



Regulatory Relief Requests – July 2017

DRUG PRICES – Medicare and Medicaid

- **Direct negotiation on drug prices** by the federal government for Medicare (and states for Medicaid).
- Removing trade barriers to permit the **purchase of drugs from other countries**.
- **Key market-based solutions include:**
 - Provide resources to **speed up FDA approval** for 4,000-case backlog of **generic drug applications**, especially for expensive drugs without competition.
 - **Shorten** the 12-year **market exclusivity period** for costly biologic drugs.
 - **Oppose “pay for delay” settlements** to keep generic products off the market.
 - **Support drug product transparency** and disclosure of more drug cost information.

HEALTH INFORMATION AND CLAIMS DATA ACCESS

- **Access to substance abuse records by treating providers.**
- **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.”
- **Access to All-Payer administrative claims data.**

PHYSICIAN SELF-REFERRAL (Stark Law) UPDATES

- **New Stark law exception to accommodate innovative payment models.** This waiver would allow a Next Generation ACO or early adopter/innovator to experiment with innovative non-fee-for-service payment methodologies.

PROVIDER REIMBURSEMENT

- **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.
- **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.
 - **Rural Health Clinic Reimbursement**
 - **Permit reimbursement for certified diabetic educators (CDEs)** as a RHC visit. While dietitians 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 provider 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.

MEDICARE REFORM

- **Exemption from RAC Audits for Hospitals in a Medicare ACO** as 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.

MEDICAID REFORM

- **Encourage state-based strategies to align with MACRA goals.** Ideally, value-based payment models would 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.
- **Requiring Medicaid Managed Care Organizations (MCOs) to honor copayments for dual eligible beneficiaries in Advanced APMs.**

SMALL GROUP INSURANCE MARKET

- **Removal of restrictions and taxes that prevent small group employers from freely comparing and shopping their premiums.**

TELEHEALTH AND BROADBAND SUPPORT

- **Revise the CMS telehealth regulatory approval process.** The current regulatory approval process for Medicare reimbursement of telehealth is on a case-by-case basis. We request a presumption that Medicare-covered services are reimbursed when delivered via telehealth, unless a case-by-case exception prohibiting its use is in place.
- **Permit the use of telehealth in home health settings.**
- **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.

HOME HEALTH AGENCY REGULATIONS

- **Elimination of the Medicare Prior Authorization of Home Health Services Demonstration (CMS–10599).** While CMS has “paused” this demonstration we request that it be eliminated altogether or, in the alternative, more narrowly targeted to agencies with a record of compliance issues. Casting the demonstration to entire states was overly broad.
- **Authorize Nurse Practitioners and Physician Assistants to sign home care orders.** Presently this is limited to physicians and delays services in areas with provider shortages.
- **Reimburse home infusion supplies and pumps** when Medicare benefit covers the medication.
- **Remove the regulation for home bound status** for home health patients in a risk-bearing Medicare ACO.
- **Eliminate physician signature/date stamping requirements** for Medicare documentation and orders to permit electronically generated time stamps.
- **Eliminate physician recertification estimate and use information** for home care continuation.
- **Allow Occupational Therapy to be a qualifying skilled service** to independently meet eligibility requirements for admitting patients into the Medicare program.
- **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.

HOSPICE AGENCY REGULATIONS

- **Remove or extend the 5-day Notice of Election timely filing 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.
- **Authorize Nurse Practitioners and Physician Assistants to certify patients for Hospice.**
- **Update Local Coverage Determination standards** to reflect accurate disease progression data and current best practice.

PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) TREATMENT

- **Maintain the separate county benchmarks for PACE** in comparison to Medicare Advantage.

- **Continue progress toward implementing the PACE pilots** that would allow PACE organizations to serve new populations.
- **Issuance of an updated PACE final regulation by CMS (CMS-4168-P)**, with its potential to offer more operational flexibility to PACE. The last update to PACE regulations was in 2006. The comment period for the proposed rule ended October 14, 2016; however, final rules were not issued prior to the transition to the new Administration.

MANDATORY BUNDLES

- **Revise the Next Generation ACO exemption.** Currently, CMS has exempted NGACO beneficiaries from mandatory bundles; however, this only creates extra burden and effort for NGACO Participants (i.e. hospitals and providers) who must abide by two sets for processes for NGACO and non-NGACO beneficiaries.
- **Provide the same CMS program officer** for entities within the same integrated health system.
- **Obtain timely access to CMS data.** Bundle Participants should have access to data at least three months in advance of the project start date.