UnityPoint Health

1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

August 12, 2019

Administrator Seema Verma
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–6082-NC
P.O. Box 8016
Baltimore, MD 21244–1816

RE: CMS–6082-NC - Request for Information; Reducing Administrative Burden To Put Patients Over Paperwork; published at Vol. 84, No. 112 Federal Register 27070-27072 on June 11, 2019.

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

Dear Administrator Verma,

UnityPoint Health ("UPH") appreciates this opportunity to provide input on the Patients Over Paperwork request for information. UPH is one of the nation's most integrated healthcare systems. Through more than 32,000 employees and our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program (MSSP) as well as providers from the Pioneer ACO Model. UnityPoint Health also participates in a Medicare Advantage provider-sponsored health plan through HealthPartners UnityPoint Health.

We appreciate CMS's past efforts under the Patients Over Paperwork initiative. UPH respectfully offers the following comments for future efforts.

REDUCING ADMINISTRATIVE BURDEN TO PUT PATIENTS OVER PAPERWORK

CMS is soliciting public comments to: (1) Modify or streamline reporting requirements, documentation requirements, or processes to monitor compliance to CMS rules and regulations; (2) align Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes; (3) enable operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support

the clinician-patient relationship, and facilitate individual preferences; and (4) recommend when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers.

Comment:

HEALTH INFORMATION AND CLAIMS DATA ACCESS

Access to patient care information is vital for health care providers to holistically manage patient care and oversee appropriate service utilization and costs. ***We encourage the removal of barriers to this information to enhance patient care, support the clinician-patient relationship, and facilitate individual preferences.***

- **Access to substance abuse records by treating providers**. Presently, individual patient consent is required for access to health records from federally funded substance abuse treatment programs. The absence of a complete health history hampers overall patient care and may jeopardize recovery efforts. We urge that requirements for sharing of patient substance abuse records be aligned to the HIPAA regulation that allow the use and disclosure of patient information for treatment, payment, and healthcare operations in accordance with the American Hospital Association's recommendation.
- **Permit the sharing of patient medical information within a clinically integrated care setting**. HIPAA currently restricts the sharing of a patient's medical information for "health care operations" like quality assessment and improvement activities, including outcomes evaluation, or activities that relate to the evaluation of provider qualifications, competence or performance. This sharing of patient information is restricted to disclosing and receiving providers that have – or have had – a patient relationship. This restriction does not facilitate team-based care nor support functions of individuals in health coaching or care coordination roles. We agree with the American Hospital Association that HIPAA should be interpreted 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.
- **Access to All-Payer administrative claims data.** At a minimum, as multi-payer initiatives are explored and implemented, we encourage federal, state and commercial payers to share full claims data feeds with providers. For the All-Payer Option to calculate Qualified Participants for Advanced APMs, participating payers should be required to share claims data. Ideally, this data feed should resemble the CMS data feed or be placed in an All-Payers Database that uploads to a common data framework. The timely sharing of claims data promotes transparency and quality care.

PHYSICIAN SELF-REFERRAL (Stark Law)

Since the enactment of the physician self-referral law in 1989 and the original enactment of the Anti-Kickback statute in 1972, the delivery of health care services and the payment for those services – among all payers, both government and private - has changed dramatically. By intent and design, Stark physician self-referral law ("Stark") separates entities that are furnishing designated health services from physicians

who are providing care to Medicare beneficiaries. Advanced APMs face the challenge of trying to achieve system-wide clinical and financial integration to lower costs and improve health access and outcomes, while simultaneously complying with Stark, Anti-Kickback, and other laws and regulations that create care silos. ***We encourage regulatory flexibility to enhance patient care, support the clinician-patient relationship, and facilitate individual preferences.***

- **New Stark law exception to accommodate innovative payment models**. The exception[1] would address innovative value-based payment models that establish networks involving designated health services entities and referring physicians to assume financial risk and provide high-value services. We would also suggest harmonizing language[2] to provide clarity within existing Stark Law exceptions for value-based arrangements.

VALUE-BASED SERVICE DELIVERY

Insurance companies, along with the federal and state governments, have traditionally borne the risk for the cost of health care. Under Medicare Advantage (MA), health plans provide managed care to beneficiaries based on a monthly capitated fee. The MACRA legislation gives providers "skin in the game" by mandating that providers assume risk for the cost of care of their patients to receive preferred reimbursement. For the most part, these risk programs are administered by the Center for Medicare and Medicaid Innovation (CMMI). ***To improve the accessibility and presentation of CMS requirements, we would recommend that Advanced APMs have common benefits and that Advanced APM requirements be achievable so as to encourage greater uptake to value-based service delivery by providers.***

- **MACRA Advanced Alternative Payment Models (Advanced APMs) regulatory flexibility.** *Risk-bearing A-APMs should be afforded greater administrative flexibility. For A-APMs that bear risk to total populations, these A-APMs will ultimately compete with MA plans, infuse competition into the market, eliminate the middle man and provide more patient-centric care.* Common ground rules for participation should include:
  - **Exemption from MIPS reporting for all Advanced APM Participants at the Participant TIN level**. This would eliminate the need by innovative and high-performing provider organizations to support two quality reporting systems for the underlying Advanced APM program and MIPS;
  - **Voluntary enrollment** for beneficiaries;
  - Eligible A-APMs should operate under **partial or capitated risk arrangements**, as shared savings is a flawed methodology;
  - Ability to **waive beneficiary co-payments and deductibles** for preventive care and chronic care management;
  - A-APMs need the option to refer to **preferred providers**; and
  - **Stark law should be waived** for entities participating in partial or capitated risk.

[1] StarkRFI_UPH_08-24-18.pdf submitted via Regulations.gov at comment tracking number: 1k2-9515-eahs; See Appendix A: New Value Based Arrangements Exception

[2] StarkRFI_UPH_08-24-18.pdf submitted via Regulations.gov at comment tracking number: 1k2-9515-eahs; See Appendix B: Other Modifications to Existing Exceptions

- **MACRA revenue threshold levels for Qualified Participants (QPs) within Advanced APMs**. MACRA progressively increases these threshold level. CMS should evaluate the capacity of A-APMs to meet current threshold levels and make recommendations to Congress alter this structure to retain current A-APMs and to encourage further A-APM establishment. We encourage CMS to seek stakeholder input when offering alternatives that uphold a transition to value-based services from volume.
- **Taxation treatment of population health infrastructure**. Tax regulations should permit independent physician groups to retain earnings tax free for the purpose of funding losses on at-risk contracts or investing in population health infrastructure that directly support success in at-risk contracts.

ACCOUNTABLE CARE ORGANIZATIONS (ACOs)

As an early adopter of ACO models (having participated in Medicare ACO models since 2012), UnityPoint Accountable Care (UAC) has and is participating in Medicare ACO models as a glide path to assuming greater risk while enhancing overall population health. UAC is one of the largest ACO participating in the Next Generation ACO Model and has received two-years of shared savings with performance results pending for the third year. Historically, UAC has providers that have participated in the MSSP as well as providers from the Trinity Pioneer ACO, which was the most rural Pioneer Model ACO and achieved two years of shared savings. In our opinion, Medicare ACO models have succeeded in offering a differentiated patient experience through enhanced provider engagement and testing benefit enhancements and programmatic waivers. The following are recommendations to enable operational flexibility, feedback mechanisms and data sharing to promote innovation, provider transition to value and enhanced patient experience:

- **Remove new beneficiary notification requirements.** ACOs must notify beneficiaries at the point of care about voluntary alignment, its participating in the MSSP and the opportunity to decline claims data sharing. This notice is in addition to current posting requirements and the availability of written notices upon request. Since MSSP had retired a similar past notification procedure due in part to beneficiary confusion and provider burden, we encourage CMS to discontinue its use again.
- **Clarify program overlap with preference for global population models**. Current regulatory overlaps have muddled program rule clarity and are increasingly viewed as a disincentive for providers to take heightened risk for total populations. These overlap rules fail to recognize the totality of population health programming and incentivize siloed, episodic care (whether procedures or condition-based) based upon Fee-For-Service constructs over total population health programming. For instance, Oncology Care Model, Comprehensive ESRD Care Model, and Bundled Payments for Care Improvement (BPCI) beneficiaries are removed from the Next Generation ACO for purposes for these episodic procedures, yet the Next Generation ACO remains responsible for the overall outcomes and costs of their care. These rules allow new episodic programs and their providers to skim off ACO infrastructure investments, do not require notice of attribution among programs nor inter-program care coordination, and impose a narrow 60- or 90-day treatment timeframe misaligned to holistic care (i.e., a significant number of BPCI

episodes, such as congestive heart failure, chronic obstructive pulmonary disease, and diabetes, require lengthy aftercare and are subject to co-morbidities). With the advent of direct contracting entity models and a new round of mandatory bundles and ESRD programming forthcoming, this issue needs resolution. To address the entanglement, ***we encourage a hierarchical approach to CMS / Innovation Center model overlap, in which precedence is given to population health risk-bearing entities.*** We would suggest that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy. Within this framework for payment models, CMS can offer a hierarchy of the various delivery models. For example, if a bundled payment were being proposed in a geographic area in which there is a prevalent ACO, the ACO should drive patient attribution and performance goals to incorporate specialty care within the patient's care plan. As for reimbursement, these payments would be included within the ACO financial framework and, for ACOs under a capitated model, the ACO could convert the bundles into sub-capitation arrangements. Such approach would prioritize holistic patient care, engage specialists, leverage ACO infrastructure investments, and provide model certainty for ACOs and high performing networks as they consider and participate in innovative payment approaches.

- **Allow two-sided ACOs a "zero year" within their contract performance periods**. This voluntary "zero year" would enable ACOs to adapt their business constructs to the new ACO model, to test pilots and to receive performance data. This zero year recognizes that CMS often does not announce model participants more than 3 months prior to the start of the contract and data lag is often three to six months in arrears. We believe CMS should include zero year provisions for new two-sided risk models.
- **Provide valuable and actionable real-time data needed for successful care coordination**. CMS does provide Medicare ACOs with claims data and performance reports, and we appreciate CMS's leadership in providing access to claims data. In the realm of real-time data, we would urge CMS to similarly lead the industry in efforts to make such data available. As a starting point, CMS incentivize hospitals to participate in electronic notifications of hospital admissions, discharges, and transfers (ADTs). CMS could consider some potential penalty/incentive frameworks which may include a new attestation process with associated penalties; revisions to one of the hospital quality programs to include participation as an offset/bonus; or, for those hospitals who choose to participate, affording hospitals some regulatory flexibility, such as expanded use of telehealth. In addition, CMS could make Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) feeds available to ACOs and Medicare providers participating in Advanced APMs.
- **Make transparent the Qualified Participant (QP) calculation within the Quality Payment Program (QPP)**. QPP thresholds are based on revenue or beneficiary counts for the ratio of attributed beneficiaries over attribution-eligible beneficiaries. These counts different from ACO assigned and assignable beneficiaries, and ACO reports cannot be used to project QP scores. We encourage CMS to make QP calculations transparent and even consider using the same definitions as within the ACO programs to promote definition consistency, enable providers to gauge QP status and encourage further transition to value and risk-based arrangements.

- **Address ongoing concerns with NGACO risk adjustment**. Simply put, the current 3-percent cap across a five-year agreement is inadequate and pales in comparison to Medicare Advantage plans. We encourage CMS to revisit this cap to promote further transition to value-based arrangements.
- **Permit ACOs to appeal a payment or alignment determination**. There is presently no provision to allow ACOs to appeal a CMS payment determination made in error. Likewise, ACOs cannot appeal a provider (TIN) misalignment – for instance, a provider TIN exits an MSSP ACO and joins an NGACO, the NGACO timely adds the provider TIN to the NGACO list, but the MSSP ACO does not timely remove the provider TIN from the MSSP list. In this instance, the MSSP ACO retains the provider TIN and the NGACO has no appeal rights. We urge CMS to revamp its appeals process to address these issues.
- **Expand opportunities to increase beneficiary engagement**. CMS should work with ACOs to permit flexibility in this arena and enable beneficiaries to be rewarded for high-value care choices. One example would be to reinstate incentives for Annual Wellness Visits. Another example would be creative methods to reduce telehealth co-pays.
- **Allow ACOs direct access to CMS program integrity to report suspected fraud and abuse**.
- **Simplify ACO marketing requirements**. We request that CMS eliminate the requirement for ACOs to submit internal provider facing materials.
- **Timing of annual Quality Payment Program (QPP) Proposed Rule**. We would suggest that CMS consider moving the QPP Proposed Rule to a notice and comment period earlier in the calendar year. By placing within the annual Physician Fee Schedule update, it is unlikely that the Final Rule will be released before November leaving only 2 months to operationalize changes. We would suggest that the QPP update occur during a timeframe that is more aligned to the annual Inpatient Prospective Payment System update (Proposed Rule in the spring and Final Rule in the summer).
- **Streamline QualityNet access to permit system level secure file exchange access for integrated health systems**. QualityNet houses reports to monitor performance under various CMS quality programs including the Inpatient and Outpatient Quality Reporting, Value Based Purchasing Program, HAC Reduction Program, and Hospital Readmission Reduction Program. UPH regularly uses QualityNet reports, such as (1) Overall Hospital Star Rating Hospital Specific Reports, (2) Hospital Value-Based Purchasing (VBP) Percentage Payment Summary Report (PPSR); (3) Hospital-Acquired Condition Reduction Program Hospital Specific Reports; (4) Medicare Spending per Beneficiary Hospital Specific Reports; (5) Public Reporting Preview Reports; and (6) Hospital Readmission Reduction Program Hospital Specific Reports. While each UPH hospital can access these reports through the QualityNet secure file exchange, our centralized UPH analytics personnel **with** approved QualityNet Healthcare System level access **cannot** receive these same reports. This requires duplicative steps by our centralized analytics team to request these reports from each hospital, which is both unnecessary and time consuming and defeats any efficiency efforts to centralize reporting functions.
- **Flexibility in Web Interface submission requirements** for Next Generation ACO quality reporting. In 2018, CMS changed the reporting format from an xml format to an Excel format. The new Excel file template was provided, including 146 columns to capture data for all measures in one spreadsheet and drop-down lists to help ensure only valid data was submitted in each cell. While

this format might be helpful for an organization that manually abstracts their data into the spreadsheet, it was and is very burdensome for organizations that have automated this process to pull directly from their EHR. UAC had been required to use the xml format since its participation in the Pioneer ACO Model in 2012. We would request that CMS consider reinstating the xml format for early adopters and also suggest that in the future CMS work with stakeholders as it considers "upgrading" reporting systems to consider timing and impact.

MEDICAID REFORM

The growth of Medicaid managed care is well documented. We believe that this trend has generally resulted in states turning over their regulatory keys concerning some of their most vulnerable residents to private health plans with little accountability and virtually no avenue for public input. We have significant concerns that loose federal parameters for Medicaid managed care usurps decision-making authority that should appropriately lie with, and be maintained by, taxpayers and the federal and state governments. In this arena, we suggest that Patients Over Paperwork should focus efforts on maintaining clear guidelines that assure single sources of regulatory truth and enable stakeholder input, including input from consumers and providers. CMS regulations should:

- **Encourage multi-payer state-based strategies to align with MACRA goals.** Specifically UPH highly supports multi-payer strategies in which **states align with existing Medicare models**, instead of encouraging state-specific new payer models. UPH recommends that value-based payments models include the following:
  - **Different types of Value-Based Payment options**, including total cost of care for the general population, voluntary bundled care arrangements, and total care for special needs populations;
  - **Graduated levels of risk for providers**, including fee-for-service with bonus, fee-for-service with upside only, fee-for-service with risk sharing – both upside and downside risk, and global capitation;
  - **Innovator programs** for provider ready to assume more risk;
  - **Medicaid quality program** that aligns with and qualifies for Medicare programming incentives;
  - **Input from providers** in the form of steering committees and/or clinical advisory groups; and
  - **Clear delineation of State Value-Based Payment objectives** in MCO contracts.
- **Require Medicaid Managed Care Organizations (MCOs) to honor copayments for dual eligible beneficiaries in Advanced APMs.**
- **Encourage the streamlining and alignment of quality measures** when feasible to Medicare Quality Payment Program constructs and the Meaningful Measures Initiative.
- **Adopt uniform standards for Medicaid managed care** that create a third-party appeal process for providers, improve the prior authorization process, mandate timely data sharing, enforce contractual obligations and institute a centralized credentialing process.
- **Enable funding of inpatient substance use disorder (SUD) treatment**. The Medicaid Institutions for Mental Diseases (IMD) exclusion prohibits the use of federal Medicaid financing for care provided to most patients in mental health and substance use disorder residential treatment

facilities larger than 16 beds. With the opioid crisis, this funding is even more vital. Although not a comprehensive solution, we encourage CMS to consider excluding SUD from the definition of mental disease for the purposes of determining if a treatment facility is an IMD. This would enable states to draw down federal funds for SUD treatment provided in inpatient settings with more than 16 beds if less than 50 percent of patients had cooccurring mental illnesses that required an inpatient level of care.

TELEHEALTH AND BROADBAND SUPPORT

Telehealth is a vital service delivery modality that enables access to services for patients with distance or transportation barriers, mobility issues and/or provider shortages. At UPH, telehealth visits are up 41% compared to the same period last year, and 45% of telehealth visits are attributed to Medicare or Medicaid patients (although these patients comprise more than 60% of our payor mix). ***Regulatory barriers prevent further use of telehealth to enhance patient care, support the clinician-patient relationship, and facilitate individual preferences.*** We would recommend that CMS:

- **Examine the elimination of geographic restrictions imposed on originating sites**. This geographic limitation draws arbitrary service eligibility lines, which do not necessarily correlate to patient barriers to care but do restrict service delivery options and preferences and hamper population health initiatives. In particular CMS should
    - Advocate to Congress to outright eliminate geographic restrictions imposed by Section 1834(m);
    - Lift this rural limitation for providers participating in risk-bearing arrangements (i.e. participation in an Advanced Alternative Payment Model under the Quality Payment Program); and
    - Redefine originating sites to include patient homes, schools, long-term care hospitals, hospice centers, and employer work sites.
- **Revise the CMS telehealth regulatory approval process**. Currently regulatory approval process for Medicare reimbursement of telehealth is on a case-by-case basis, which results in a small percentage of services being reimbursed. We request that CMS reverse this process and instead have a presumption that Medicare-covered services are reimbursed when delivered via telehealth, unless a case-by-case exception prohibiting its use is in place.

HOSPITALS

Hospitals have been closing at an alarming rate and, for non-profit hospitals, operating margins have experienced a downward trend. We would request that CMS consider regulatory relief in the targeted areas below:

- **Exempt hospitals in a Medicare two-sided ACO from RAC audits.** This is an unnecessary expense for ACO Participants who are already trying to limit their Medicare spend.
- **Eliminate utilization review regulations around intensity of services and qualifying days for Medicare patients after meeting Admission criteria**. Since payment is based on DRGs, the scrutiny and regulations focused on appropriate documentation and coding are sufficient.

- **Reduce number of notifications during an inpatient stay of appeal rights through the Important Message from Medicare** to one notification, instead of two if the length of stay dictates per CMS regulations.
- **Limit validation surveys** performed by CMS after a survey by an accreditation organization, such as the Joint Commission or Det Norske Veritas (DNV), to ensure that the accreditation organization is doing its job. These surveys create additional burdens on providers and should instead target the initial survey documentation to minimize such burden.
- **Reform the Preadmission Screening and Resident Review (PASRR) process**. This federal requirement was put in place to help ensure that individuals are not inappropriately place in nursing homes for long term care. This requirement has resulted in unintended consequences including delays in PASRR approval as well as unrealistic conditions or recommendations for a patient's care. To promote timely placement and decrease avoidable days, we would recommend that CMS institute shorter timeframes for PASRR approvals, round-the-clock staffing (24-7) of PASRR approvals and expedited processes or exceptions for beneficiaries subject to 3-day SNF waivers.
- **Revise the local transportation safe harbor to the Anti-Kickback Statute to permit free or discounted ambulance-level transports for management of certain chronic conditions**. In 2017, the OIG included a local transportation safe harbor to exempt free or discounted local transportation from the statutory definition of remuneration. Ambulance-level transports were specifically excluded from the existing safe harbor. We urge CMS to consider permitting non-emergent ambulance transportation for purpose of obtaining medically necessary items and services to established patients (i.e., those with a scheduled appointment or previous appointment) within 50 miles of the rural provider (including CAHs). This would also allow bi-directional transportation (both to or from the healthcare provider where the patient is being transported).

CRITICAL ACCESS HOSPITALS (CAHs)

In response to a decade-long trend of rural hospital closures, Congress created the Critical Access Hospital (CAH) designation in 1997. The CAH designation is designed to reduce the financial vulnerability of rural hospitals and improve access to health care by keeping essential services in rural communities. CAHs represent nearly 30% of all hospitals. ***The following regulations are overly burdensome, not achievable, or cause unintended consequences to care in a rural setting and make it difficult for CAHs to participate in value-based arrangements with regional Prospective Payment System (PPS) hospitals and clinics.***

- **Remove leased space restrictions to allow mixed use** in support of efficient and enhanced healthcare access in rural communities. This policy limits the ability of CAHs to utilize their space on days, or times, when it is not being leased to a visiting provider. As a result, square footage in safety net facilities is not being maximized and CAHs have abandoned opportunities to expand access to additional services which would require more capital investment for underutilized space. This rule contradicts a tenet of the CMS Rural Health Council – "improving access to care for Americans living in rural settings." **More broadly, we would encourage CMS to expand**

revisions within the *Final Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities* to apply to CAHs.

- **Eliminate the 96-hour physician certification**. By requiring physicians to state that every admission is expected to be less than 96 hours, physicians may be forced to transfer patients who could be safely cared for in the CAH but are expected to need more than 96 hours.
- **Permanently remove the direct supervision requirement** for CAHs, along with small and rural hospitals. Direct supervision requires physicians or advanced practice providers (nurse practitioners or physician assistants) to be "immediately available" and "interruptible" to provide assistance and direction throughout the performance of a procedure. The individual providing supervision must be permitted to do so under state law, scope of practice regulations, and their hospital-granted privileges. In addition, the individual must have sufficient knowledge and training to be able "to furnish assistance and direction, not merely manage an emergency." Direct supervision is labor-intensive and pulls from scarce provider resources in rural areas.
- **Limit validation surveys** performed by CMS after a survey by an accreditation organization, such as the Joint Commission or Det Norske Veritas (DNV), to ensure that the accreditation organization is doing its job. These surveys create additional burdens on providers and should instead target the initial survey documentation to minimize such burden.
- **Reconsider elimination or relaxation of the 35-mile rule for cost-based reimbursement of EMS services**. This rule limits the ability of CAHs to cover the costs of EMS units as well as prohibits CAHs from assuming responsibility for EMS when desired.
- **Eliminate the requirement that outpatients are prohibited from using a hospital bed** and must use a gurney. Observation stays and certain procedures require some patients to stay overnight, but regulations dictate they not be cared for in a hospital bed.
- **Re-calibrate scoring of patient satisfaction surveys for low-volume hospitals** to reflect true quality outcomes and not low rate of survey returns. Due to the limited number of patients who complete the surveys, patient satisfaction scores for CAHs are often lower than hospitals with a large patient population and may erroneously lead the public to conclude that CAHs provide a poor patient experience.

PROFESSIONAL SERVICES

As we are transitioning to value, it is important to leverage scope of practice and enable a variety of healthcare providers to offer services. It is also vital that, when data is to be collected (such as in registries) and intended to inform healthcare decisions, collection efforts should apply equally to all providers to result in a comprehensive dataset. ***We encourage CMS to consider the following to enhance patient care, support the clinician-patient relationship and facilitate individual preferences***.

- **Promote further flexibility to care for individuals with diabetes**. First, podiatrists should be permitted to order diabetic shoes. Second, Hgb A1c should be able to be used as a diagnosis for diabetes when referring to diabetes education. Currently, referrals can only be made if there are two documented fasting blood sugars over 126.
- **Require IRIS program for immunization documentation**. When there is a statewide registry, it should be required and not voluntary for all authorized providers and sites of care, including

pharmacies, work sites, and care facilities. In the example of immunization reporting, voluntary participation results in incomplete information, the inability to accurately advise patients on immunization gaps in their care, and a risk for over immunization.

- **Recognize State laws to permit top of practice licensure**. As an integrated health system within a largely rural geography, advanced practice healthcare professionals are vital to provide access to high quality healthcare in our communities. We further encourage CMS to consider holistically revisiting CMS regulatory requirements that restrict State scope of practice laws. We urge that CMS's review to start with the following:
  - For skilled patients with Physical Therapy / Occupational Therapy / Speech Therapy orders, authorize Nurse Practitioners (NPs) and Physician Assistants (Pas) to sign orders.
  - For cardiac and pulmonary rehabilitation, authorize MPs and PAs to sign orders and individualized treatment plans.
  - For diabetes education (Medical Nutrition Therapy), authorize MPs and PAs to sign orders without physician co-signature.
  - For diabetic shoes, authorize NPs and PAs to sign orders.
  - For home care, authorize NPs and PAs to sign home care orders.
- **Permit nurses and licensed social workers to bill for Advanced Care Planning**. Presently both physicians and non-physician providers can bill for advance care planning, and the service is not limited to a particular specialty or to a particular site of service. We would suggest that other healthcare professionals may be involved in this conversation and should be reimbursed accordingly.

RURAL HEALTH CLINICS (RHCs)

Rural Health Clinics are needed in rural communities to ensure access to primary care through physicians as well as nurse practitioners and physician assistants. Ready access to physician services for preventive care as well as maintenance of chronic conditions cannot be understated. ***Current regulations hamper efforts by RHCs to become a hub, or one-stop shop, for ambulatory services and provide more comprehensive health care access as needed by their rural residents.*** We would recommend removing the following barriers to care:

- **Permit reimbursement for certified diabetic educators (CDEs)** as an RHC visit. While dieticians can be included on the cost reports, nurses who are CDEs cannot be included on the cost report.
- **Permit reimbursement for same day Annual Wellness Visits and medically necessary E&M visits.** RHCs are only reimbursed one per diem rate for this date of service in comparison to Medicare B providers being reimbursed for each provider service.
- **Loosen direct supervision rules.** RHCs are restricted to the type of services that can be provided in the absence of a provider being physically present in the office. Simple nurse visits for weights, blood pressure checks, etc. should be able to be provided without direct provider supervision and would be on par with clinics reimbursed under Medicare Part B.
- **Authorize telehealth reimbursement for Rural Health Clinic providers to offer remote service to their own patients.** While patients may travel to their RHC for a specialist telemedicine visit (i.e.

the RHC remotes to a distance specialist from their clinic), the RHC provider themselves cannot provide a home-based telemedicine visit.

- **Redefine primary care to include certain specialists**. Currently, at least 51% of services provided by RHCs must be at the hands of primary care providers. Typically, primary care is equated with primary care providers in general practice, family medicine, internal medicine, pediatric medicine or geriatric medicine and would also include nurse practitioners, physician assistants and clinical nurse specialists. For Medicare accountable care initiatives, patients are attributed to Accountable Care Organizations based on primary care services, which may include specialists other than primary care providers. Specialists who can get primary care alignment are cardiology, osteopathic manipulative medicine, neurology, obstetrics/gynecology, sports medicine, physical medicine and rehabilitation, psychiatry, geriatric psychiatry, pulmonology, nephrology, endocrinology, addiction medicine, hematology, hematology/oncology, preventive medicine, medical oncology, gynecology/oncology, and neuropsychiatry and have been identified by CMS. To enhance access to specialists and recognize that they are often acting in a primary care role, the definition of primary care services should be expanded to include services offered by this subgroup of specialists who are eligible for ACO primary care attribution. This RHC flexibility is particularly important for individuals with chronic and complex conditions who need more intense care coordination and management.

HOME HEALTH AGENCIES

Patient preference and value-based care delivery emphasize retaining beneficiaries in their homes when practicable. Home Health Agencies (HHAs) are a cornerstone in delivering this care. ***We encourage the following actions to support quality home-based care and remove administrative burden***:

- **Authorize Nurse Practitioners (NPs) and Physician Assistants (PAs) to sign home care orders**. Presently this is limited to physicians. Particularly in rural areas where NPs and PAs are the primary care workforce, this rule prevents these providers from following their patients. As a result, there are patients that may have never seen the physician that is expected to sign a plan of care for those patients. At the very least, we urge CMS to consider allowing NPs and PAs to give interim orders for medication changes and plan of care updates – this is currently allowed in hospice, but not in home health care.
- **Embed flexibility within Electronic Visit Verification (EVV).** We appreciate the delay of EVV until 2020 and would request that CMS adopt a pro-HHA approach by encouraging “open models” in states. This would allow each HHA to choose an individualized solution that meets their needs as well as minimum federal requirements. As an organization that has HHAs in several states, including border communities, it would allow us to choose one solution and minimize compliance efforts.
- **Reimburse home infusion supplies and pumps** when Medicare benefit covers the medication.
- **Permit the expanded use of telehealth in home health settings**.
- **Eliminate physician signature/date stamping requirements** for Medicare documentation and orders to permit electronically generated time stamps.

- **Defer to HHAs in a risk-bearing ACO to determine home health eligibility.** Currently, patient eligibility is dependent upon homebound status. This would allow HHAs in two-sided ACOs to determine whether the HHA can provide as appropriate and effective service that meets the current definition of reasonable and necessary.
- **Allow Occupational Therapy to be a qualifying skilled service** to independently meet eligibility requirements for admitting patients into the Medicare program. Like the prior bullet (home health eligibility), the effectiveness of this request could be demonstrated first by HHAs in a risk-bearing ACO.
- **Remove the Face-To-Face encounter requirement for patients with a qualifying inpatient stay.** This aligns to the Patient Driven Groupings Model (PDGM) to be implemented in 2020. Specifically, if the episode would be classified as an institutional referral source, the Face-To-Face encounter requirement would be removed; however, if the episode would be classified as a community referral source, the Face-To-Face encounter requirement would remain.
- **Expand the role of resident physicians.** We would suggest that residents, who are credentialed and licensed physicians as well as PECOS enrolled, should be treated as a physician in their ability to perform and sign Face-To-Face encounters and to otherwise refer, order and certify home care services. To otherwise limit these activities, significantly reduces access to home care for patients who receive their care from teaching institutions (often with a staffing ratio of 12-15 residents per one faculty physician). In this situation, it becomes nearly impossible for a faculty physician to perform necessary Face-To-Face encounters and review home health plans of care for the entire staff of resident physicians.
- **Recalibrate discipline actions for technical and/or single instance errors** in coordination with other healthcare service lines. Currently errors result in loss of payment for an entire episode of care or hospice length of stay.
- **Add flexibility to Durable Medical Equipment benefit:**
  - **Eliminate face-to-face requirement** to promote timely access;
  - **Remove health system DME operations from the competitive bidding process**;
  - **Re-evaluate circumstances requiring a Written Order prior to Delivery**; and
  - **Reduce administrative requirements**, such as date stamps and administrative elements unrelated to medical/clinical necessity.
- **Recognize efficient patient home health transitions between traditional Medicare and Medicare Advantage.** Presently, when a home health patient switches between Fee-for-Service Medicare and Medicare Advantage, the HHA must re-establish the patient's home health eligibility to continue home health services. To avoid gaps in service and reduce HHA administrative and clinical documentation burden, we recommend that home health eligibility should not be re-established – just as it would not be required for two consecutive episodes being billed to the same payer. At a minimum, we would request that a Face-To-Face encounter not be required for a home health patient who is changing between traditional Medicare and Medicare Advantage. The Face-To-Face encounter requirement is targeted because its sole purpose (to establish home care eligibility) is only retriggered due to a payer change, any scheduling delays result in delays in care, and it creates an unnecessary expense to Medicare. Because of the

structure of Home Health Prospective Payment System, we would alternatively recommend that the entire home care episode be paid by the payer verified at the beginning of the episode. In the event the patient changes between traditional Medicare and Medicare Advantage, the home care payment source would change at the beginning of the first episode FOLLOWING the change in coverage, but at the start of the month if this falls during an open home care episode.

- **Reevaluate CMS approaches to monitoring fraud and abuse.** UnityPoint at Home has HHAs in Illinois and is subject to the Home Health Review Choice Demonstration (CMS–10599). We are extremely disappointed that CMS has continued to pursue this overly broad demonstration that equally applies to HHAs regardless of their record on compliance issues. In the future, we encourage CMS to undertake one of the following more narrowly targeted regulatory approaches:
    1. Target high-risk counties within high-risk states.
    2. Allow HHAs that had successful compliance rates in an iteration or cycle to be exempt.
    3. Utilize PEPPER reports to identify utilization and billing patterns that indicate high potential for fraud, waste and abuse and implement monitoring programs for these HHAs versus casting a wide net creating unnecessary administrative burden on HHAs with no history or suspicion of inappropriate utilization or billing.

HOSPICE AGENCIES

Hospice is a program of care and support for people who are terminally ill and their families. To enable beneficiaries to have timely access to hospice services, we offer the following suggestions for regulatory relief:

- **Remove or extend the 5-day Notice of Election timely filling submission requirement.**
- **Eliminate Part D Pre-authorization for hospice** patients in relation to drugs received during hospice care.
- **Authorize Hospice room and board pass-through** for Medicaid patients in nursing facilities, removing Hospice Agencies as an intermediary in the billing process.
- **Replace the election statement addendum requirement.** This newly enacted rule requires "a written list and a rationale for the conditions, items, drugs or services that the hospice has determined to be unrelated to the terminal illness and related conditions." It will be challenging at best to develop a beneficiary-specific addendum within the timeframes contemplated and to keep this updated and appropriately distributed. As an alternative, we would recommend that documentation be included as an advanced beneficiary notice outside the election statement and that the documentation be general in nature but detail what is not covered under the hospice benefit – equipment, supplies and medications that are outside the hospice benefit, not medically necessary and subject to beneficiary financial responsibility. If this notice was general, instead of beneficiary specific, it could be a standardized CMS form and its standardized content would virtually eliminate time and effort for completion or updates and further cement CMS expectations.

PACE ORGANIZATIONS

Program of All-inclusive Care for the Elderly (PACE) provides comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. To assist with seamless administration of this program and encourage program awareness by beneficiaries, we encourage the following actions:

- **Continue progress toward implementing the PACE pilots** that would allow PACE organizations to serve new populations. The PACE Innovation Act (a) allows CMS to develop pilots using the PACE model to serve those under 55 years of age and those at risk of needing a nursing home, and (b) encourages CMS to allow operational flexibilities that would support adaptation of the PACE model for new populations and promote PACE growth, efficiency and innovation. In particular, the pilots rely on the waiver authorities of CMMI.
- **Require training for Medicaid Options Counselors on PACE.** PACE regulations have restrictions on marketing by PACE Organizations. To increase PACE awareness by beneficiaries, especially in PACE services areas, we would encourage CMS to require training for Options Counselors on this program.

We are pleased to provide input in response to this request for information and to offer suggestions to reduce administrative burden which impacts our integrated health system and the individuals and communities we serve. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government & External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

Sabra Rosener, JD
VP, Government & External Affairs