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Aug. 15, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphry Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

Re: - CMS-3295-P - Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care

Dear Mr. Slavitt,

I am writing on behalf of Vizient, Inc. to offer our comments on the proposed changes to the conditions of participation for hospitals participating in the Medicare and Medicaid programs. Vizient is the new company that represents the integration of VHA Inc., the University HealthSystem Consortium and Novation in 2015, as well as the recently acquired elements of MedAssets' Spend and Clinical Resource Management segment and Sg2 data and analytics capacity. We are dedicated to serving members and customers through innovative data-driven solutions, expertise and collaborative opportunities that lead to improved patient outcomes and lower costs. Vizient's diverse membership includes academic medical centers, pediatric facilities, community hospitals, integrated healthcare delivery networks and non-acute health care providers whose best practices in clinical areas, including antibiotic stewardship have been highlighted nationally.[1] Our headquarters are in Irving, Texas, with locations in Chicago, Washington, D.C., and other cities across the country.

Vizient appreciates the opportunity to provide comment on this important proposed rule. Our comments reflect the views of our organization, as well as input received from our hospital members from across the U.S.

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Vizient is supportive of the goals included in the proposed updates to the conditions of participation to prohibit discrimination, enhance infection control and prevention efforts and improve antimicrobial stewardship. We applaud CMS's efforts to formally

[1] Pew Charitable Trust. A Path to Better Antibiotic Stewardship in Inpatient Settings.

bring Medicare and Medicaid in compliance with existing federal laws relating to discrimination. While concerns exist regarding specific proposals relating to access to medical records and record services, we offer our support for the proposed rule and the steps it takes to reduce discrimination.

In relation to infection control and prevention, and antimicrobial stewardship, Vizient recognizes the importance of the provisions included in the proposed rule. We work closely with our hospital members to improve care delivery and ensure patients receive the highest quality of care. We support efforts to reduce or eliminate harms that take place during a hospital stay and engage to improve stewardship efforts for antimicrobial agents. Overall, we support CMS's proposals in the rule, while requesting some technical improvements to provide greater clarity and flexibility for hospitals seeking to comply with the changes it includes.

Patient's Rights

Section 1557 of the Affordable Care Act included a requirement that health programs and activities that receive federal financial assistance, such as Medicare and Medicaid, would be prohibited from excluding beneficiaries based on their race, color, national origin, sex (including gender identity), age, or disability. CMS also proposes to establish explicit requirements that a hospital not discriminate on the basis of religion or sexual orientation. In the proposed rule, CMS seeks to formally include those protections barring discrimination in hospital conditions of participation and requires the hospital establish and implement a written policy prohibiting such discrimination.

Vizient is firmly against discrimination in health care in any form, and strongly supports CMS's proposal. Patients should never be denied care based on discriminatory considerations, and formally including the requirements in the conditions of participation will ensure that hospitals receiving Medicare and Medicaid patients will serve all patients regardless of their race, color, nationality, sex, gender identity, age or disability.

Access to Medical Records

While Vizient is supportive of the general goals for patients' rights included in the proposed, we are concerned about some of the specific language included requiring patient access to medical records and record services.

The proposed rule requires that patients have the right to access the information in their medical record within a reasonable time frame. HIPAA as well as recent guidance from the HHS Office of Civil Rights clarify the responsibilities for hospitals to provide a designated record set to patients within a reasonable time frame. Vizient is supportive of hospitals being able to provide access to medical records within a reasonable time frame. However, given the ongoing compliance requirements under HIPAA and the importance of regulatory

consistency, we request that CMS clarify that hospitals that are maintaining compliance under HIPAA would also be considered in compliance with the proposed conditions of participation.

Medical Record Services

In the proposed rule, CMS makes specific changes related to regulatory language in the Medical Record Services rules and requires that all patient medical records document discharge and transfer summaries with outcomes of all hospitalizations, case dispositions, and provisions for follow-up care of all inpatient and outpatient visits to reflect the scope of all services received by the patient. We urge CMS to ensure that the proposed changes align with discharge planning regulations that are under development concurrently. In addition, we ask CMS that the proposed changes remain consistent with the requirements of the IMPACT Act relative to discharge planning.

Vizient is concerned by CMS's proposal that requires the content of the medical record to contain final diagnoses with completion of medical records within 30 days following all inpatient stays, and within 7 days following all outpatient visits. We are concerned with the brief time frame proposed for outpatient visits. While hospitals and other outpatient providers strive to return results, diagnoses and provide full documentation in the medical record as soon as possible, delays in processing and reporting lab results, providing time for dictation and full documentation make the proposed seven day window challenging. Vizient supports extending the timeframe to allow for a minimum of 14 days for the outpatient record to be completed.

Quality Assessment and Performance (QAPI) Program

CMS is proposing an update to the final rule that was published on January 24, 2003 entitled "Medicare and Medicaid Programs: Hospital Conditions of Participation: Quality assessment and performance improvement [QAPI]". Vizient supports CMS's recommendations to update this section in recognition of current technology, including encouraging hospitals to use certified health IT systems that can exchange health information in real time with other providers. However, it has been our experience that these systems, although compliant, are fragmented and do not integrate with other commercial systems. **Therefore, we suggest the addition of a statement such as "CMS encourages electronic health record vendors to work collaboratively with other commercial systems to improve interoperability and foster the exchange of health care information."**

In §482.21 (b), we acknowledge that CMS proposes to "require" that the hospital QAPI program incorporate quality indicator data…" **We suggest CMS change the term "require" to "consider".** This provides organizations with greater flexibility to determine

how quality indicator data should be integrated into their QAPI program based on their own organizational priorities.

Infection Prevention and Control and Antibiotic Stewardship Programs (§482.42)

CMS is proposing to amend the Infection Control COPs that were originally introduced three decades ago (51 FR 22010, 22027) to reflect current terminology and practice standards related to the prevention of infections. In addition, proposed revisions to §482.42 includes recommendation that hospital develop and maintain an antibiotic stewardship program. **Vizient applauds CMS for expanding the scope of these COPs and for recognizing the combined influence that both an infection prevention program and antibiotic stewardship program have on reducing the incidence of healthcare associated infections and curbing patient risk for other future, and potentially life-threatening, antibiotic resistant infections.**

We offer the following comments and proposed changes to selected provisions contained in § 482.42.

In the summary of changes for this section, CMS proposes to introduce the term "surveillance" into the text of the regulation. Vizient supports CMS and the introduction of "surveillance" in the text. **We recommend that CMS clarify in the final rule that the definition of surveillance should not only include infection detection, data collection, analysis, monitoring and evaluation" as stated and encourage providers to disseminate data throughout the organization.**

In §482.42(a)(2) - CMS proposes to adjust the scope of the hospital's' prevention and control programs from its current focus on transmission of infections *between* patients and personnel, to the expanded focus on the transmission of multi-drug resistant infections between individuals *across* the entire hospital setting. **Vizient supports this recommendation and agrees with CMS that it reflects current best practices that are in place in many hospitals today.**

In §482.42 (b)(1) – CMS proposes a new provision that would require the hospital, with the recommendations of the medical staff leadership and pharmacy leadership, to designate an individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, as the leader of the antibiotic stewardship program. We recognize and support CMS proposal to require a qualified individual to take leadership over these efforts with support of the medical staff leadership to take leadership over these efforts. Vizient members indicated that a healthcare provider, such as a physician, pharmacist, or both, are ideal to lead such program. **At the same time, we are supportive of the flexibility the proposed changes provide in determining the individual's qualifications, "through education, training, or experience in infectious diseases**

and/or antibiotic stewardship, is appointed by the governing body as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership."

Vizient members provided the following additional comments with respect to training, education, and clinical experience proposed in the rule:

- *At this point in time, keeping the definition of qualifications broad is appropriate. As more programs mature and more training opportunities become available, then (required training and credentialing of leadership) can be better defined.*

- *We prefer the lack of specificity in the recommendation (for training and education). There is a need for more formal training programs (i.e. infectious diseases residencies/fellowships). In addition, there is a need for additional antibiotic stewardship training programs for practicing clinicians, especially cost effective ones. Some of the programs are cost prohibitive.*

- *In California where stewardship programs are mandated in the Health and Safety Code, the law does not specify who can lead a stewardship program but state that there should be a physician leader and a pharmacist leader, both with stewardship training from "professional societies" - there are specific training programs sponsored by SHEA, ASHP, etc. that could fulfill this, or a certain number of CME credits in antibiotic stewardship from conferences.*

Vizient supports the recommendations provided in sections §482.42(a)(4) and §482.42 (b)(4) that states that the infection prevention and antibiotic stewardship programs, respectively, reflect the scope and complexity of services offered at the hospital. Additionally, Vizient asks that CMS provide flexibility in allowing larger hospital systems and integrated delivery networks with multiple campuses the ability to maintain a centralized infection control and prevention program, and antibiotic stewardship program. While it would continue to be important to support the characteristics and patient population served by each individual facility, the ability to maintain system-wide controls will improve overall infection prevention and control and antibiotic stewardship efforts.

In §482.42(b)(2) (i), (ii) and (iii) – **We appreciate that CMS proposes requirements in this section that will help ensure that the goals for the antibiotic stewardship program are met. We agree with the recommendation that coordination among all components of the hospital should be required and evidenced–based use of antibiotics should be documented throughout the hospital.**

However, we request that CMS consider amending the third goal of an antibiotic stewardship program that is defined in this section. The current language states that the program should "demonstrate improvements in antibiotic use, such as through

reductions in CDI and antibiotic resistance in all departments and services of the hospital." Since there are many external hospital factors that contribute to the spread of *Clostridium difficile* infection (CDI) and antibiotic resistance such as population risk factors, community spread, and transfer of patients from outside facilities, a reduction in CDI or antibiotic resistance may be difficult for the hospital to demonstrate, even in the highest performing organizations, despite documented reductions in antibiotic use in the inpatient setting. Eliminating reference to these specific metrics will allow hospitals the opportunity to define the best metrics and priorities for their own facilities.

We offer the following correction for §482.42(b)(2)(iii)

> *"(iii) Demonstrate improvements, including sustained improvements, in proper antibiotic use~~, such as through reductions in CDI and antibiotic resistance~~ in all departments and services of the hospital."*

In §482.42(c)(1)(ii) - CMS proposes that "all HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership." We agree with the CMS recommendation that the QAPI program must include, but not be limited to, and ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors. Inclusion of HAIs and other infectious diseases, along with critical issues such as antibiotic stewardship, will strengthen and improve outcomes of care.

In §482.42(c)(2)(i) and §482.42(b)(3) CMS includes provisions that require hospitals ensure that the infection prevention and antibiotic stewardship programs, respectively, adhere to nationally recognized guidelines, as well as best practices for improving antibiotic use. **Several Vizient acute care and critical access hospital members expressed support of the flexibility that this provision allows.** Specific to antibiotic stewardship, many acute care and critical access hospitals are surveyed by the Joint Commission and beginning in January 2017, their antibiotic stewardship program will be surveyed as part of the new Medication Management standard.[2] Many members stated that it would create confusion if CMS created very specific guidelines for what constitutes an antibiotic stewardship program that did not align with the Joint Commission standards.

Vizient members provided the following additional comments with respect to this section:

- *The broad statement provides more flexibility in implementation as well as the potential to keep the requirements more relevant to current practice.*

[2] Prepublication Standards – New Antimicrobial Stewardship Standard. The Joint Commission

- *Leave it as a broad statement. At this time, many institutions are struggling to implement stewardship and if given very specific guidance, it could strain budgets and (impair our) ability to meet the requirements at this time.*
- *I think it is reasonable to leave a broad statement about the elements of an ASP. In application, it would help if surveyors recognized that a given program cannot possibly implement all of the strategies that are endorsed in the current version of (national) guidelines.*

Finally, we respectfully ask that CMS clarify the definition of "hospital-wide" specifically in the context of the antibiotic stewardship program. We noted that the preamble of the proposed rule for Medical Records (§482.24) includes a statement that "The Medicare hospital COPs apply to services being provided to all patients and to both inpatients and outpatients of a hospital." It is not immediately apparent whether or not this same definition applies to the rules in this section. Vizient requests that CMS consider providing clarification in section 483.42 on the scope of the patient populations that will be encompassed by the antibiotic stewardship COPs including pediatrics, inpatient rehabilitation units and the outpatient settings that fall under a single hospital provider number. By including the general term "outpatient settings", the potential application of this rule to stand-alone settings such as ambulatory surgery centers and hospital based clinics will require increased resources and expertise that in some cases are substantially different from the type of program that has been or is being implemented for the inpatient population.[3],[4] While hospitals have been leaders in striving to improve care coordination across settings, we remain concerned about the potential that such an expansion may create an additional resource burden on the hospitals.

Critical Access Hospitals (CAH)

We appreciate the recognition by CMS of the challenges that CAHs face due to resource availability and geographical restrictions and the recognition of these challenges in the proposed COPs for CAHs. Our comments above can largely be extended to apply in the CAH setting with ongoing encouragement for needed flexibility based on the scope and complexity of services delivered at any individual hospital.

In §485.640(c)(3), CMS proposes that the requirements for the leader of the antibiotic stewardship program be similar to the proposed responsibilities for the CAH's designated

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[3] CDC. Core Elements of Hospital Antibiotic Stewardship Programs. Atlanta, GA: US Department of Health and Human Services, CDC; 2014.

[4] Arnold SR, Straus SE. Interventions to improve antibiotic prescribing practices in ambulatory care. Cochrane Database System Rev 20015 Oct 19;(4): CD003539.

infection preventionist(s)/infection control professional [in paragraph c(2)]. Unlike in larger hospitals, in the CAH hospitals the leader may be an infection preventionist.

Vizient CAH members provided the following additional comments with respect to program leadership.

1. *Many CAHs do not have "qualified" staff on site. For example, their infection control/prevention nurse might be the senior-most nurse who has the responsibility by default. Many CAHs do not have a staff pharmacist; they are contracted and come to the facility once/week or less frequently and I am sure the majority of CAHs definitely do not have a staff ID physician. The COPs should reflect/be mindful of CAH resource limitations.*
2. *Our medical staff consists of five family practice physicians and one PA. We do not have access regularly to a physician who specializes in infectious diseases. Our pharmacist is only physically in the building once a week. She is available for consultation by phone every day. Designating a "champion" for antibiotic stewardship could be accomplished but, it would be a hardship for our hospital if CMS specified who that person should be if we did not have a person available with the specific qualifications if required by CMS.*
3. *CMS should not designate specific disciplines, but could provide recommendations. Again, CAHs are extremely limited in terms of resources (staffing, financial) and CMS should be mindful of CAH resource limitations.*

We recognize that few CAHs have convenient access to infectious diseases physicians and pharmacists. One proposed model that may help alleviate this burden is "tele-stewardship". In this model, a telehealth technology is used to connect clinicians at the CAH with experts off site at a larger institution. This expertise can range from administrative guidance of the antibiotic stewardship program to individual patient consultation. Additionally, a similar model can be used to increase the amount of resources available to a CAH for their infection prevention program. This model required secure, data encrypted digital connectivity, where an infectious diseases physician and an antimicrobial stewardship pharmacist located remotely can communicate with the physician and/or pharmacists at the originating CAH site on a regular basis. One barrier to developing this service on a national scale is financial reimbursement for tele-health services. By providing support for funding for tele-stewardship through CMS, this novel service delivery model would increase access to expertise resulting in improvement in population health, coordination of care, and reduce antimicrobial resistance.

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In closing, on behalf of Vizient, Inc., I would like to thank CMS for providing us this opportunity to comment on the Proposed Rule. Please feel free to contact me at (202) 354-

2607 if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

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Vizient, Inc.