program terms that were important to modify and make more flexible so the program can be more meaningfully utilized by providers. Vizient encourages HHS to consider making the changes to the AAP program permanent and accessible beyond the PHE.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 220: Accelerated/Advance Payments

Medicaid

During the PHE, like Medicare, Medicaid has undergone a significant transformation to adapt to patients' and states' needs. Several of these policies have helped increase access to care and, therefore, states should continue to be able to maintain such access after the PHE.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 332: Extend Presumptive Eligibility (PE) to non-Modified Adjusted Gross Income (MAGI) Populations
- 336: Medicaid Disaster Relief State Plan Amendment (SPA) - Adopt Continuous Eligibility for Children
- 339: Suspend Deductibles, Copayments, Coinsurance and other Cost Sharing Charges
- 340: Suspend Deductibles, Copayments, Coinsurance and other Cost Sharing Charges

Drug and Device Policies

During the pandemic, FDA has provided numerous flexibilities, including enforcement discretion and emergency use authorizations, to support provider use of certain devices (e.g., personal protective equipment) and medications. Vizient appreciates these flexibilities and encourages FDA to conduct more targeted outreach with stakeholders to more carefully revise these policies as their duration may, in part, depend on supply and demand.

Regarding device shortages, Vizient particularly appreciates FDA's efforts to implement actions to support device shortage tracking (e.g., Action 61: Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency). While Vizient recognizes Congressional action is needed to extend this policy, Vizient encourages HHS and FDA to share more information regarding the potential benefits of such reporting beyond the PHE to support subsequent legislative activity. In addition, Vizient emphasizes the importance of creating a more resilient supply chain, for both drugs and devices, through enhanced transparency, redundancy and diversification.

Vizient also appreciates FDA's efforts to provide more flexibility to compound medications and encourages the agency to consider making these policies, or variations of these policies, permanent after the PHE. For example, Action 67: Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised) and Action 68: Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry (Revised), has helped increase access to critical medications that would otherwise be ineligible for compounding. Vizient encourages HHS and FDA to consider making this policy permanent after the PHE.

Actions HHS should extend beyond the PHE as listed in Attachment A of the RFI:

- 61: Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency
- 67: Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised)
- 68: Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry (Revised)

Conclusion

Vizient welcomes HHS's extensive discussion of options and its emphasis on requesting comments, which provides a significant 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 HHS for providing us the opportunity to comment on this important RFI. 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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