

June 13, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services Attn: CMS-1677-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Re: CMS-1677-P, Requests for Information: CMS Flexibilities and Efficiencies

Dear Ms. Verma,

Trinity Health appreciates the opportunity to offer recommendations in response to the Request for Information on CMS Flexibilities and Efficiencies. We very much appreciate your interest in reducing burdens for hospitals, physicians and patients while improving the quality of care, decreasing cost and ensuring that patients and their providers/physicians are making the best health care choices possible. 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. Trinity Health includes 93 hospitals as well as 121 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 almost \$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 2,080 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

Trinity Health shares the CMS commitment to transforming the health care delivery system. We work each day to create a People-Centered Health System focused on delivering better health, better care, and lower costs in our communities. Trinity Health is committed to working with you to reduce unnecessary regulatory burdens for clinicians, other providers, patients and their families. That said, Trinity Health complies with all laws and regulations, and has made extensive investments in our

compliance program, including workforce training. Set forth below are our specific recommendations. Note that they are not in priority order; rather they are grouped by topic.

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I. GENERAL COMMENTS AROUND CMS PROCESS

Trinity Health is delighted that this Administration is asking industry participants to describe 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. We believe the old framework of overregulation can be modified and instead regulation can rely on transparency, database monitoring, and selective focus where abuse has been detected. For example, the sepsis bundle (SEP-1) initiated in October of 2015 continues to be a very labor intensive measure. With more than 60 abstracted fields covering seven process components of care, abstraction burden is considerable. Many vendor systems are unable to reflect compliance within the components of care and are only able to reflect compliance of the bundle measure. A hospital can be unaware if their primary problem exists with timing of blood cultures versus fluid resuscitation since the abstraction tool output reflects only overall bundle compliance. CMS should measure outcomes not process to generate care improvement data that is meaningful.

Medicare has excellent mechanisms in place to hold providers accountable for the outcomes—not the processes—of care via value-based payment programs as well as transparency initiatives such as Hospital Compare and the star ratings system. We believe the greatest opportunity for change is for CMS to use these value-based and transparency mechanisms to drive provider innovation around the processes of care that can deliver the best outcomes. In general, CMS has gone too far with process details in many regulations and 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 that reflect successful performance against the desired outcomes of better care, smarter spending and healthier people. Coupling measurement that is based on outcomes with transparency tools allows the marketplace to drive providers to develop and continuously improve upon the most effective care processes.

In addition, CMS should provide more time to implement new regulations, and that the agency 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.

For many of our suggested changes, hospitals and health systems have already provided significant feedback and enunciated specific concerns to CMS; however, the agency often moves forward without giving proper consideration to these concerns. Recent examples of this include the two-midnight rule, and the repeated reporting changes related to laboratory packaging. While Trinity Health often agrees with the intent behind proposed changes (e.g., beneficiary notification of observation status), the regulatory schematic is often conflicting and very administratively burdensome to implement (e.g., the NOTICE Act and MOON form). Further, the too often-used solution of CMS is to require the use of modifiers to collect information, which is typically extremely burdensome to implement.

RECOMMENDATION: Trinity Health strongly recommends that CMS rely more heavily on transparency, monitoring and the creation of a more efficient marketplace that will drive self-correction through competitive means. In addition, we recommend that CMS give more credence to provider comments and concerns prior to implementing new regulations. Additionally, we recommend that CMS 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. Also CMS needs to consider the aggregate burden of new regulations, not simply their individual burden. In many instances the same staff bear the brunt of responsibility for implementing multiple new federal regulations as well as new state laws and regulations.

II. ALTERNATIVE PAYMENT MODELS

a. Flexibility in Payment Rules and Legal Requirements

Trinity Health believes CMS should advance policies that provide additional flexibility to ACOs and align payment rules in order to provide the most efficient and high-quality care to beneficiaries. There are, however, payment rules that run counter to the goals of an ACO. Within an ACO, the goal is to treat the patient in the right setting regardless of payment policies that micromanage care and restrict innovation. As long as the ultimate outcome is high-quality, cost-effective care, the ACOs should be able to direct patients to the appropriate setting without reduced payment.

RECOMMENDATION: Trinity Health recommends the following changes to provide this needed flexibility to ACOs.

- ***Provide MSSP ACOs the option to choose prospective beneficiary assignment. Trinity Health strongly encourages CMS to allow ACOs the option to choose prospective beneficiary assignment for Track 1 and 2 ACOs.*** Prospective assignment would increase

certainty for the ACO and provide a more narrowly defined, stable, target population and help minimize unexpected changes in its benchmark. These outcomes are valuable to ACOs in all tracks, not just those that take on increased risk.

- ***Allow ACOs in all MSSP tracks and other programs to apply for a waiver of the SNF 3-day rule. In the June 2015 MSSP final rule, CMS provided ACOs participating in Track 3 with additional flexibility to attempt to increase quality and decrease costs by allowing these ACOs to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries. The SNF 3-day rule requires Medicare beneficiaries to have a prior inpatient stay of no fewer than three consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We encourage CMS to waive this requirement and provide this flexibility to other MSSP Tracks and incorporate this waiver into other models, as appropriate.***
- ***Waive other post-acute care payment rules that unnecessarily restrict ACOs from making the most optimum treatment option for Medicare beneficiaries. This includes the IRF 60 percent rule and the three-hour of therapy per day rule. Trinity Health also encourage CMS to develop waivers to provide IRFs additional payment and regulatory flexibility in its bundling programs. With respect to LTCHs, CMS should waive the 25 percent threshold rule and the short-stay outlier payment.***

b. Additional Waiver Expansions

Waiving additional payment regulations is essential so that ACOs can effectively coordinate care and ensure that it is provided in the right place at the right time. Additional waivers would provide ACOs with valuable tools to increase quality and reduce unnecessary costs and should be available to advance the success of all ACOs. CMS should ensure that the waivers are easily accessible to ACOs and should rely on the ACOs' existing cost and quality metrics to ensure that ACOs continue to provide high-quality, appropriate care to their ACO populations.

RECOMMENDATION: Trinity Health strongly encourages CMS to make available to all Medicare ACOs waivers related to the following and implement them in a manner that is not prohibitively burdensome to ACOs that utilize them:

- ***Hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the providers who may provide post-hospital services.***
- ***Medicare requirements for payment of telehealth services, such as limitations on the geographic area and provider setting in which these services may be received.***
- ***Homebound requirements for home health, which mandate that a Medicare beneficiary be confined to the home to receive coverage for home health services.***
- ***Medicare primary care co-payments, which would reduce or eliminate cost-sharing otherwise applicable under Medicare Part B for some or all primary care services furnished by health care professionals within the network of the ACO.***

We further recommend that CMS consider consistent payment and legal waivers across APMs and Advanced APMs. 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.

Lastly, CMS should work with the relevant legal agencies to create a process for program participants to ask questions. 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 arrangements (e.g. gainsharing), which leaves providers (and their lawyers) in new programs unsure of whether they are interpreting the program requirements 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, Advanced APMs and other models being tested by CMS.

III. MEDICARE REGULATIONS

a. Direct Supervision Requirements

In the 2009 OPPTS final rule, CMS mandated “direct supervision” of outpatient therapeutic services. As a result of this regulatory position, hospitals – particularly small and rural hospitals, and critical access hospitals – have found themselves at increased risk of unwarranted enforcement actions. From 2010-2013, CMS prohibited its contractors from enforcing this policy. Since 2014, Congress has annually extended the enforcement moratorium. The annual reconsideration of the misguided direct supervision policy places affected hospitals in an uncertain and untenable position.

RECOMMENDATION: CMS should permanently prohibit its contractors from enforcing the direct supervision rule for CAHs and small, rural hospitals.

b. 3-Day Stay for Skilled Nursing Facility (SNF) Coverage

A 3-day qualifying inpatient hospital stay requirement for SNF coverage has been in place since the beginning of Medicare. This requirement conflicts with short-term stay initiatives and promotion of efficient health care delivery to the elderly population. In cases where the patient does not meet the requirements, the patient is obligated to self-fund the SNF stay, or the patient stays in the hospital until a safe discharge plan can be executed, which leads to longer lengths of stay in the hospital. Some MA Plans have eliminated this requirement, and it is also waived under the Next Generation ACO program.

RECOMMENDATION: Eliminate the outdated 3-day inpatient hospital stay requirement. Note that a blanket elimination may require a legislative fix, although another approach could be through the Innovation Center, which has waived, for example, the 3-day stay for some Pioneer ACOs and Next Gen ACOs.

c. Medicare provider numbers – Outpatient Prospective Payment System

In implementing the site neutrality policy, CMS provided some guidance about the impact of a merger on OPPTS payments. However, the guidance did not explicitly state that OPPTS would continue for outpatient services that were provided on the campus of a hospital prior to November 2015, but that become off-campus services of another hospital as the result of a merger that discontinues inpatient services on the campus of the merged hospital.

For example, assume one hospital merges into another, and as part of the merger plan, the merging hospital discontinues its inpatient services. Its on-campus outpatient services will then become an

off-campus outpatient site of the surviving hospital. Fairness, policy and logic support continuing to recognize the OPSS-eligible provider-based status of such site. The nature and location of the outpatient services by the merged hospital are unchanged, so the reimbursement for such services should be unchanged. The same rationale that supports “grandfathering” the merging hospital’s off-campus provider-based sites supports grandfathering the merging hospital’s on-campus provider-based site.

The failure to more specifically recognize the continued OPSS-eligible provider-based status of such former on-campus services could deter either the entire merger, or prompt the continuation of inpatient services at the merged campus. Either result would prevent both overall savings to the Medicare program from the merger, and a reduction in excess inpatient beds.

RECOMMENDATION: For OPSS site neutral policy, CMS should more forthrightly support the continuation of OPSS payments to outpatient services that were provided on the campus of a hospital prior to November 2015, but that become off-campus services as the result of a merger that discontinues inpatient services on the campus of the merged hospital.

d. Parts C and D Compliance Requirements

CMS has established extensive compliance program and other requirements for Medicare Part C and D health plans. CMS extended these requirements recently to include First Tier, Downstream Related Entities (FDR) that contract with Part C and D plans, including health care providers.

Because health care providers are already subject to mandatory compliance program requirements as a result of enrollment in the Medicare and Medicaid programs, these additional requirements are duplicative, unnecessary and burdensome.

RECOMMENDATION: Suspend the CMS extension of Medicare Part C and D health plans compliance requirements to First Tier, Downstream and Related Entities that are already subject to mandatory compliance programs as enrolled providers in the Medicare and Medicaid programs.

e. Program Integrity Enhancements to Provider Enrollment Process

The Program Integrity Enhancements to Provider Enrollment Process was a proposed rule CMS-6058-P issued on March 1, 2016. The proposed rule is part of the CMS effort to prevent questionable providers and suppliers from entering the Medicare program and to enhance the ability of CMS to promptly identify and act on instances of improper behavior. It includes provisions related to reporting disclosure of affiliations, reporting disclosable events and reporting “uncollected debt”.

RECOMMENDATION: The final Program Integrity Enhancements to Provider Enrollment Process rule should contain language that provides significantly clearer directions and guidance on reporting affiliations and histories, and should mainly focus on individuals and organizations that are known for non-compliance.

f. Fraud and Abuse Training Requirements

Currently CMS makes payors and providers responsible for the fraud and abuse training of others, resulting in a chaotic web of multiple duplicative and inconsistent training requirements. Despite some recent improvements, the burden remains enormous and the benefit doubtful.

RECOMMENDATION: CMS should offer a single web-based fraud and abuse training program, require certification by payors, providers and vendors that they took the relevant components of that course. Furthermore, CMS should not require payors and providers to impose more or different training than the CMS program.

g. Nursing Home Staffing and Census Information

CMS recently mandated that nursing homes submit staffing and census information through a Payroll-Based Journal (PBJ) system. CMS already collects staffing information annually during a survey using a two-week look back.

RECOMMENDATION: Eliminate the mandate that nursing homes submit direct care staffing information.

h. Disclosures of Ownership and Control

CMS regulations require Medicaid managed care organizations (MCOs) to collect ownership and control information annually from downstream providers. Since providers may contract with numerous MCOs they have to provide the same duplicative information many times over the course of a year. Worse, MCOs typically require that the provider complete the information on the MCO's form, preventing any efficiency.

RECOMMENDATION: Eliminate the requirement for providers who have submitted Form 855. Others should submit ownership and control information only once a year to CMS.

i. 72-Hour Review Period for Medicare Managed Care

Medicare Managed Care rules should not afford 72 hours to respond to prior approval requests.

RECOMMENDATION: The 72-hour review period should be reduced to 24-hours.

j. Co-Location Rules - Allow Flexibility for Providers to Share Space

Many hospitals share treatment space with other providers in order to offer a broader range of medical services and better meet patient needs. In rural areas, hospitals may lease space to visiting specialists from out-of-town for several days per month. Recently, CMS issued several very restrictive interpretations of the shared space rules – such as disallowing arrangements for visiting specialists because the spaces for the specialists are not completely separate from the hospital and do not provide an independent entrance and waiting areas. Overly prescriptive interpretations of the sharing or co-location rules can create patient access and quality-of-care problems, and subvert broader goals to provide more coordinated and patient-centered care at lower cost.

RECOMMENDATION: CMS should relax co-location rules to allow hospitals to have alternate uses for parts of their facilities, including use by other providers or non-providers.

Additionally, CMS should not categorically disallow shared space arrangements because they do not have separate spaces, entrances and/or waiting areas.

k. Medicare RAC Contingency Fee

Medicare RACs are paid a contingency fee that financially rewards them for denying payments to hospitals, even when their denials are found to be in error. Because the incentive is to deny claims, with no recourse for errors/improper denials, the RACs lean toward denying valid claims. The resulting multitude of invalid denials creates an undue burden for providers.

RECOMMENDATION: RAC contracts should be revised to incorporate financial penalties for poor performance, as measured by ALJ appeal overturn rates.

l. Medicare Telehealth Coverage

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 payors with only limited telehealth reimbursements (rural locations). 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 they are delivered via telehealth.

RECOMMENDATION: 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 is inappropriate.

m. Provider Reimbursement Review Board (PRRB)

The PRRB is an independent panel to which a certified Medicare provider of services may appeal if it is dissatisfied with a final determination by its Medicare contractor or by CMS. Changes made in 2015 (42 CFR 405.1873) requiring a claim or protested amount as a "condition of payment" requires a PRRB review of compliance with the reimbursement requirement of an appropriate cost report claim before considering the case on the merits. This change in the regulations effectively stripped the PRRB of the power to rule on an appeal's jurisdictional status.

RECOMMENDATION: Trinity Health recommends that CMS should reverse this regulation, which removes or limits the Provider Reimbursement Review Board's statutory authority and ability to grant jurisdiction. This regulation results in limiting access to the provider's right of board review provided by section 1878(a)(1)(A) of the Act, when "dissatisfied". There are instances in cost report preparation where the provider could not reasonably be expected to know the facts needed to either make a claim or protest, particularly given the level of specificity required, such as CMS' own calculation inaccuracies and misinformation as shown in recent court cases, i.e. Baystate, Cape Cod, and Allina. There is a need to maintain access to the board through Bethesda-type cases for CMS changes and clarifications, like the Labor & Delivery days change in the FFY 2010 IPPS Final Rule, for when cost reports are filed in compliance with the rules prior to the change or clarification. There is also a need for access to appeal directly from the Federal Register final rules, without waiting to voice

dissatisfaction until the filed cost report. Payment should be allowed, and not precluded as proposed, when the reviewing entity has ruled in favor of the provider, as the appeals/review process is part of the entirety of the “claims” process.

n. Home Care Face-to-Face Requirement

Under the ACA, a home care provider cannot bill Medicare for home care services without a signed narrative from the physician indicating that the patient had a face-to-face encounter with that physician 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 physician of a face-to-face encounter, however, the Medicare payment system includes no incentives, and very limited penalties, to encourage physicians to submit this information to Medicare or share it with the HHA in a timely manner.

Trinity Health urges CMS to expand the methods of acceptable documentation of face-to-face encounters, such as allowing mid-level providers to sign the certification documentation or HHA staff to complete the encounter documentation with physician or mid-level provider signature. For example, nurse practitioners have the training and qualifications to sign home care orders, and it is a more efficient use of health care resources. The CMS requirement for a physician signature impose a more expensive and burdensome requirement than is warranted.

RECOMMENDATION: The Trinity Health preference would be that CMS eliminate the home care face-to-face requirement. This has been a key priority of the National Association for Home Care and Hospice. In fact, Trinity Health would assert that the objective of CMS could be achieved with a simple notation on the 485 form or the plan of care. If the face-to-face is not eliminated, we recommend that CMS allows nurse practitioners to sign home care orders. As a more general point, CMS should expand decision-making authority for nurse practitioners 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.

o. Eliminate Home Health Agency Pre-Claim Review

Under the CMS home health pre-claim review demonstration, home health agencies in five states were unfairly subjected to a mandatory Medicare demonstration launched in August 2016 that is testing a requirement for pre-claim review. Launched in Illinois in August 2016, but currently under a national pause, the demonstration added unnecessary and complex time and paperwork requirements, which—if fully implemented—would impact an estimated one million home health claims per year.

RECOMMENDATION: Trinity Health supports the Administration’s current pause on this onerous demonstration and urges CMS to instead consider more targeted policies, such as education and other interventions that only focus on agencies and/or claims with high payment error rates. Home health agencies with no payment or fraud issues should face no additional compliance interventions.

p. 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.

RECOMMENDATION: 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.

q. Remove the Mandatory Free-Text Field from the Medicare Outpatient Observation Notice

(MOON) The MOON's mandatory free-text field requires that hospital staff describe the patient-specific clinical considerations made by the physician when ordering outpatient observation services rather than inpatient admission. This requirement is burdensome to hospitals and of no benefit to patients. For example, it negatively impacts the hospital's workflow by precluding hospital registration or access staff from preparing the MOON. This is because the medical record does not contain information about why a patient is not an inpatient; rather, it contains information about the patient's evolving clinical situation during his/her outpatient observation encounter. In addition, these clinical specifics would be difficult and confusing for most beneficiaries to understand. In contrast, beneficiaries who do wish to understand such clinical specifics would have ample opportunity to ask questions during the required oral explanation of the MOON.

RECOMMENDATION: CMS should remove the mandatory free-text field from the MOON. It should be replaced with CMS-prepared standard language that describes the established reason why physicians order observation services for patients. Indeed, CMS itself acknowledged the standard explanation for why a patient is placed in outpatient observation status and included it in the preamble to the FY-2017 IPPS final rule.

IV. STARK LAW - ANTI-KICKBACK REGULATIONS

a. Update Fraud and Abuse Laws, Safe Harbors and Exceptions to Better Reflect Evolving Models of Health Care Delivery and Population Health

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 easy to demonstrate. 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, 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 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. Greater flexibility to comply with these laws is needed for providers.

RECOMMENDATIONS: 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 payors. 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. Yet, the parties entering into these arrangements do so at their peril or must create complex and cumbersome structures to avoid violation of these laws.

RECOMMENDATIONS - 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).

RECOMMENDATIONS - . To level the playing field, AKS laws should be evenly applied to all parties, including insurers and other non-hospital parties. Third party payor/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 but 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 recently announced a national partnership with a transportation company to provide free transportation for certain of its enrollees; yet, it is not burdened by having to comply with the recently adopted 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.

RECOMMENDATIONS - 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.

RECOMMENDATIONS: Regulations should aim to create an efficient marketplace where providers and payors alike can compete on value without being hampered by unnecessary regulations, particularly as providers are moving away from volume-based models toward taking risk for populations. Additionally, 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.

b. Stark: Missing Signature Noncompliance

In practice, 90 days is not enough time to remedy a Stark defect, which necessarily involves two parties.

RECOMMENDATION: 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 reference the date of discovery of noncompliance and not the date that the relationship became noncompliant.

c. Stark: "Set in Advance"

§411.354(d)(1). Occasionally, an FMV agreement is reached in advance with a physician and commences before the writing is fully executed. Such incidents should not be subject to onerous penalties.

RECOMMENDATION: Amend regulatory definition of "Set in Advance" to remove the "in writing" requirement.

d. Stark: Physician Productivity Pools

Stark allows a physician group to pool work Relative Value Units (wRVUs) for distribution as it determines, but does not allow the pool to include physician assistants (PAs) and nurse practitioners (NPs). This is disruptive and should be changed.

RECOMMENDATION: 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.

V. AFFORDABLE CARE ACT REGULATIONS

a. Section 1557

Section 1557 is the nondiscrimination provision of the ACA. The law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. This regulation requires hospitals to replicate all significant communications on websites, posters, forms, etc. in at least the top 15 languages. This places a burdensome and unnecessary requirements upon health care providers without a clear benefit to patient care. Hospitals already provide interpreter services.

RECOMMENDATION: Review the existing Section 1557 provisions and identify opportunities to streamline with existing services that providers are offering to overcome language barriers.

b. Proposed Rule on Conditions of Participation (CoPs)

In 2016, CMS proposed to amend 42 CFR Section 482.13 which lays out the CoPs addressing patients' rights, to ensure nondiscrimination as required in Section 1557 of the ACA. Earlier this year, HHS finalized regulations implementing Section 1557 prohibiting discrimination on the basis of

race, color, national origin, sex, age or disability. The proposed amendments to Section 482.13 would also forbid discrimination on the basis of religion or sexual identity.

Trinity Health provides health care services to any person in need of care, without regard to race, color, national origin, sex, age, disability, or any other category or status. Despite this, Trinity Health has concerns that pertain to the incorporation of nondiscrimination language in the Proposed CoPs.

RECOMMENDATION: Ensure that neither the CoPs nor Section 1557 require the provision of, referral for, or coverage of abortion, and ensure the inclusion of an exemption from the proposed requirements with respect to sex discrimination for organizations that hold themselves out as religious organizations to the extent that applying the requirements would be inconsistent with their religious tenets. In addition, CMS should consider that individuals who believe they have been discriminated against in violation of Section 1557 have recourse to the Office of Civil Rights (OCR) or federal courts to pursue their claims. Trinity Health urges CMS to consider simply referring to the OCR's implementation of Section 1557 as the HHS policy regarding hospital compliance with civil rights law instead of promulgating new regulations in the CoPs.

c. Employee Wellness

The ACA created new incentives and built on existing wellness program policies to promote employer wellness programs and encourage opportunities to support healthier workplaces. Final regulations recently issued by the Equal Employment Opportunity Commission (EEOC) would change standards applicable to certain workplace wellness programs that use incentives to encourage workers to provide personal health information. The notice and other requirements in the EEOC regulations hinder the development of innovative workplace wellness programs.

RECOMMENDATION: The EEOC and ACA regulations should be harmonized and scaled back.

VI. PHARMACY & DRUG REGULATIONS

a. 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 include 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.

RECOMMENDATION: Eliminate the one-mile limitation and replace it with an alternative approach. Trinity Health urges the FDA to consider allowing 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 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.

b. Handling Hazardous Drugs in Health Care Settings

The U.S. Pharmacopeial Convention (USP) published Chapter 800 (Hazardous Drugs) on February 1, 2016 in its final form. The enforcement date is currently July 1, 2018. While the USP does not have enforcement powers, the Joint Commission, CMS and state boards of pharmacy do and will expect compliance on July 1, 2018. The purpose of the chapter, per USP, is “to describe practice and quality standards for handling hazardous drugs (HDs) in health care settings and help promote patient safety, worker safety, and environmental protection.” Under this guidance all antineoplastic agents used for sterile compounding are required to be stored separately from other inventory in a dedicated negative pressure room with 12 ACH (Air Changes per Hour). The guidance would essentially require hospitals to use two storage rooms, one for storing chemotherapy drugs and one for storing other drugs. Currently, co-storage is common because many non-HDs are used adjunctively with HD (e.g., oncology clinics also routinely prepare steroids, anti-emetics and other supportive drugs as part of the regimen).

RECOMMENDATION: Delay enforcement of this chapter to allow for at least a five-year transition period in order to allow organizations to assess facilities, plan capital budgets, and consider personnel and training requirements among other factors.

c. Modifier JW Reporting Requirement

Effective January 1, 2017, the use of the JW modifier is required for claims with unused drugs or biologicals from single use vials or single use packages that are appropriately discarded. Providers are required to document the discarded drug or biological in the patient's medical record. The JW modifier is only applied to the amount of drug or biological that is discarded. The JW modifier is not required for drugs that are not separately payable, such as packaged OPPS drugs or drugs administered in the FQHC or Rural Health Clinic setting, or drugs paid under the Part B drug Competitive Acquisition Program (CAP). The JW modifier is not intended for use on claims for hospital inpatient admissions that are billed under the IPPS. [Note: The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used on a Medicare Part B drug claim to report the amount of drug or biological that is discarded and eligible for payment under the discarded drug policy. The modifier shall only be used for drugs in single dose or single use packaging.]

RECOMMENDATION: Eliminate the JW modifier requirement on hospitals and physicians.

Instead, CMS and the OIG could work with the FDA, drug manufacturers and the medical community by using other information such as average dose to understand whether the available vial sizes are inadequate and are leading to increased waste of expensive pharmaceuticals, and driving up costs of healthcare unnecessarily.

d. 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.

RECOMMENDATION: 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.

VII. QUALITY REPORTING REGULATIONS

a. Measure Outcomes, Not Process

Trinity Health encourages CMS to remove redundancy when selecting measures across programs and evolve all quality reporting to focus on outcome rather than process measures. Harmonization across quality reporting programs, including utilization of the same definitions, is important. **We strongly believe that quality measurement should be focused 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. For example, the sepsis bundle (SEP-1) initiated in October of 2015 continues to be a very labor intensive measure. With more than 60 abstracted fields covering seven process components of care, abstraction burden is considerable. Many vendor systems are unable to reflect compliance within the components of care and are only able to reflect compliance of the bundle measure. For example, a hospital can be unaware if their primary problem exists with timing of blood cultures versus fluid resuscitation since the abstraction tool output reflects only overall bundle compliance. Again, CMS should instead focus these measures on the outcome not the process to make it meaningful, care improvement data.

RECOMMENDATION: Any new measure should be 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.

VIII. HIPAA REGULATIONS

a. 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.

RECOMMENDATION: Eliminate the redundant HIPAA requirement for "business associate agreements."

b. 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.

RECOMMENDATION: Eliminate the requirement that covered entities annually report all breaches affecting less than 500 individuals to HHS.

c. 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).

RECOMMENDATION: Eliminate the requirement for covered entities to physically distribute the Notice of Privacy Practices to patients. Covered Entities would continue to post the NPP on their websites, and make physical copies available upon request.

d. 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.

RECOMMENDATION: 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.

e. Substance Abuse Disorder Records

Requiring an individual patient’s consent for access to addiction records from federally-funded treatment programs—as current requirements do—is an obstacle to an integrated approach to patient care. Substance abuse information should be available to all treating clinicians to enable them to provide high quality care.

RECOMMENDATION: Fully align requirements for sharing patients’ substance use records with the requirements in HIPAA that allow the use and disclosure of patient information for treatment, payment and health care operations.

IX. HEALTH IT & INTEROPERABILITY

While the Health Information Technology for Economic and Clinical Health statute envisioned the “development of a nationwide health information technology infrastructure” and “improved outcomes in health care services,” the Meaningful Use (MU) programs have not yet realized this vision. While Trinity Health hospitals and physicians have enjoyed significant success in the Medicare MU program, it has not been easy and it has diverted clinician and staff attention as well as considerable resources away from activities with greater direct patient benefit.

The stages of the MU program have been too focused on modifying functional requirements and lacks sufficient emphasis on outcomes and interoperability. Accordingly, Trinity Health urges a re-orientation of the MU programs on encouraging activities in both the public and private sectors that will facilitate an efficient and effective infrastructure to accelerate the nation’s move to interoperability.

The infrastructure needed to support interoperability is multi-faceted and includes mature standards for data architecture, content and exchange; a way to effectively match patient data from multiple sources and affordable networks to move data. To date, the MU programs have required the use of standards that have not yet reached the basic level of maturity required before widespread use and that do not always meet clinical needs. Certified products have not always functioned as intended and have often required expensive workarounds and numerous patches, often due to shifting MU requirements and compressed timelines. Vendor interpretation of standards has been varied, further complicating data exchange.

As providers have implemented EMRs, the burden of documentation has shifted from other clinical staff to physicians to identify codes. This has made physician work more timeconsuming and mundane and has effected physician productivity and satisfaction.

a. Implementation of Uniform National Standards for Health IT

CMS should refocus the MU program on standards. Adherence to open-source, consensus-based, transparent standards that are sufficiently mature should be an essential aspect of certification of electronic health record technology. While great progress has been made on standards, there is significant additional work to be done. For example, existing standards in areas such as lab, vital

signs, and clinical documents need to be deepened. Additionally, clinical logical observation identifiers names and codes (LOINC) should be used on all documents. This will improve usability by allowing care teams to identify the outside document immediately as opposed to clicking on a more generic title and not finding the expected document. Further searching is then needed and the care teams do not have time to do this while caring for their patients.

New areas such as scheduling, pathology reports and patient-reported data are needed. However, HIT vendors often provide tools designed to help with interoperability but too often providers are required to develop new workflows that add time without patient or other benefit. Vendors should be required to build new tools within existing workflows. Vendors should also be required to have easily available metrics to measure outcomes. Certification should also test EHRs for usability in a broad array of settings, from complex academic medical centers to rural critical access hospitals. Post-installation testing should confirm that installed systems work as intended.

RECOMMENDATION: Trinity Health recommends accelerated public and private sector efforts toward the consistent implementation of uniform national standards for health information technology. Further, existing standards should be utilized whenever possible. The nation should follow Argonaut standards for Fast Healthcare Interoperability Resources (FHIR). Continue development of additional FHIR standards as recommended by the Argonaut Project such as scheduling and clinical documents. Certification of HIT by the government should increasingly be focused on standards and specific use cases. The work of private sector efforts including CommonWell, Care Quality and CARIN should inform our shared path forward.

b. Matching Patients to Their Data

One of the primary challenges impeding the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. Consistency in patient data matching is foundational to interoperability and remains conspicuously absent. Consistency in patient matching is also essential to patient safety and to ensuring that the information in a patient's EMR actually belongs to that patient and includes all available information.

RECOMMENDATION: CMS should seek to promote an effective national strategy for accurately matching patients to their data.

c. Common National Standards for Privacy and Security

The current patchwork of state laws impedes information flow. Establishing common national standards will improve both the appropriate as well as the secure flow of health data.

RECOMMENDATION: Establish common national standards for privacy and security.

d. Consumer Interoperability Standards

Too many patients struggle to gather and synthesize coherently their health data.

RECOMMENDATION: Require consumer interoperability standards so that it is easy for consumers to access all of their health information—free of charge—and incorporate it into any certified tool they wish to use. Ensure interoperability standards such as FHIR APIs are

within each vendor's EMR and portal, consumers and care teams are able to send, receive, collate, and integrate data regardless of the source. Consumers should have the ability to aggregate all their medications from all care venues to a single mobile device where the medications are mapped correctly, allowing the consumer the ability to modify doses/schedules. This information is then communicated back to all care venue EMRs.

X. OTHER REGULATIONS

a. Medicaid Enrollment Applications

Hospitals treating out-of-state Medicaid patients must complete and submit each state's Medicaid enrollment application form. Those forms vary in significant respects, making it very difficult for hospitals to secure payment for Medicaid patients from another state who visit their hospital.

RECOMMENDATION: Create a uniform application that all states must use for providers to apply for Medicaid.

b. Hart-Scott-Rodino Act

The Hart-Scott-Rodino (HSR) Act established the federal premerger notification program, which provides the FTC and the DOJ with information about large mergers and acquisitions before they occur. The parties to certain proposed transactions must submit premerger notification to the FTC and DOJ. The parties may not close their deal until the waiting period outlined in the HSR Act has passed, or the government has granted early termination of the waiting period. There are multiple aspects of the requirements imposed by the HSR Act that are onerous to providers while offering little benefit to the federal government: 1) a national system like Trinity Health is required by the HSR Act to provide the data for all divisions and subsidiaries in every one of its regions within 22 states for a transaction that affects only one region in one state. The amount of resources required to complete one HSR Act filing can exceed 23 person days or 183 hours. The rationale for collecting national data to assess a regional or statewide market does not make sense. 2) the HSR Act data submissions requires Trinity Health to classify the financial information into the North American Industry Classification System, and this has to be done by address location. This type of financial breakout does not reflect accounting standards and forces us to perform significant data manipulation, which again consumes resources. 3) the assessment of market share that is done as part of the HSR Act filing does not appear to be the same for providers and payors. One example, in Michigan, Blue Cross Blue Shield (BCBSM) has not been subject to the same antitrust standards for market share as Michigan providers. BCBSM is a dominant payor in Michigan with 75 percent of the market share, while no one health system would be able to have the same dominance. Applying anti-trust standards fairly is particularly relevant as providers and payors are competing for covered lives in emerging delivery system models.

RECOMMENDATION: 1) streamline HSR Act filing requirements to narrow the focus on markets and surrounding areas to reduce the burden on providers that operate in multiple markets in multiple states. 2) modify financial reporting requirements to be consistent with hospital standards to alleviate wasted time manipulating data. 3) apply anti-trust standards consistently across payors and providers to ensure a competitive marketplace.

c. Visa Restrictions

The H-1B visa program applies to employers seeking to hire nonimmigrant aliens as workers in specialty occupations. The intent of the H-1B program is to help employers who cannot otherwise obtain needed business skills and abilities from the U.S. workforce by authorizing the temporary employment of qualified individuals who are not otherwise authorized to work in the U.S. Currently, the visas (85,000 each year) are doled out by a lottery, and the number of applicants continues to grow. In 2016, demand was three times more than the quota.

RECOMMENDATION: Reduce visa restrictions on health care professionals, and allow qualified foreign physicians work permits to address some of our nationwide access issues, particularly in health care provider shortage areas.

XI. CONCLUSION

We thank CMS for the opportunity to comment on this RFI and intend for our comments and recommendations to reflect our 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. The complexity and redundancy of the existing regulatory process has become overly intrusive and is distorting the practice of medicine. We believe the old framework of overregulation can be modified and instead regulation can rely on transparency, database monitoring, and selective focus where abuse has been detected. We look forward to working with you advance this goal. If you have any questions or need further information, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,



Tonya K. Wells
Vice President, Public Policy & Federal Advocacy
Trinity Health