Trinity Health

July 8, 2020

Dr. Leith States, Chief Medical Officer
Office of the Assistant Secretary
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Information - Long-Term Monitoring of Health Care System Resilience

Submitted electronically to OASHcomments@hhs.gov

Dear Dr. Leith States

Trinity Health appreciates the opportunity to submit recommendations for how to improve resiliency of the US health care system. The responses below reflect a 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. We are building a People-Centered Health System to put 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.

Barriers and Opportunities for Health System Resilience

Federal Guidance

Dueling federal guidance has been a significant challenge as we have responded to COVID-19 across our 22-state footprint. There has not appeared to be interagency coordination or collaboration on requirements and protocols across CDC, OSHA, and the FDA for key policies, including personal protective equipment, masking and repurposing masks. For example, the CDC released guidance the week of June 22nd that has different requirements than OSHA.

Further complicating our response to COVID-19 in our communities are the separate state requirements. For example, each state has their own requirement for provider licensing and moving medications across state lines, adding barriers to a quick response across our health system.

We urge federal agencies to better communicate and collaborate to ensure consistent guidance and reduce confusion.

Telehealth

As part of COVID-19 relief, states, Congress and the Department of Health and Human Services (HHS) have provided temporary flexibilities to make telehealth services more readily available, relaxing long-existing barriers to providing care through telehealth.

These telehealth changes have had many advantages, including keeping patients and providers safe from exposure to COVID-19, preserving personal protective equipment and improving access to care. In addition, they have allowed patients access to their existing physicians, which has been critical for patients with chronic conditions.

COVID-19 will impact how care is delivered for the foreseeable future and telehealth plays a key role in maintaining our ability to respond to the current pandemic. In addition, the positive experience Trinity Health has had with the increased adoption and expansion of telehealth across our health system makes it clear telehealth is a critical component for how we provide high quality, patient-centered care moving forward.

For example, since the onset of COVID-19, Trinity Health telehealth video visits increased from <1% to 37%, with an average of 7,072 video-visits conducted a day. In addition, we have conducted 31,662 Medicare Annual Well Visits since the onset of COVID-19, predominantly through telehealth. In addition, telehealth is user friendly and gives patients easier access to providers. Our patient satisfaction scores have improved with telehealth adoption from 92.5% to 94%. As one of our patients from Springfield, MA put it,

> "I feel fortunate that I was able to schedule a telehealth appointment with my primary care physician. [The telehealth visit] was a simple and seamless way to get high quality care. My PCP had immediate access to all my electronic medical records. I didn't feel rushed, and I felt like I got the care I needed in short order - and the resulting prescription ended up being precisely what I needed."

Unfortunately, much of the telehealth transformation is dependent on temporary flexibilities. Absent additional action from policymakers, patients stand to abruptly lose access to many telehealth services after the national emergency declaration, public health declaration and individual state flexibilities end.

We recommend policymakers act to make key telehealth flexibilities provided to-date permanent, including:

- Allow clinicians to furnish and bill with parity of payment with in-office visits across all payers and settings.
- Allow reimbursement of telehealth visits when originated within the patient's home or location of their choosing where clinically appropriate.

- Allow clinicians to be reimbursed for telehealth when seeing new patients or a patient not previously seen at their practice.
- Remove limitations on frequency of services.
- Expand types practitioners eligible to bill for telehealth services.
- Expand covered services reimbursable for telehealth, ensuring to include prescribing and behavioral health services.

Supply Chain

The COVID-19 pandemic has highlighted the inadequacies in the health care supply chain. There is a global reliance on China for both raw materials and finished goods. Approximately 80 percent of active pharmaceutical ingredients (API) originate in China. Countries all around the world are going to China at the same time for the same goods creating competition and security risks.

In the United States, the lack of coordination and transparency in the governmental response has acutely appeared in the supply chain that has been charged with bringing life-saving medicines, supplies and personal protective equipment (PPE) to hospitals and other providers. This lack of coordination is coupled with the reality that the federal government is now a new competitor for these same products as well.

While well intentioned, the efforts of the Federal Emergency Management Agency (FEMA) to build the Strategic National Stockpile (SNS) as well as the attempts by legislators to help acquire those supplies has ultimately resulted in competition with hospitals for the same products. Additionally, suppliers are not being transparent with hospitals and other providers regarding product capacity, demand and allocation. Remdesivir is the one medicine shown to be effective against COVID-19. The distributer initially sent allocations directly to hospitals without any advance notice. States took over the distribution but that was chaotic in the beginning as well. In one instance, a state trooper dropped off cases of Remdesivir to a Trinity Health facility without prior notification.

COVID-19 testing is critical to reopen the economy safely. Insatiable demand, including for non-COVID-19 care, increased symptomatic testing and state regulations, continues to outstrip our supply and will have a significant impact on hospital operations going forward. However, hospitals and other providers have no visibility into the availability of test kits. For example, on a Friday, Trinity Health was informed that its allocation of test kits would be reduced by 65 percent for the next week. HHS directed the manufacturer to send more test kits to Michigan facilities than needed, because Michigan was a hot spot, to the detriment of other states. Trinity Health was able to redistribute the test kits from Michigan, but the process was unnecessarily inefficient.

Ultimately, these competing variables have resulted in a supply chain that is inefficient and inadequate to meet the demands of the COVID-19 pandemic. We recommend policymakers take the following actions:

- Develop transparent SNS policies that include information on the inventory, location and accessibility of the stockpile, along with a process to track the status of critical product shortages.
- Ensure efforts to augment the SNS do not impede hospitals and other providers from accessing the medicines, supplies and PPE needed now for immediate patient care.

- Establish a coordinated national supply chain through a public-private partnership that includes a "marketplace" for supplies with information on demand. This effort should be led by supply chain experts with government at the table.

Data Sources Standardization

One of the greatest challenges we have experienced is our country's health information technology (HIT) infrastructure has not been able to keep up with key data needs during the COVID-19 pandemic. We have seen significant variation in disease and test data being collected and reported by states, making it difficult to collect, track and aggregate data and inform a meaningful public health response and intervention.

Data collection is defined as the ongoing systematic collection, analysis, and interpretation of health data necessary for designing, implementing, and evaluating public health prevention programs. To develop effective prevention strategies, we need to improve these data collection methodology. These data elements should be collected by local, state, and federal agencies and all levels of public health agencies can all play key roles by incorporating race, ethnicity, and primary language data into existing data collection and quality reporting efforts.

In addition, given the gaps in HIT infrastructure, local health departments have varying degrees of HIT readiness for receiving and reporting public health data. For example, some of the local governments we have shared data with fax machines, making it difficult to report and aggregate data in a state or region in real time.

Furthermore, it has been exceptionally burdensome meeting reporting requirements for state and local governments, the CDC, and other federal agencies. For example, we are required to report essentially the same data elements to multiple federal agencies, but there is no standard data elements and definitions across these agencies. We have spent an inordinate amount of time trying to meet reporting requirements during this pandemic at a time we should be focused on treating patients.

Trinity Health recommends:

- HHS establish a working group with public and private entities to develop a standard data set and an infrastructure for reporting data to prepare for future pandemics and public health crisis. Included in this solution should be the ability for various federal agencies to pull this data and reduce the burden on providers.

- HHS, Congress, and states must work to provide more funding for the HIT infrastructure necessary to ensure providers can electronically transmit data to local, state and federal public health entities. HHS has recently pushed the FHIR interface as a standard in the industry, something similar that can be used by states could make data sharing and disease interventions more successful.

Alternative Payment Models (APMs)

To truly make our nation's health system more resilient, the Department of Health and Human Services and the Congress must continue to push for *all payers*—public and private—to move toward value-based care and decrease reliance on fee-for-service. Trinity Health sites across the nation are committed to rapid, measurable movement toward value in the delivery of and payment for health care, including the assumption of downside risk. Trinity Health participates in 11 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations

(ACOs), which includes five markets partnering as a national MSSP Enhanced Track ACO. We also have three markets partnering as a Next Generation ACO and 2 participating in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Experience in alternative payment models creates health system resiliency in the form of advanced, flexible and responsive clinical and operational capabilities. This is because experience in APMs builds a population-based clinical approach that aligns with population-based payment.

Clinical capabilities
The clinical team within a population-based enterprise is skilled at assessing and identifying the needs of the whole person and the payment model aligns with the approach most clinicians believe is more effective, which is to create a care plan that addresses clinical and social needs and the patient's own priorities.

Our clinical teams were able to quickly apply the same expertise that was developed to manage patients attributed to an APM to develop a whole-person plan of care for patients at risk of COVID-19 or being monitored for COVID-19.

Within our ACOs in Syracuse NY, for example, the care team was able to create patient-centered care plans for over 13,000 individuals at risk for COVID-19 due to underlying clinical conditions. The care team was able to teach sign and symptom management, ensure patients were safe and knew how to keep themselves healthy, had their medications, knew when to call a provider, and other preventative measures. This is work they would do in usual times for patients to prevent exacerbation of chronic disease, that they were able to quickly pivot and apply to patients at risk for COVID-19. Of note, the teams did this for the broad swath of patients at risk for COVID-19, including but not limited to patients attributed to an APM. This may be very different from a "purpose-built" ACO or practice that doesn't live within a health system and kept their focus only on the populations attributed to APMs.

In each of our markets, we set up social care hubs to respond quickly to the social needs both for patients at risk for COVID-19 but also to reach other at-risk populations with social needs that were amplified by the pandemic. We were able to do this quickly because of our long-standing and deep commitment to our communities, and the network of services and supports we have developed. The way we live out our mission through this work enabled us to quickly identify and address individual social needs.

Operational capabilities
Trinity Health is the leading health system dedicated to transforming care delivery through APMs when you consider depth, breadth and successful outcomes. The operational capabilities we have built to support this enterprise helped us respond to the impacts of COVID-19. For example, a core component of success in APMs is population-based risk stratification and identification of sub-population needs. We have built analytic capabilities on top of our own multi-payer claims data warehouse as a key population-health enabler, and we were able to use those same tools to identify and segment patients at risk for COVID-19 to design a tailored

outreach program. For Medicare beneficiaries, for example, we use the same CCLF data files which Medicare used in its recent date release. For patients not attributed to our APMs, we used the same approach to mine EHR and registry data so each practice has a complete picture of patients who needed extra support.

Because the majority of physicians in our Clinically Integrated Networks (our operational homes for managing APMs within our community) are independent providers in the communities we serve, we have built up network support capabilities that we were able to immediately deploy to support our independent providers in responding to the pandemic. We created communication tools to provide them ready access to clinical information, guidance for use of PPE (and access to pricing discounts for PPE), patient-facing materials and support, all updated multiple times a day. We provided a daily outgoing communication with links to newly posted/updated materials, and also provided them with guidance and support on understanding waivers and funding, implementing telehealth and other rapid solutions.

We had in place in each market a network of Skilled Nursing Facilities that we work closely with for both our population-based and episodic-based APMs. Because we had built those relationships to support our success in APMs, we were able to quickly stand up daily two-way communication when a market was surging and/or when an outbreak hit one of the SNFs. We replicated the "drop team" model of rapid response education, testing, and clinical support for those SNFs.

Throughout this experience, we have seen first-hand how the clinical and operational capabilities we have built over nearly a decade's strong commitment to value-based care and population health were readily available to deploy to respond to a once-in-a century global pandemic. As important are the collaborations we have built with other systems, payers, employers and patient advocacy groups who are well along their own journey to value, such as through the Health Care Transformation Task Force. As members of these groups, we continue to learn from each other and spread effective interventions across a national learning laboratory.

Our experience deploying our population-health clinical and operational capabilities to address the impacts of COVID-19 has taught us that APMs create and support health system resiliency—they scale and translate effectively and foster innovation and collaboration. COVID-19 has demonstrated the importance of paying for value. In the current fee-for-service model, we are losing money caring for COVID-19 patients, about $25,000 per case, even with the 20 percent increase in Medicare payment. These losses will be exacerbated by the recent pricing for Remdesivir. This is why we worked hard with our payer partners on protections for these models during the pandemic, so the movement to value would not lose momentum nationally amidst severe disruption from COVID-19.

We are committed to working with our federal, state and health plan partners to accelerate participation in these models – both for ourselves and others. The faster we can move the nation away from payment built on fee-for-service and towards true population-based payments models, the more resilient we and the national health system as a whole will be.

To that end, we recommend CMS move aggressively toward direct contracting with clinically integrated delivery systems like Trinity Health and cut out the non-value add of commercial payers as middlemen. We have developed all of the capabilities to manage care without putting barriers in place like claims denials.

Administrative Waste with Payer Denials

There is a massive financing and administrative superstructure on top of the delivery of care that consumes almost 30 percent of health care expenditures. Commercial payers and providers are locked into escalating battles around underpayment, appropriate coding, claim denials, and appropriate care determinations that create administrative waste.

Denial of claims is prevalent across all payers and has been increasing over time. Administrative burden associated with denials has led our health system to incur upwards of $15 million per month:

- 8-10 percent of our total hospital encounters incur a payer denial on first submission.
- Subsequent claim submissions and secondary payor submissions consistently range 12-15 percent for all encounters.
- 80-95 percent of denied claims are undertaken with a corrective action to respond and resolve, including re-submission, correction, or appeal efforts.
- Attempting to overturn clinical denials through the arduous appeal process is successful 55-65 percent of the time yet creates increased burden that often includes engaging physician involvement for peer-to-peer reviews.

Examples include:

- Sepsis 3/DRG downgrades – several large payers have adopted the Sepsis 3 criteria to recode DRG classifications and reduce reimbursement to providers which is inconsistent with the CMS quality measure – effectively denying reimbursement for early stage Sepsis treatment.
- Readmissions— denying any inpatient admission within 30 days of a hospital stay regardless of whether the two conditions are related.
- Reclassification of inpatient admissions to observation – payers are downgrading inpatient admissions at an increasing and alarming rate, often relying on patient status days after initial presentation to the hospital.

There is significant variation in prior authorization requirements, which leads to inappropriate denials, creates significant burden and further increasing costs. To reduce administrative waste, Trinity Health recommends CMS standardize the prior authorization requirements and processes. Specifically, we recommend standardizing:

- services requiring prior authorization,
- formats,
- criteria used to deny requests, and
- timelines for responses from health plans.

CMS must also ensure enrollees have access to covered services including:

- Set thresholds for appropriate levels of prior authorization and payment delays/denials.
- Thoroughly review existing access standards and test networks.
- Publish performance data of plans.
- Increase frequency of audits.
- Penalize plans found to be out of compliance with thresholds.

Key Indicators & Data Sources of Health System Resilience

To assess the impact COVID-19 has had on our patients, we have been reviewing the decrease in necessary ambulatory and emergency department visits for chronic conditions secondary to

COVID-19. For example, we have patients that have had heart attacks and strokes and did not access care because they are afraid of entering hospitals during the pandemic. In addition, we are looking at the numbers of excess deaths that are both COVID-19 and non-COVID-19 related over our baseline.

Another key indicator are childhood immunizations. Immunization rates for children across our health system are down 65 percent and we expect the reduction of these critical services is consistent nationwide.

In addition, the mandate for elective procedures to end put a significant burden on our health system. These requirements from states and the federal government did not well define "elective procedures" and led to an increase of morbidity and mortality as result of forgone procedures. More refined guidance would allow clinical judgement when considering the deleterious effects of waiting or delaying specific procedures for certain patients.

Our challenge is to catch up and meet the needs of our patients for services that have been delayed for months so as not to further increase morbidity and mortality at a time during which many people are still cautious about receiving needed medical treatment. And we must do this with less resources.

Provider burnout is associated with decreased access, reduced patient satisfaction, and possibly increased medical errors. We also know that provider burnout was a problem prior to the pandemic and the problem has increased as providers deal with the emotional and physical toll of treating large numbers of high-needs COVID-19 patients or suspected COVID-19 patients. The Federal government should thoroughly examine policies that will reduce burnout.

To help address burnout, HHS and Congress should provide resources to help providers access behavioral health services, including via telehealth, to support proactive mental health treatment and support for providers experiencing burnout.

Another step that can be taken is to allow health care professionals to practice at the top of their licenses and permanently permit out-of-state providers to perform certain services when they are licensed in another state. The flexibility this would create in addressing workforce shortages is extremely valuable. We urge CMS to:

- Permanently eliminate specific practice limitations on nurse practitioners that are more restrictive under CMS rules than under state licensure to allow professionals to practice at the top of their license.
- Permanently remove certain licensure requirements to allow out-of-state providers to perform telehealth services.

Public/Private Data Sources

As noted above, Trinity Health has a multi-payer claims data warehouse that we use to measure the impact of our population health activities on clinical and financial outcomes. Our operational capabilities we have built to support alternative payment models (APMs) have helped us respond to COVID-19 in our communities; we were able to use these tools to identify and segment patients at risk for COVID-19 to design a tailored outreach program. For patients not attributed to our APMs, we mine EHR and registry data so each practice has a complete picture of patients who need extra support.

Public-Private Partnerships

Data and infrastructure

As we have shared above, it is critical that we develop a standard data set and invest in our country's public health infrastructure. HHS should pull together public health experts, including providers and hospitals, to develop a standard data set, an interface for sharing data, and work with Congress to increase funding for public health infrastructure—including IT.

Supply Chain

In addition, HHS needs to rethink how to operationalize the supply chain—the "just in time" supply chain model has not worked to protect providers on the front lines, other critical personnel or patients. For years our country has relied on the federal stockpile for potential health crises and it fell short during a critical time. Not only was the process disjointed and unclear, products we received from the stockpile were unusable because they were expired, outdated, or didn't work. HHS needs to critically examine the purpose of the stockpile, the role it is expected to play in future public health emergencies and be transparent about how much providers should—or should not—be reliant on it in the future.

Group purchasing organizations (GPOs) have worked with providers to get data and understand the need for PPE and other supplies and there are a number of GPOs who represent a significant portion of the supply chain. We recommend HHS think through how to partner with GPOs to access this information and share real time data to better understand the demand for supplies and a more efficient supply distribution methodology.

Alternative Payment Models

CMS must continue to encourage the adoption of value-based care models. Specifically, private payer participation must be encouraged, especially in models categorized by the Health Care Payment Learning and Action Network (HCP-LAN) as level 3B and 4 (those that have higher levels of risk). Moving to models that are premium-based rather than rely on fee-for-service will increase sustainability of these models that in turn promote health system resiliency.

Federal Playbook and Leadership

There has been inconsistent messaging across federal agencies that could have be avoided in part by designating an agency, such as the CDC, as the "true north" for requirements and guidelines during the COVID-19 pandemic. During SARS and Ebola, the CDC was in frequent communication and provided guidance and webinars for health care leaders that were reassuring and led to confidence in our nation's preparation and response.

As a result of the competing guidance and requirements from federal agencies, Trinity Health decided early on that all of our facilities and providers would follow the CDC guidelines. This gave our providers and staff serving on the front lines and our leadership the confidence to address the COVID-19 pandemic in our communities.

The Joint Commission comes into our hospitals to review our disaster recovery plans and if we have made a mistake or have failed to do something correctly, we get written up for it. The federal government should be held responsible for ensuring there is a coordinated response across the nation for public health emergencies. The federal government should also be required to review and update the pandemic playbook frequently. We urge HHS, in conjunction with other departments, to undertake a complete review of the playbook in light of COVID-19.

This review should include engagement of public health experts, including hospitals and state officials, and should occur on a reoccurring timeframe (such as every two or three years).

Included in this review should be the waivers and authorities provided during COVID-19. There were inconsistent rules across states for transferring providers, supplies, and medications that led to barriers for quickly preparing for and responding to COVID-19 surges across our footprint. These need to be reviewed to determine if these flexibilities should be made consistent across states for future public health emergencies.

As the playbook is revised, the federal government should share this information in a transparent way to ensure public health experts are informed.

As a health system that spans 22 states and multiple judications, we offer an important perspective on the nationwide response to COVID-19 and how to improve health care resiliency. We would be happy to serve on any workgroups developed to further this work and are available to answer any questions. Please feel free to contact me at granttw@trinity-health.org or 734-343-1375 if you'd like more information.

Sincerely,

Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy