Trinity Health

August 12, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244-1850

Re: CMS-6082-NC, Requests for Information: Reducing Administrative Burden to put Patients over Paperwork

Submitted electronically via http://www.regulations.gov

Dear Administrator Verma,

Trinity Health appreciates your continued interest in reducing burdens for hospitals, physicians and patients while improving the quality of care, decreasing cost, and ensuring patients and their providers are able to make the best choices possible for care. This submission reflects Trinity Health's strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. Our People-Centered Health System puts the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs).

General Comments

Trinity Health is delighted that the Administration continues to seek stakeholder feedback on opportunities to increase flexibility and efficiency in the regulatory process. The complexity and redundancy of the existing regulatory process has become overly intrusive and is distorting the practice of medicine. The existing framework of overregulation can be modified to instead rely on transparency, database monitoring, and selective focus where abuse has been detected. In addition, CMS should measure outcomes, not process, to generate care improvement data that is meaningful.

Many providers and health systems, such as Trinity Health, are seriously committed to value-based care and have invested greatly in developing the infrastructure for alternative payment models and managing total cost of care for patients. As we work to provide people-centered care, commercial insurers emboldened by existing flexibilities create administrative burden and waste with through arbitrary denials and downgrades of care—all of which distort the appropriate delivery of care. **CMS should increase the ability of qualified provider Accountable Care Organizations and Clinically Integrated Networks to function as full-risk recipients for Medicare Advantage and other alternative payment models to remove such barriers for more efficient and higher quality care.**

The greatest opportunity for change is for CMS to use existing value-based and transparency mechanisms to drive provider innovation around the processes of care that can deliver the best outcomes. In general, rather than focus on process details in many regulations, Trinity Health recommends that the agency instead focus on an outcomes-based regulatory scheme that identifies a small number of high-level key metrics that are meaningful to patients and reflect successful performance against the desired outcomes of better care, smarter spending and healthier people.

In addition, CMS should provide adequate time to implement new regulations and more fully consider hospital and health system comments and concerns prior to implementation. There have been an enormous number of regulatory changes over the last several years. CMS continues to add new forms and requirements without reducing, eliminating or condensing related regulations and requirements. Many of these regulatory efforts require significant changes in software, other technology, and processes; and these changes are multi-step endeavors involving stakeholders across hospitals and health systems as well as outside partners including vendors. We urge CMS to provide more realistic timetables for regulatory implementation and ensure that these timetables take into consideration the fact that hospitals and health systems are continuing to provide direct patient care 24-hours-a-day/7-days-a-week alongside implementation of regulatory changes. We also urge CMS to reduce front-end administrative burden, such as costly data gathering and reporting.

Trinity Health strongly recommends CMS rely more heavily on transparency, monitoring and the creation of a more efficient marketplace that will drive self-correction through competitive means.

Additionally, CMS should consider the creation of an advisory panel that includes hospital and health system participants to discuss impending regulations and assist in developing more realistic timelines and solutions.

<u>Alternative Payment Models</u>

Trinity Health believes CMS should advance policies that provide additional flexibility for alternative payment models and align payment rules in order to provide the most efficient and high-quality care to beneficiaries.

Additional Waiver Expansions

CMS should streamline waiver flexibility across alternative payment models (APMs) and across Medicare and Medicaid to allow providers who are in down-side risk arrangements to have the ability to use all waiver flexibility afforded by Medicare, regardless of the level of risk assumed. Providers and beneficiaries can be in more than one program and a core set of waivers

would be more simplistic for all involved. Moreover, it would be easier for CMS to implement and easier for providers to comply. These flexibilities (including the telehealth and SNF Three Day waiver) have been successful in reducing the costs, improving care access, and increasing quality.

CMS should work with the relevant legal agencies to create a process for program participants to seek guidance on what is allowable under the fraud and abuse waivers available to ACOs. At present, there is no option short of the resource intensive and fact specific Advisory Opinion process. CMS itself cannot opine on such questions and cannot approve new programs/services provided free or not cost to beneficiaries, which leaves providers (and their lawyers) unsure of whether they are interpreting the ACO waivers correctly. Unfortunately, this has had the chilling effect of many program participants opting not to use the waivers. CMS and the legal agencies should create an FAQ process for providers to inquire about compliance with waiver within APMs and other models tested by CMS.

Next Generation ACO

As a Next Generation ACO with 80,000 attributed beneficiaries and having generated tens of millions of dollars of savings with year over year improvements in quality, we have demonstrated that physician-led clinical integrated networks with a commitment to vulnerable populations can be successful in managing risk and accountability for cost, quality and patient experience. The evaluation of the first performance year of Next Generation ACO model overall resulted in an estimated $63 million in net savings while maintaining quality for patients.

CMS should continue to offer a full-risk model similar to the Next Generation ACO in the Pathways to Success program. Allowing participants to remain in the Next Generation model reduces the administrative burden of learning new data and reporting systems, submission and audit tools, and different contractual requirements.

<u>Medicare Telehealth Coverage</u>

Hospitals are embracing the use of telehealth because it offers benefits such as virtual consultations with distant specialists, the ability for high-tech monitoring without requiring patients to leave their homes, and less expensive/more convenient care options for patients. However, coverage and payment for telehealth services remain major obstacles. In particular, Medicare lags far behind other payers with only limited telehealth reimbursements. For example, CMS approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when delivered via telehealth.

CMS should expand Medicare coverage of telehealth services, and presume that Medicare-covered services are also covered when delivered via telehealth, unless CMS determines on a case-by-case basis that such coverage in inappropriate.

<u>Home Care Face-to-Face Requirement</u>

Under the ACA, a home care provider cannot bill Medicare for home care services without documentation from a physician or approved mid-level provider indicating the patient had a face-to-face encounter with that provider within 90 days prior to the start of home care, or 30 days after the start of home care.

Therefore, home health reimbursement is dependent upon documentation by a provider of a face-to-face encounter; however, the Medicare payment system includes no incentives, and very limited penalties, to encourage providers to submit this information to Medicare or share it with the Home Health Agency in a timely manner. The guidance on what is acceptable documentation for a face-to-face encounter is also very objective. There are many examples of entire episodes of care being denied because the exact same diagnosis is not used in the face-to-face encounter documentation as what is used in the home health plan of care. This is unfortunate as it is clear that skilled care was provided and the patient shows a benefit from that care. As we know, elderly patients may suffer with many comorbidities, the primary focus of care in the home may not be the same focus as in the hospital or medical office—there should not be a penalty for this.

Trinity Health recommends CMS eliminate the home care face-to-face requirement for patients who are admitted to home care after being discharged from an inpatient facility. This has been a key priority of the National Association for Home Care and Hospice. We also recommend that CMS allows mid-level providers to sign home care orders and to certify patients for the home health benefit. **As a more general point, CMS should expand decision-making authority for mid-level providers including authorization of performing screenings, ordering testing and diagnostics, prescribing medications and admitting privileges in the areas of primary care, home health care, skilled nursing facility care and hospice care to advance the care of patients.**

Modify Readmission Measure to Reflect Differences in Sociodemographic Factors

A body of research demonstrates that readmission rates are higher in communities that are economically disadvantaged. This is because patients' likelihood of being readmitted is affected by access to resources that support them while out of the hospital, such as access to affordable medication, primary care physicians and appropriate foods. For this reason, the 21st Century Cures Act requires CMS to implement sociodemographic adjustment in the hospital readmissions penalty program starting in FY 2019. At the same time, a recent series of reports from the National Academy of Medicine shows that other outcome measures, such as 30-day mortality rates and measures of efficiency and patient experience, are similarly impacted by sociodemographic factors. Moreover, a report from the Assistant Secretary for Planning and Evaluation (ASPE) shows that providers caring for large numbers of poorer patients are more likely to perform worse on a wide range of hospital, physician and post-acute care pay-for-performance programs.

CMS should ensure its implementation of sociodemographic adjustment in the hospital readmissions penalty program is undertaken in a transparent and fair manner. Trinity Health also urges CMS to use the evolving science around the best ways to adjust for sociodemographic factors to update its approach as needed. Lastly, we urge CMS to incorporate sociodemographic adjustment into its other quality measurement and pay-for-performance programs where necessary and appropriate.

Stark Law/Anti-Kickback Regulations

Update Fraud and Abuse Laws, Safe Harbors and Exceptions

The federal Anti-kickback Statute (AKS) makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward referrals of items or services reimbursable by a Federal health care program, unless the arrangement fits within a regulatory safe

harbor. The AKS is an intent-based statute, meaning that a violation of the law requires the intent to do so. However, as noted below, improper intent is relatively allege by inferring intent. A violation of the AKS can also give rise to a violation of the FCA.

The federal Physician Self-Referral Law (aka the Stark Law) prohibits a physician from making a referral for certain designated health services payable by Medicare or Medicaid to an entity in which the physician (or an immediate family member) has an ownership/investment interest or with which he or she has a compensation arrangement, unless an exception applies. The Stark Law is a strict liability statute, meaning that intent is irrelevant in determining whether a violation has occurred.

The federal False Claims Act (FCA) imposes civil liability on any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the federal government. The terms "knowing" and "knowingly" mean a person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information related to the claim. No proof of specific intent to defraud is required to violate the civil FCA.

The Civil Monetary Penalties Law authorizes the imposition of civil monetary penalties (CMP) for a variety of health care fraud violations. Different amounts of penalties and assessments may be authorized based on the type of violation. CMPs also may include an assessment of up to three times the amount claimed for each item or service, or up to three times the amount of remuneration offered, paid, solicited, or received.

To support continued accountability of providers and improved quality, current methods of enforcing and expanded use of these laws need to be significantly curtailed or modified and new exceptions and safe harbors adopted. Changes are needed to encourage patient care innovations and improvements, and to level the playing field among those engaged in funding and those directly providing health care services. In the current form these, and other (antitrust) laws, restrict the extent to which providers can operationalize value-based systems in which hospitals and physicians can align and share risk and rewards while improving patient care, enhancing access, and achieving quality and improved savings. More specifically, the strict liability nature of the Stark Law and the ready ability of the government and qui tam relators to infer improper intent under the FCA and AKS chill the ability of providers to engage in legitimate business arrangements that are not expressly described in a safe harbor to the AKS, or an exception to the Stark Law, but that promote improvements in patient care and quality and reduce cost.

A *Stark Law exception and an AKS safe harbor should be adopted to protect clinically integrated networks.* Although the AKS and Stark Law have a safe harbor and exception for MSSPs, there is no safe harbor or exception for clinically integrated networks, which is a model by which hospitals, physicians and other providers align in broad networks and engage in managed care contracts with third party payers. The goals of these programs are similar to the goals of shared savings programs in that they establish basic accountabilities for care delivery through the use of incentive payments or shared savings programs among hospitals, physicians and other providers. By removing barriers to innovation the parties can shift the focus to outcomes. Currently, the parties entering into these arrangements do so at their peril or must create complex and cumbersome structures to avoid violation of these laws.

An AKS safe harbor should be adopted to protect collaboration among providers to identify and deliver to patients the services needed to restore or maintain health in the continuum of care ranging from transportation vouchers, in-kind help for meal preparation, social services, lodging, etc. The limitations intended to restrict improper patient inducements impede providers in their efforts to care for the whole patient. Although a safe harbor recently was finalized for free or discounted transportation, the criteria for qualifying for that safe harbor diminish its value (e.g., a provider cannot market the availability of the transportation, which makes it difficult to make patients experiencing transportation problems aware of the service).

To level the playing field, AKS laws should be evenly applied to all parties, including insurers and other non-hospital parties. Third party payer/insurance companies and other non-hospital parties (e.g., venture capital firms) are increasingly becoming involved in various aspects of services for patients and the provision of care. These entities are not hampered by these laws because 1) they are not directly subject to the Stark Law; and 2) they typically are not in a position to provide remuneration in exchange for inducing or rewarding referrals for health care services payable by a federal health care program to the same extent as hospitals. For example, one national health insurance company announced a national partnership with a transportation company to provide free transportation for certain enrollees; yet, it is not burdened by having to comply with the safe harbor for free or discounted transportation. Likewise, as health insurance companies acquire physician practices, they need not be concerned about meeting AKS safe harbors governing those acquisitions and the amount paid for the practices to the extent they are not in a position to induce referrals for health care services or items payable by a federal health care program. To level the playing field, all involved parties should be subject to the same laws.

When an AKS safe harbor and Stark Law exception exist for a single type of arrangement, the more burdensome of the applicable – AKA safe harbor or Stark Law exception – should be modified to be identical to the less burdensome regulation. Certain arrangements are the subject of an existing AKS safe harbor and Stark Law exception where the applicable AKS safe harbor and Stark Law exception have different compliance requirements.

Regulations should aim to create an efficient marketplace where providers and payors alike can compete on value without being hampered by duplicate and burdensome regulations, particularly as providers are moving away from volume-based models toward taking risk for populations. Existing waivers, safe harbors and exceptions should be simplified and new safe harbors and exceptions added to facilitate the ability of providers to focus on population health strategies that are in the best interest of patients and their families. Finally, the harsh strict liability standards set forth in the Stark Law and the relative ease with which improper intent can be asserted under the AKS and FCA are too punitive and create obstacles to embracing and implementing evolving standards of care. They too, should be evaluated and revised.

Missing Signature Noncompliance

In practice, 90 days is not enough time to remedy a technical Stark defect, which necessarily involves two parties. Importantly, a missing signature does not cause increased cost or evidence improper payment. **CMS should extend period to remedy a temporary noncompliance of missing signature to at least 180 days, or at least allow an extension request if a provider can provide**

documented affirmative steps to rectify noncompliance. Further, the 90-day period to rectify should begin on the date of discovery of noncompliance and not the date that the relationship became noncompliant.

Physician Productivity Pools
Stark allows a physician group to pool work Relative Value Units (wRVUs) for distribution as it determines, but does not expressly allow the pool to include physician assistants (Pas) and nurse practitioners (NPs). This restriction is disruptive to coordinated care delivery and should be changed—**CMS should allow PAs and NPs to participate in physician productivity pools. The bona fide employee rules should be amended to allow groups of employed physicians, Pas and NPs to pool wRVUs.**

Pharmacy and Drug Regulations
Compounded Drugs
In April 2016, the FDA issued draft guidance for hospital and health system compounding of drugs that included an exception to its "prescription requirements". This provision was intended to allow hospital pharmacies to compound and distribute a limited amount of drug products prior to the receipt of a patient-specific prescription, as long as the compounded products were used only within the hospital's facilities for its own patients. This exception included a provision to limit the distribution of these compounded products only to the hospital facilities located within a one-mile radius of the hospital's compounding pharmacy.

The FDA should eliminate the one-mile limitation and replace it with an alternative approach. Trinity Health urges the FDA to allow hospitals and health systems to use the USP Chapters 797 and 800 beyond-use date (BUD) timeframes for handling of non-hazardous and hazardous sterile compounding. USP 797 delineates the procedures and requirements for safe compounding sterile preparations. Similarly, USP 800 describes the standards for the handling of hazardous drugs with patient safety, worker safety, and environmental protection taken into considerations.

National Drug Code (NDC) Reporting Requirement
The Deficit Reduction Act of 2005 requires all state Medicaid agencies to collect rebates from drug manufacturers for physician-administered drugs. The National Drug Code (NDC) code reporting requirement arose out of this drug rebate program. NDC codes have been required in some States since approximately 2007. The Medicaid program requirement to report NDC codes is inconsistently applied across state Medicaid programs.

CMS should evaluate whether NDC information reported by hospitals and physicians is really used for the purposes intended. Trinity Health asks that the Drug Rebate Program (1991) be evaluated for effectiveness and whether information needed can be obtained through mechanisms other than hospital/physician claims.

Quality Reporting
Measure Outcomes, Not Process
Trinity Health encourages CMS to remove redundancy and reduce complexity when selecting measures across programs and evolve all quality reporting to focus on outcomes rather than process measures. Harmonization across quality reporting programs, including utilization of the same

definitions consistently applied across programs and years, is important to reducing unnecessary administrative burden. **We strongly believe that quality measurement should focus on a small number of metrics that emphasize patient-reported and patient-generated data. Trinity Health urges CMS to focus on outcomes-based measures that are meaningful to patients, and reflect successful performance against the desired outcomes of better health, better care and lower costs.**

As quality reporting shifts from manually abstracted data to electronic reporting, we especially encourage CMS to focus efforts on development and refinement of outcome measures rather than process measures. Definition changes and electronic health record (EHR) vendor-specific challenges result in considerable effort and re-work to obtain specified data on process measures from the EHR. Once data can be obtained, the value of it in accurately representing the clinical process is questionable. Measure exclusions and clinical process specificity is often not retrievable in a way that compares with the manually abstracted data. The exercise of producing the data is extensive however, because of the challenges noted above, the value of the data produced and the ability to utilize the data to improve care is minimal.

CMS should ensure new measures are well-defined, tested and designed to fill gaps in measurement without adding undue burden on providers. Quality measures used for payment should be limited such that there are no more than five clinical measures and two patient experience measures. These measures should be primarily patient reported functional status outcome measures. Quality metrics should also include other components that are critical to accurately assessing the role of a provider in affecting patient outcomes, and ease provider burden across multiple programs. CMS should provide alternative reporting approaches (e.g., electronic reporting from certified electronic health records and q-data intermediaries), and align measures with other Medicare measure reporting programs.

HIPAA

Business Associate Agreements

The HIPAA Privacy Rule requires health care providers and their "business associates" to maintain the confidentiality, integrity, and availability of patients' protected health information. But HIPAA also imposes a redundant requirement that they also enter into “business associate agreements” with each other; agreements which merely restate the legal requirements in a contractual form. This creates an excessive administrative paperwork burden.

Trinity Health recommends HHS eliminate the redundant HIPAA requirement for "business associate agreements."

Annual Reporting of Breaches

Health care providers and other covered entities are required to report to HHS breaches involving more than 500 individuals within 60 days, and all breaches involving less than 500 individuals on an annual basis. The annual reporting provision provides no additional protection to patients and is administratively burdensome to covered entities. Patients are already required to receive an individual notification of such breaches, and covered entities are already required to maintain a log of such breaches for inspection.

We recommend HHS eliminate the requirement that covered entities annually report all breaches affecting less than 500 individuals to HHS.

Notice of Privacy Practices
Covered entities are required to physically distribute the Notice of Privacy Practices (NPP) to patients. This requirement creates administrative burden and requires significant physician resources (e.g. printing and individual distribution).

We recommend HHS eliminate the requirement for covered entities to physically distribute the Notice of Privacy Practices to patients. This requirement creates administrative burden and requires significant resources (e.g. printing and individual distribution). **Covered Entities would continue to post the NPP on their websites, and make physical copies available upon request.**

Information Sharing for Clinically Integrated Care
The HIPAA Privacy Rule requires hospitals and other HIPAA-covered entities to make reasonable efforts to limit the scope of individually identifiable patient health information that it uses, discloses or requests, to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. The minimum necessary standard does not apply to disclosures to or requests by a health care provider for treatment purposes, disclosures to the individual who is the subject of the information, uses or disclosures made pursuant to an individual's authorization, among other exceptions. Further, federal HIPAA rules and state privacy rules are inconsistent, making compliance challenging for providers and others.

The HIPAA Privacy Rule enforced by the Office for Civil Rights (OCR) should be modified to permit a patient's medical information to be used by and disclosed to all participating providers in an integrated care setting without requiring that individual patients have a direct relationship with all of the organizations and providers that technically "use" and have access to the data.

Align HIPAA and 42 CFR part 2 to improve the quality and safety of clinical care
Trinity Health recommends that Part 2 be aligned with HIPAA with regard to permitting the disclosure of protected health information for treatment, payment, and health care operations purposes (TPO) including care coordination. In addition, care providers would benefit from focused education on the appropriate criteria needed for sharing information with family members. Medical professionals recognize the interdependence of physical and behavioral health and the role care coordination has on both quality of care and cost; aligning HIPAA and Part 2 is necessary to treat the whole patient. As OCR works to ensure regulations are revised to address these concerns, proper parameters must be included to prevent misuse of patient information.

HHS should also align the Home Health Conditions of Participation with HIPAA. The Home Health Conditions of Participation (484.110) effective January 2018 require Home Health Agencies to provide a patient's medical record to a patient within 4 business days or at the next skilled visit which could be the very next day. This requirement causes the potential for a clinician to physically take a paper record to a patient, which is a HIPAA security risk. Many of our elderly patients do not have access to electronic methods to obtain their record or simply prefer a hard copy. It is not as secure to have clinicians driving around the community with paper copies of patient medical records in their

vehicles as they make multiple stops to other patient homes throughout their day. This requirement also does not give proper time to the agency to ensure there is an appropriate request if there is a POA or guardian making the request on behalf of the patient.

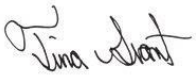
Further, we recommend eliminating the prohibition of re-disclosure and the requirement to provide notice to lawful recipients of identifiable substance use disorder information that the information cannot be re-disclosed. Aligning the confidentiality of substance use records with HIPAA requirements – thereby granting health care providers access to information to diagnose and effectively treat patients who use opioids and other controlled substances – will better ensure integrated care across providers and settings. While this recommendation will require a federal regulatory change, it is necessary to provide quality care to this population. As a result of antiquated regulations, opioid and substance use disorder diagnosis and treatment information gets locked away from other providers and care managers, fueling bifurcation, limiting care coordination, and creating safety risks for beneficiaries. In addition, we recommend HHS explore if there is an opportunity to combine Part 2 funding with patient safety and data sharing language requirements to improve data sharing.

Conclusion

Trinity Health thanks CMS for their commitment reducing unnecessary regulatory burdens for providers, patients and their families and look forward to collaborating with the agency on this work.

Thank you for your continued interest in reducing burdens, we look forward to working with you to advance this goal. If you have any questions or need further information, please feel free to contact me at granttw@trinity-health.org or 517-643-0784.

Sincerely,



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