



UnityPoint Health

Government and External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

September 17, 2021

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1753-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: CMS-1753-P - Medicare Program: Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Request for Information on Rural Emergency Hospitals; published at Vol. 86, No. 147 Federal Register 42018-42360 on August 4, 2021.

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

Dear Administrator Brooks-LaSure,

UnityPoint Health appreciates the opportunity to provide comments on this proposed rule related to Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 33,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

In addition, UnityPoint Health is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care is the Accountable Care Organization (ACO) affiliated with UnityPoint Health and has value-based contracts with multiple payers, including Medicare. UnityPoint Accountable Care is a current Next Generation ACO, and it contains some providers that have participated in the Medicare Shared Savings Program (MSSP) as well as some providers from the Pioneer ACO Model. With the sunset of the Next Generation ACO model, UnityPoint Accountable Care is intending to participate in the Global and Professional Direct Contracting Model through the Center for Medicare & Medicaid Innovation in CY 2022. UnityPoint Health also participates in a Medicare Advantage provider-sponsored health plan through HealthPartners UnityPoint Health.

UnityPoint Health appreciates the time and effort of CMS in developing this proposed rule and respectfully

offers the following comments.

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) UPDATE

CMS proposes an update to the OPPS payment rates by 2.3% in 2022 with a conversion factor of \$84.457 for hospitals meeting quality reporting requirements. CMS also proposes to continue increased payments to rural sole community hospitals (SCH) by 7.1%. Due to COVID-19 impacts, CY 2019 claims data will be used for CY 2022 rate-setting. Additionally, OPPS payments will continue to apply a 60% labor-related share and, to ensure budget neutrality, a 44.35% increase to unscaled relative weights is proposed.

Comment: UnityPoint Health generally supports the increase to the OPPS base rate. We are also pleased that CMS is continuing the current payment rate for SCHs. Within our integrated health care system, we have three SCHs located in Iowa (Fort Dodge, Marshalltown, and Muscatine), which provide vital access to health care for their communities. In recognition of this vital safety-net role, we support a reimbursement structure for rural facilities that recognizes payment for access as a component and provides differentiated eligibility criteria for participation in the 340B Drug Pricing Program. On occasion, the SCH designation and reimbursement advantages are not sufficient, as evidenced by participation in the Rural Community Hospital Demonstration model by one of our SCHs (and another SCH had applied unsuccessfully for demonstration status in the last application cycle). As CMS encourages providers to transition to value-based arrangements, the price of access for essential hospitals and safety-net facilities will require continued vigilance to assure their sustainability.

OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

CMS proposes to maintain the CY 2021 packaging threshold at \$130 per day. The current policy and pay for separately payable drugs and biologicals is continued at the statutory default rate of ASP plus 6%. The payment rate for new non-pass-through Part B drugs and biologicals not acquired under the 340B program is continued at a rate of WAC plus 3%.

Comment: UnityPoint Health focuses our comments on the preservation of access to low-cost medications for vulnerable patients. As a large nonprofit, integrated health care system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals (DSHs), SCHs, Critical Access Hospitals (CAHs), and Rural Health Clinics provide vital access to health care services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois, and Wisconsin. *Of our senior affiliates, we have 12 hospitals that participate as covered entities under the 340B Drug Pricing Program.* Our hospitals are eligible to participate in the 340B Drug Pricing Program by virtue of high volume of Medicaid and low-income Medicare patients as well as rural locations. We rely on our 340B savings to meet the needs of low-income patients and rural patients in our communities.

Across our health system, UnityPoint Health has used our 340B savings to help meet the needs of our local communities. For instance, in our Fort Dodge and Des Moines hospitals, we have ensured 24-hour access to medications at our local UnityPoint Health pharmacies or via an automated dispensing cabinet in our Emergency Department. Other regions such as Waterloo, Madison, and Cedar Rapids have provided access to comprehensive services, which are otherwise lacking in the community, such as inpatient mental health services (both adult and child/adolescent) or free dental clinics. Our Blank Children's Hospital has

used the 340B savings to ensure that children can receive their specialty infusions close to home rather than driving hours away. And in Peoria, we helped patients save over \$1.2 million of out-of-pocket expenses on diabetes prescriptions last year before the manufacturers restricted access to 340B pricing.

These are just a few examples of how the 340B Drug Pricing Program helps patients throughout our communities. Reductions to the value of the program by other stakeholders – whether via CMS’ reduced reimbursement to 340B hospitals or manufacturers withholding pricing – threaten our ability to continue services such as these. **The Administration and its executive agencies need to act to protect the 340B program to ensure that the safety net continues to be robust.**

UnityPoint Health urges CMS to reinstate the 340B payment rate to 2017 levels. For CY 2018, CMS instituted a nearly 30% reduction in reimbursement for certain 340B hospitals. The Medicare payment policy for 340B drugs implemented by the prior administration negatively affects the safety net, does not reduce overall costs for Medicare beneficiaries, and has negative implications outside of Medicare. CMS has justified its policy of cutting 340B drug payments by saying that the cuts align Medicare payments more closely with 340B hospitals’ drug acquisition costs. Because acquisition costs do not reflect true market costs and negotiated discounts, it is not an appropriate benchmark for 340B drugs. Drug companies are required by law to provide 340B discounts with the express goal of subsidizing care provided by safety net providers to patients with low incomes and those living in rural areas. Aside from payment reductions, the CMS framework takes the revenue from drug companies generated under 340B and uses it to enhance Medicare Part B payments for entities that are not part of the safety net. We oppose this diversion of 340B Drug Pricing Program resources to subsidize non-340B providers, and we urge CMS to eliminate these cuts to safety-net hospitals, especially during the COVID-19 pandemic.

UnityPoint Health encourages HRSA/HHS/CMS to enforce 340B program requirements and stop unilateral action by drug manufacturers to establish conditions of participation. At last count, there were eight major drug manufacturers engaging in actions to limit the distribution of certain 340B drugs by hospitals. Specifically, drug manufacturers are engaging in strategies to interfere with 340B discounts for drugs distributed through contract pharmacy arrangements and/or demanding of 340B hospitals superfluous claims data requirements. These actions apply to all 340B hospitals, including SCHs and CAHs, and undermine 340B hospitals’ ability to serve vulnerable communities, particularly in rural areas, where contract pharmacies are vital to providing access to more affordable medications.

We do understand that the contract pharmacy issue is the subject of a lawsuit; however, in the meantime, patients are caught in the middle with limited avenues to access affordable and often life-sustaining drugs for their chronic conditions. The 340B Drug Pricing Program statute is clear that manufacturers participating in the Medicaid program must enter into agreements with the Department of Health and Human Services (HHS) that “require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.”¹ There is no statutory provision that allows these manufacturers to deny 340B pricing to eligible hospitals for any drug. In addition, 340B programmatic guidance states unequivocally that, “[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a

¹ 42 U.S.C. 256b(a)(1)

covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price.”² **HHS has the authority to administer the 340B program and to prevent external parties, including drug manufacturers, from inserting additional conditions of participation within the 340B Drug Pricing Program.**

INPATIENT ONLY (IPO) SERVICES

CMS proposes to temporarily halt the elimination of IPO list and add back the 298 services removed from the IPO list in CY 2021. In addition, CMS codifies longstanding criteria for determining whether a service or procedure should be removed from the IPO list. Furthermore, CMS is requesting comments on the merits of maintaining an IPO list.

Comment: UPH is pleased to see the pause in elimination of the IPO list as well as the reinstatement of 298 services removed in CY 2021. As stated in UnityPoint Health’s comment letter last year, the IPO list contains mostly surgical procedures that are majorly invasive, complicated, and require the care and coordinated services provided in the inpatient setting of a hospital. We continue to urge CMS to reference an ample evidence basis from the Medicare population as well as evidence-based safety criteria to support any future change in setting. In addition, we recommend that any pilot or trial to elect an outpatient procedure be authorized only for providers participating in an Advanced Alternative Payment Model. This would encourage providers to transition to risk-based service delivery models and also provide a platform to develop best practices in terms of workflows, beneficiary eligibility, and quality outcomes.

More generally, we encourage CMS to place these site of care issues within a larger policy context. As an early adopter of value-based arrangements, including ACO contracts, UnityPoint Health understands and supports transitioning care to lower acuity settings as dictated by each patient’s status and population health principles. From a policy perspective, this again raises issues related to inequities perpetuated within the Fee-for-Service structure. Currently, lesser costs from “healthier” patients balance greater costs from more complex patients. As procedures are removed from the IPO list, “healthier” patients are transitioned to outpatient settings leaving more complex, costly patients within inpatient settings. These policies perpetuate a for-profit mentality and encourage more infrastructure builds to cater to younger, healthier, and less costly patients, divert resources from existing inpatient settings, and lead to greater health care costs overall. In the Midwest where access is determined by geography, this approach significantly impacts the sustainability of inpatient services, particularly in the nonprofit arena, and ultimately undermines access to care. Case in point are SCHs, where IPO list erosion will directly impact their financial sustainability. While our preference is for CMS to encourage value-based arrangements instead of further Fee-For-Service arrangements, we urge CMS to monitor procedures that are removed from the IPO list to determine if baseline Fee-For-Service payments should be readjusted to reflect heightened patient acuity and assure access to inpatient services. At the very least, we would recommend that CMS consider inpatient rate updates that more closely follow the consumer price index.

COINSURANCE FOR COLORECTAL SCREENING

² <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

Parallel to the Provider Fee Schedule proposal for CY 2022, CMS proposes to provide a special coinsurance rule for procedures that are planned as colorectal cancer screening tests but become diagnostic tests when the provider identifies the need for additional services (e.g., removal of polyps). This rule, over time, reduces the amount of coinsurance a beneficiary will pay for such services (i.e., 20% for CY 2022, 15% for CYs 2023 through 2026, 10% for CYs 2027 through 2029, and zero percent beginning CY 2030).

Comment: The coinsurance policy update for colorectal cancer screenings is a positive move in the right direction and supports adherence efforts in preventative care. This proposal will shore up frequently voiced beneficiary grievances around unexpected bills for diagnostic testing confused as covered under a screening test benefit. While the Affordable Care Act attempted to make similar proposals for preventative services that were given a USPSTF grade recommendation of A or B, exceptions were made for colorectal cancer screening. **UnityPoint Health agrees with the substance of the proposal - that the screening test benefit should apply regardless of whether a tissue biopsy or polyp removal is performed. On process, we disagree with the proposed phased-in approach.** We believe that the 80% coverage proposal for 2022 has little impact as many beneficiaries are currently billed 20% coinsurance for their screening test because a polyp is found. **UnityPoint Health strongly recommends CMS not delay full coverage for this screening test until 2030. Full coverage should begin in 2022 so beneficiaries are not deterred from completing this important cancer screening test.**

COVID-19 TEMPORARY POLICIES

CMS seeks comments around the value and possible continuation on a number of temporary policies put in place during the Public Health Emergency (PHE). Areas of focus include providing mental health services remotely, virtual direct supervisions for certain rehabilitation services, and payment for COVID-19 specimen collection in hospital outpatient departments (HOPDs).

Comment: UnityPoint Health is grateful to CMS for the PHE flexibilities granted to providers to enable innovative and effective care delivery. As referenced in the preamble, the temporary lifting of telehealth service restrictions to enable beneficiaries to be served without regard to urban versus rural distinctions as well as in their homes and other more convenient sites of service has been a game changer. For Medicare beneficiaries, roughly 33% of our telehealth visits have occurred in urban sites since the PHE flexibilities were instituted. **UnityPoint Health supports the continuation of flexibilities in the delivery of telehealth services and strongly recommends that CMS encourage Congressional action for permanency.** This includes lifting provider/beneficiary location limitations through 'originating site' and geographic restrictions in §1834(m) of the Social Security Act. As a multi-state health system, flexibility related to licensure enabling the deployment of health care professionals across state lines has also been monumental, especially in regions where our hospitals are located on state borders.

Direct Supervision by Interactive Communication Technology: **UnityPoint Health encourages CMS to make permanent virtual direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.** We have relied on this flexibility and do not understand why CMS would not be proposing to maintain this flexibility outside the PHE. This PHE flexibility has allowed vital access to high quality patient care particularly in rural communities. In addition, this flexibility has improved program adherence, helped address workforce shortages, and has been well received by beneficiaries.

Code and Payment for COVID–19 Specimen Collection: During the PHE, CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2, any specimen source), which is conditionally packaged. **UnityPoint Health supports the continuation of this Hospital Outpatient Department payment stream.** The COVID-19 virus will not cease to exist once the PHE terminates, and specimen collection should be similarly encouraged despite PHE status.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS proposes a number of updates to the OQR measure set and validation process and requests feedback on several issues including potential new measures, data on health disparities, and transitioning to digital quality measurement.

Comment: In terms of the proposed revisions, UnityPoint Health requests that CMS consider the following:

- COVID-19 Vaccination Coverage Among Health Care Personnel Measure (HCP) - **UnityPoint Health opposes this as a quality measure for reporting.** While our organization has instituted a COVID-19 vaccination requirement for employees, we are concerned with the precedent that a CMS pandemic quality measure will establish. First, CMS proposed this measure while COVID-19 vaccines were under an emergency use authorization (EUA). As multiple vaccines are approved and protocols change, this is not reflected in the measure. Second, if quality measures are developed and required for each disease-specific pandemic, this runs counter to principles of meaningful measures that target outcomes rather than outputs. Third, we question whether CMS's intent is best served through a quality measure of a vaccination requirement. The proposal to measure, and potentially tie, COVID-19 vaccination adherence to reimbursement gives the appearance that CMS is indirectly mandating vaccines for health care workers. If CMS is going to mandate vaccines, it should do so directly and clearly rather than through an indirect reimbursement incentive. Fourth, UnityPoint Health reports this information under the HHS COVID-19 reporting requirement as directed through the federal PHE and thus, additional reporting of this measure becomes duplicative. In particular, as proposed, this measure based on quarterly reporting to NHSN does not align with our current weekly reporting to HHS – creating both confusion and potential inconsistency in data. Lastly, our hospitals as well as other sites of service typically keep employee health records outside of their electronic health record (EHR) due to health privacy concerns. With that said, attempting to identify and collect data on employee vaccine adherence is inherently difficult and burdensome. UnityPoint Health appreciates CMS's attempt to curb the devastating impact of the COVID-19 pandemic; however, we have concerns with the proposed measure.
- Breast Screening Recall Rate Measure – **Overall, to enable more evidence to be collected and to better determine recall rate measure reliability, UnityPoint Health recommends that this measure be an optional measure and its performance not tied to payment.** This measure is recommended and endorsed by the American College of Radiology. Although UnityPoint Health recognizes the importance of recall rates, we believe this measure is premature as proposed. As described, we question: (1) Whether the recall range of 5% to 12% is supported by sufficient

research, (2) whether CMS should seek NQF or similar quality organization endorsement when instituting quality measures, and (3) whether CMS should require screening professionals (e.g. American College of Radiology) to collaborate with and/or seek formal input from treatment professionals (e.g. oncology associations) for quality measures. In terms of the measure's look-back period, **we encourage CMS to exclude 2020 and 2021 data at the height of the COVID-19 pandemic**, which will be inaccurate as a result of many beneficiaries skipping preventative care.

- ST-Segment Elevation Myocardial Infraction (STEMI) Electronic Clinical Quality Measure (eCQM)
– This measure will replace two very similar chart abstracted measures (i.e. OP-2: Fibrinolytic Therapy Received within 30 Minutes of ED Arrival; and OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention) that are currently collected. **UnityPoint Health generally supports this new measure, which transitions from chart-abstracted data collection to an electronic auto-reporting modality.** While we appreciate the reporting burden reduction, there are costs associated with eCQM reporting – namely, software vendors must build logic, which entails an 18- to 24-month implementation period for development, validation, and certification, for rolling out to the organization, and for adopting any new workflows and training. It should also be noted that, while two measures are essentially being combine into one, this consolidation simply makes room for an additional measure to be reported in the following year.
- Outpatient and Ambulatory Surgery (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey-Based Measures (OP-37a-e) – The biggest deterrent to the OAS CAHPS survey going live in 2018 was the lack of evidence to demonstrate its worth. UnityPoint **Health still has concerns** with:
 - **Survey length.** This lengthy survey is in itself a patient dissatisfier. We encourage CMS to revisit this survey and reduce its length.
 - **Use of CPT codes to trigger survey distribution.** The exclusion list is relatively short, and the CPT code list is extensive. As a result, coding is onerous and time-consuming, and this often delays survey distribution. In some cases, the timeframe around submission of claims and coding information simply does not match – meaning that coding may not be completed to accommodate the 21- to 60-day survey timeframe. We encourage CMS to eliminate the use of CPT codes to trigger survey distribution.
 - **Administrative burden.** While CMS opines that web-based distribution reduces burden, there is still a cost associated with processing. In addition, the proposal is not limited to web-based distribution, so hospitals still need to have the capacity to distribute via web+phone or web+mail, an overall increase in burden. We encourage CMS to permit web-based distribution as a stand-alone option without pairing web-based distribution with phone and/or mail.

Overall, UnityPoint Health does not believe that OAS CAHPS is ready for prime time and should not be mandated for services provided to Medicare beneficiaries.

REQUESTS FOR INFORMATION

A. Rural Emergency Hospital

CMS seeks comments on a range of requirements and feedback related to Rural Emergency Hospitals

(REHs) including type and scope of services offered, health and safety standards, health equity issues, quality measures, payment provisions, and enrollment.

Comment: We are extremely pleased that Congress has authorized this new designation for rural hospitals. UnityPoint Health has worked with Senator Chuck Grassley (R-IA) on prior iterations of the Rural Emergency Acute Care Hospital (REACH) Act. At heart, UnityPoint Health is a largely rural integrated health system and serves many rural beneficiaries through our hospitals (inpatient and outpatient), rural health clinics, urgent care, emergency medical services, community mental health centers, home care services, hospice services, and nursing facilities. As small prospective payment system (PPS) hospitals and CAHs within our integrated health system continue to struggle with thin operating margins, they remain economic engines for, and important employers, within their communities. We firmly believe that rural communities (not reimbursement structure) should determine the right size of health care access and services, and communities should have for their consideration a menu of health care options. With the shifting nature of rural populations, the REH designation has the potential to offer needed emergency services for communities that may no longer support inpatient volumes. If structured appropriately to enable integrated care, it is our hope that REHs may remain vital and sustainable health care hubs for rural communities.

With a common commitment to accessible health care in rural areas, including support of a REH designation, UnityPoint Health participated in the Iowa Hospital Association's rural task force in collaboration with American Hospital Association advocacy efforts. As such, **UnityPoint Health is generally supportive of the comment letters submitted by both the Iowa Hospital Association (IHA) and the American Hospital Association (AHA) in response to this REH request for information.**

Intent of REH: The tenet underlying REHs is that where you live, should not determine if you live. The quality of care and access to health care services in rural areas, including services provided by REHs, should not be equated to lesser care standards; however, **REHs should have different service standards, which represent the absence of inpatient services and supports quality emergency department services.** If the scope of service standards is not narrowly tailored, we fear that REHs will need to squander their scarce resources on overly expansive regulatory requirements.

Key REH Considerations: As a supplement to the IHA and AHA letters, we request that CMS consider the bulleted content within the REH rules. Also **woven throughout this content is the need for REHs to be sustainable and predictable** both financially and as an attractive work environment to recruit and retain dedicated health care professionals.

- Timing for Proposed Rules. **UnityPoint Health urges CMS to release proposed REH rules in the Inpatient Prospective Payment System proposed rule or sooner.** Per the authorizing statute, REHs may be established as soon as January 1, 2023 and as authorized by state law. We are extremely concerned with the short turn around for rule development with associated notice and comment period(s) given operational implications for hospitals considering a REH conversion as well as states seeking to authorize this designation.
- Type and Scope of Services Offered. In a rural community, REHs should be incentivized to offer ambulatory and continuity of care services to fully utilize existing buildings and leverage scarce

health care professionals. **When inpatient beds are eliminated from a community, this should not necessarily equate to the removal of other continuum of care services.** While the primary charge of REHs is to provide emergency department care, regulations should not prevent but facilitate the provision of other service lines outside inpatient care at the discretion of the REH and based on community needs.

- Emergency Medical Services (EMS). **Foremost is our belief that the success of the REH designation is dependent upon the ready availability of EMS transportation.** In fact, we would suggest that EMS services should be paired with REH services, and that reimbursement should be at a cost basis for transports by REH-owned EMS. If beneficiaries cannot be timely transported to and from an REH to accommodate beneficiary acuity, this may ultimately hamper beneficiary safety and care and may even result in the further decrease in visit volumes to REHs. A sustainable EMS funding source is needed, as the availability and timeliness of volunteer EMS in rural areas is variable.
- Skilled Nursing Services. To keep care local and maintain residents in their home communities, **the ability to offer skilled nursing services is vital**, especially with the elimination of inpatient services. Like EMS services, REHs should be reimbursed at a cost basis for these services provided within a distinct unit. Under this reimbursement, as volume increases, costs decrease as infrastructure remains virtually the same.
- Home Care and Hospice Services. During the PHE, the transition of care to the community has become even more prevalent. **Rules should permit and even encourage REHs to offer home care and hospice services.** For REH-owned services, again we believe that cost-based or enhanced reimbursement is appropriate.
- Rural Health Clinics. UnityPoint Health supports **REHs as an entity to operate provider based RHCs and the transfer of grandfathered RHCs upon conversion of their hospital to REH status.** To further encourage REH transition, we would even urge CMS to work with Congress to consider bestowing grandfather status to RHCs established as, or converted to, provider based RHCs by an REH.
- Health and Safety Standards. **Conditions of Participation should be limited to the REH designation and emergency services.** In terms of staffing, rural areas are riddled with Healthcare Professional Shortage Areas (HPSAs) and overall health care workforce shortages that have been exacerbated during the COVID-19 pandemic. As such, **health and safety standards should support and not hinder top of licensure practice**, whether by physicians, advanced practice professionals, nurses, and/or medical technicians.
- Health Equity. UnityPoint Health values health equity and focuses on reducing care variation with all patients no matter race, ethnicity, gender, sexual orientation, or other demographic or social risk characteristics. While we do not believe that REHs should be subject to special reporting, **we urge CMS to standardize the use of “equity”** as defined in the Executive Order on Advancing Racial Equity and Support for Underserved Communities. This definition is detailed later in this comment letter under the *RFI: C. Health Equity* narrative. Of note, the definition includes

“individuals who belong to underserved communities that have been denied such treatment, such as . . . persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.” Using a rural access lens, REHs can and should be leaders in health equity.

- Collaboration and Care Coordination. As REHs are intended to provide emergency services, we encourage CMS to consider **removing arbitrary distinctions and regulatory barriers between providing urgent care and emergency services** – both of which are unexpected yet require medical services and treatment. CMS should not shift to beneficiaries the onus of determining whether their emergency/urgent condition rises to the level of emergency care versus urgent care. This should fall squarely to the clinical judgment of medical professionals – not to reimbursement structure or beneficiary speculation.
- Quality Measurement. We view this as an opportunity for REHs to be rewarded for quality performance and reporting. Since it is important for REHs to have consistent and sustaining funding, quality measures should be **structured as a payment bonus**, not a withhold or penalty; funding should be available to assist with **reporting infrastructure**; initial reporting periods should be considered **pay-for-reporting** instead of pay-for-performance; and reporting and measure weighting must consider the real **potential for small values (i.e. absolute numbers) and outlier impacts**. Instituting a quality measure framework should be viewed as a work in progress with reasonable timeframes for implementation.
- Payment Provisions. **Cost-based or add-on payments should be available to REHs for ambulatory services to encourage efficiencies and enable these hospitals to function as a community health care hub**. As listed under our *Type and Scope of Services Offered* input, these services should be eligible for enhanced reimbursement if offered onsite or under agreement with an REH. Heightened reimbursement reflects the price of access to (i.e. availability of) care and should not be confused with convenient care, but rather necessary care. In terms of REH rate setting, we believe that low volume makes PPS rates suspect as a predictable and sustainable funding mechanism. CMS should work with Congress to reconsider REH benchmarking and rate-setting methods to emphasize predictability and sustainability and to avoid financial surprises. One potential option to increase predictability is to trend rates over a multiple-year period (i.e. three years) to diminish the impact of one down year.
- Enrollment Process. **CAHs under necessary provider designation should be an eligible hospital for purposes of the REH application and enrollment**. In Iowa, all 17 UnityPoint Health CAHs (wholly owned or under management agreements) applied and received necessary provider designation status. In fact, all 82 CAHs within Iowa have a necessary provider designation. Without this provision, only small PPS hospitals would be eligible for the REH designation.
- Program Officer. We encourage CMS to name a dedicated program officer to the REH program as soon as possible so stakeholders have a point of contact on this new hospital designation.

While the above bullets are crafted in response to the REH request for information, it should be noted that **if many of these flexibilities were applied to existing CAHs and small PPS hospitals, they would not need to convert to REH and would be able to retain both inpatient and emergency department services.**

Likewise, if Congress were to suspend sequestration reductions for CAHs and small PPS hospitals, the financial health of these hospitals would be improved and, in some cases, closure decisions would be averted.

Challenges to Health Care in Rural Areas: While the creation of an REH designation props up an emergency care presence in rural areas, **UnityPoint Health views REH as one tool among many to equip rural communities to make available the appropriate care at the appropriate level at the appropriate time.** Small and mid-size Iowa hospitals are facing pressures from the convergence of several factors, including Medicare and Medicaid reimbursement structures, loss of population base, and the changing nature of health care services. As a result, service lines have closed, facilities have downsized, and some hospitals are on the brink of closure. The changing inpatient landscape in rural areas has a domino effect – health care access is impacted in specific communities, surrounding regions, and the state. For example, maternal health and obstetrics (OB) deserts have grown in Iowa, leading to potential delayed prenatal care and poorer birth outcomes.

When crafting rural health options, policymakers and regulators must consider:

- **Cost of Access / Availability vs. Cost of Services.** **Medicare PPS reimbursement is a volume-based strategy that is ill-suited to rural settings with small volumes where cost relates to service availability.** Congress recognized the value proposition of access to health care in rural areas and created the CAH designation in 1997 to reduce the financial vulnerability of rural hospitals and improve access to health care by keeping essential services in rural communities. In other settings, fee-for-service schedules institute enhanced payment for access to health care service via rural add-on payments.
- **Population Health Preparedness and Capacity.** **Regional impact on health care resources and capacity must be considered** as rural health care delivery options are developed and adopted. As alluded to above, the closure of service lines or facilities creates a domino effect. The closure of a hospital OB unit shifts those births to other hospitals. The closure of inpatient services similarly shifts those services to other hospitals. During the COVID-19 pandemic, all hospitals experienced capacity surges. Rural hospitals' census ballooned from observations, admissions, transfers, and reverse transfers. As hospitals are encouraged to right size, it begs a temporal question – what frame of reference should communities/regions use to determine access? Once an OB unit is gone, those specialists are no longer available at that hospital, and similarly once inpatient services are forgone, inpatient beds, staffing, and equipment will be gone from that hospital.
- **Efficiency Cannot Compromise Safety.** Financial pressures are further strained as **rural hospitals are limited in their ability to downward scale services and operations.** Rural hospitals have finite sunk costs. When considering a conversion to REH status, a break-even financial move that entails losing inpatient beds is a non-starter. A REH conversion also assumes decreased expenses (and increased bottom line) and/or workforce efficiencies – both of which are hard, if not impossible, to achieve with small operating margins.

Larger Lens on Rural Health Care: Aside from REH, **UnityPoint Health encourages CMS and Congress to remain vigilant in efforts to provide a menu of rural health care delivery options.** Communities and

regions should be allowed to self-select solutions based on their varied needs and priorities.

The chart below was developed in 2019 by a UnityPoint Health workgroup charged to develop rural health care policy recommendations. We are pleased to report that several recommendations, including but not limited to REH as well as RHC telehealth flexibilities, have been adopted. That said, we still believe that six top-line strategies are valid and should be prioritized.

UnityPoint Health 2019 Rural Advocacy Priorities



B. Fast Healthcare Interoperability Resource (FHIR)

CMS seeks feedback on future plans to advance digital quality measurement under the Outpatient Quality Reporting Program (OPQR). Potential actions to transition to digital quality measures by 2025 include use of provider FHIR-based application programming interfaces (APIs); redesign of measures to be self-contained tools; data aggregation support; and measure alignment across reporting programs.

Comment: With health care systems historically being the first to implement electronic health records (EHRs) and FHIR, our biggest concerns lie within the variation of FHIR versions, lack of version requirements, and variation in industry timelines. With three different versions of FHIR and no version

requirements, this puts limitations on a provider's ability to connect to certain application interfaces. There is no consistency in who is required to have FHIR, how to submit data, and when to submit data. This becomes a large challenge for providers who attempt to submit data utilizing these vendors and payors. UnityPoint Health uses a combination of DSTU 2, STU 3 and R4 FHIR Versions to meet our requirements for sending data. Since 2017, four main versions have been released in addition to sub-versions released to correct errors or issues in technological builds, meaning vendors and providers have had to sort through up to six version updates to land at v4.1.0, the most recent "Permanent Home" version of FHIR. It should be noted that not all hospitals are at v4.1.0 yet because vendors and providers are not required to meet ONC CURES Edition CEHRT.

While UnityPoint Health appreciates the attempt to align health care interoperability resources, integrated health systems have competing information technology builds and priorities across care settings, which is true on a smaller scale for individual providers and smaller hospitals. When UnityPoint Health rolled out an EHR through Meaningful Use requirements in the hospital inpatient setting, it was a multiyear process. **Overall, UnityPoint Health recommends slowing down the implementation and updates of new standards in health care interoperability, allowing all parties, including CMS' technology, to catch up and align as an industry.** Specifically, we urge CMS to consider:

- **A stair step approach to implementation**, first incentivizing milestones along the way and, at an appropriate point in the timeline, introducing a negative incentive to promote long-term adherence.
- **Biennial updates to FHIR for all providers.** If releases are consistent and across the board, providers can better plan for resourcing, allocations, and cost.
- **Incorporating social determinates of health (SDOH) as part of the standardized CCD documentation applicable to all providers.** This will allow the integration of such information into a patient's chart and ultimately promote transparency in health equity.
- **Standardized reporting requirements across all programs** to enable utilization of software and quality measures across all care settings allowing better continuity of care. This will facilitate vendors and providers to concentrate efforts universally and lessen the chances for some providers and/or care settings to be left behind.
- **Program incentives for stakeholders to partner with vendors in pilot programs and models.** Payment or flexibilities to participating providers would encourage a robust testing environment in which stakeholder input is included.

C. Health Equity

CMS requests information on several proposals in advancing health equity. Specifically, CMS seeks comment on additional measure stratification, data collections, and a health equity summary score.

Comment: UnityPoint Health values health equity and focuses on reducing care variation with all patients no matter race, ethnicity, gender, sexual orientation, or other demographic or social risk characteristics. UnityPoint Health appreciate CMS' commitment to addressing health equity and looks forward to partnering with CMS in advancing this important focus. UnityPoint Health is an active member of The Academy Advisors and generally supports comments provided in The Academy Advisors' comment letter

to CMS-1752-P, which targets the health equity topic in the inpatient setting. This feedback is generally transferrable to the hospital outpatient setting. Additionally, UnityPoint Health offers some supplemental input below:

- Measure Stratification. In order to accurately focus on driving palpable change in health equity, measure stratification becomes vital to the process. **Stratification must be robust to high variations in local market populations, including imbalanced race/ethnicity distributions or other identified equity attributes.** For less densely populated areas where imbalanced populations tend to exist, results can be disproportionately impacted by sentinel events to minority populations as compared to highly populated urban locations with greater balance. Existing quality measure serve well to define health care quality, but equity should be defined as gaps in these measure amongst attributes and targeted for improvements. UnityPoint Health recommends “descriptive” modeling using traditional predictive modeling techniques to study equity imbalance by only including equity attributes as model features with the health measure as the target, fitting a predictive model, and then examining the feature importance. Highly predictive features in this context suggest the type and magnitude of equity imbalance in a given population. In conclusion, **UnityPoint Health strongly discourages use of an algorithm to estimate race and ethnicity and recommends using existing quality measures utilizing predictive modeling techniques to study health disparities.** This statement would apply to Hospital OQR Program measures proposed for disparities reporting stratified by dual eligibility (i.e. OP-8: MRI Lumbar Spine for Low Back Pain; OP-10: Abdomen CT—Use of Contrast Material; OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery; OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy; and OP-36: Hospital Visits after Hospital Outpatient Surgery).
- Expanded Demographic Data Collection/Reporting. In order to accurately measure data, the data itself must be of high quality. Challenges exist today in effectively capturing this type of information. Manual collection by health providers leads to high administrative burden and would require standardized data collection protocols, many of which do not exist today. However, UnityPoint Health agrees collection of self-reported data is the most precise method to capture current and accurate race and ethnicity information. Data lag can be significant between census surveys and performance periods and high variance, even at the census block level, given social determinates of health (SDOH) factors. Using a proxy would still require patient addresses to map to census locations identifiers. UnityPoint Health has a 55%-60% match rate when taking patient addresses, geocoding to a census block, and joining results. While proxies are not ideal for capturing data, should CMS choose to continue development utilizing this method, it will be imperative for hospitals to have the opportunity to address self-identified inaccuracies as well as a process to appeal data and outcome results should they deem appropriate. **UnityPoint Health urges CMS to consider offering hospitals financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data,** a gold standard as noted by CMS.

- **Facility Equity Summary Score.** UnityPoint Health is supportive of health equity and developing a framework for measuring so that hospitals can be transparent and accountable in closing the gap in health equity. That said, we have concerns and recommendations with the proposed facility health equity summary score. Developing a score, while potentially effective in the future, may not be as helpful at this time in advancing efforts in this space nor closing the gap in health equity. Variation in process exists today:
 - Data collection and measurement stratification efforts are unclear and have not been appropriately analyzed to ensure accuracy and effectiveness. **UnityPoint Health strongly urges CMS to develop standard data definitions as well as continue to partner closely with stakeholders in identifying measures that effectively and accurately measure health equity for diverse patient populations and a variety of geographical regions.**
 - In general, developing a “facility score” that is inadequate or too early in the process can inadvertently lead to a negative impact on health equity as a whole. We are not convinced that a score targeted for payors is adequate or appropriate for providers. In fact, we are aware of other hospitals, organizations, and national groups with more robust and researched efforts underway to develop a facility/provider score. We urge CMS to tap into these resources. **UnityPoint Health strongly recommends that CMS establish a diverse stakeholder taskforce to partner with CMS on any future facility health equity score to ensure a comprehensive measurement will yield an effective, accurate and actionable score. A health equity summary score should only be implemented after development and through testing with stakeholders.**
 - If scored on race, ethnicity, and dual eligibility alone, gaps would still exist in other equity categories including gender, sexual orientation, health literacy, language barriers, and other social risk factors. **UnityPoint Health supports and recommends that CMS standardize the use of ‘equity’ as defined in the Executive Order on Advancing Racial Equity and Support for Underserved Communities.** In particular, “(a) The term “equity” means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. (b) The term “underserved communities” refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of “equity.”³ While UnityPoint Health supports a broader definition of health equity, we also support a consistent definition. An approach that phases in equity categories or social risk factors over time has the potential to penalize facilities early on that

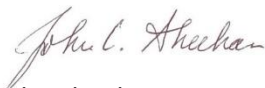
³ (<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>)

will perform better under a more comprehensive definition.

While UnityPoint Health appreciates the Administration's pervasive emphasis on health equity through the rulemaking process and its interest in closing disparity gaps, the measurement framework is still within the early development phase and its impact on reimbursement and operations is unclear. We encourage CMS to be thoughtful of these provider implications and to use a carrot approach, not a stick approach. We recommend CMS to study the large variation in defining health equity as well as additional ways in which to accurately collect and measure demographic and social risk factors. UnityPoint Health looks forward to partnering closely with CMS in future efforts to advance health equity.

We are pleased to provide input on this proposed rule and its impact on our hospitals and health system, our beneficiaries, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,



John Sheehan, MHA
Senior Vice President & Chief Operating Officer
UnityPoint Health



Cathy Simmons, JD, MPP
Executive Director Government & External Affairs
UnityPoint Health