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To: Clients and Friends
From: John Gorman and Jean LeMasurier
Date: April 21, 2010
**Re: Gorman Health Group Summary of Final Rule:
CMS-4085-F – Policy and Technical Changes to the Medicare Advantage
and the Medicare Prescription Drug Benefit Program**

The final rule published on April 15, 2010 makes very few changes from the provisions in the October 22, 2009 proposed rule. Notable changes from the proposed rule include a modification of the out-of-pocket limit for PPOs; change to allow more flexibility to plans in the design of the quality improvement programs; modification of procedures in the RADV audit process; revision of the definition of materials classified as marketing materials; change in the MTM incurred cost threshold; elimination of the proposed criteria for designation of Part D protected classes to be consistent with the changes in PPACA; and clarification of the bases and processes for plan termination.

Full text of the rule is available at:
<http://edocket.access.gpo.gov/2010/pdf/2010-7966.pdf>

Medicare Advantage Requirements

Maximum Out of Pocket (MOOP) for Local MA Plans – The final rule adds a mandatory requirement that local Medicare Advantage (MA) plans must establish a maximum out of pocket (MOOP) for A and B services that is no greater than the annual limit set by CMS. CMS will continue to allow plans to establish a voluntary MOOP that is lower than the mandatory MOOP in exchange for more flexibility in cost sharing thresholds. The mandatory MOOP for PPOs would apply to in-network services and a higher catastrophic maximum would apply to both in and out-of-network providers, consistent with the limit for Regional PPO plans.

Quality Improvement Program – The final rule provides greater flexibility for plans to identify topics for the development of Chronic Care Improvement Programs (CCIPs) and quality improvement projects that will meet the needs of their patient populations than was included in the proposed rule.

Based on CMS analysis of data, CMS will annually inform MAOs of individual or general CCIP/QI processes and priorities. Under certain circumstances, some MA plans will conduct chronic care improvement programs and quality improvement projects that address populations and other requirements identified by CMS.

CMS intends to expand quality performance data. Thus the final rule includes a provision that MA plans are required to collect, analyze and report quality performance data identified by CMS that are of the same type of data that plans currently collect. There will be two opportunities for public comment on the new requirements.

The final rule narrows the scope of the quality review study (QRS) data disclosed to CMS from QIOs that was included in the proposed rule. In the final rule, QIOs will disclose QRS information related to MA organizations collected as part of the Reporting Hospital Quality Data for Annual Payment Update program following hospital review of the data. CMS will use this for specified purposes, e.g. evaluation of plan performance and beneficiary information.

Prior Notification for Out of Network Services – The final rule precludes PPOs, PFFS or MSA plans from reducing cost sharing when the out of network provider or enrollee voluntarily notifies the plan prior to provision of services.

Point of Service (POS) Option – The final rule provides that POS options must be offered as a mandatory or optional supplemental benefit. Only HMOs may offer a POS benefit. HMOs must report enrollee utilization data for both in network and out of network providers.

MA Payment – The minimum percentage increase does not take into account any adjustment for a year before 2004. This eliminates the 2 percent minimum update for all rate calculations except ESRD.

Risk Adjustment Data Validation (RADV) – The rule includes a new dispute and appeal rights process for risk adjustment. The final rule specifies the elements to be included in a RADV audit report and defines the compliance date for meeting medical record submission requirements as part of validation of risk adjustment data. The rule defines the “one best medical record” for purposes of a RADV audit. The rule allows attestations for medical records (other than inpatient medical records) but only for missing or illegible signatures or credentials. Attestations must use CMS forms and procedures.

The final rule eliminates the documentation dispute process included in the proposed rule and allows MAOs to appeal medical record review determinations made at the RADV IVC review level, provided all audit and appeals requirements were met. This appeal relates to medical record review related determinations whose outcome was determined by the existence or absence of an attestation. The appeal is conducted by a Hearing Officer whose report is binding unless the MAO requests review by the CMS Administrator.

MAOs are also allowed to appeal the RADV payment error calculation. The preamble clarifies that this appeal does not extend to the error calculation methodology which will be discussed in an annual notice process. The payment calculation error appeal includes a three-level administrative process.

Network Adequacy – CMS will use community patterns of care to evaluate provider networks including geographical distribution of providers, prevailing market conditions, rural or urban, and time and distance standards.

Service Area and Incarcerated Beneficiaries – Consistent with Part D, MA plans can exclude a jail or prison within its service area.

Intermediate Sanction and CMP –The final rule provides CMS the discretion to require plans under sanctions to hire an independent auditor to provide additional information on the deficiencies and likely recurrence. When an enrollment and marketing suspension has occurred, CMS has the discretion to offer a “test period” to allow CMS to determine if the deficiencies have been corrected.

The final rule includes technical changes in the Intermediate Sanction provisions and conforms the regulatory language to statutory language, e.g. a specification that suspension of payment applies to individuals enrolled after the date the Secretary notifies the organization of an Intermediate Sanction and clarification that suspension of marketing activities applies at the organization level and not the plan level.

Coverage Determinations – The rule adds a new provision to clarify the method for filing requests for standard organization determinations. The regulation requires MA organizations to accept a request orally or in writing, except for standard requests for payment which must be in writing (unless the MAOs voluntarily adopt a policy of accepting oral payment requests.)

Organization Determination and Notices – The rule clarifies that notices and appeal rights are required in all settings when a beneficiary’s treatment was discontinued and/or the previously approved course of treatment was discontinued or reduced. After a QIO decision that an enrollee may remain in a hospital, the rule would require the hospital (and not the MAO) to deliver the second Important Message of Non-coverage to the beneficiary upon actual discharge.

Representatives – Consistent with Part D, representatives are allowed to file grievances and appeals.

Visitor Traveler Benefit – The regulation amends the current policy to require plans to furnish all plan covered services including mandatory and optional supplemental benefits at in-network cost sharing levels.

MSAs - All beneficiaries who enroll in a MSA plan after January 1 pay pro-rated deductibles.

Parts C and D Requirements

Applications – CMS will not accept applications from organizations that do not submit a timely Notice of Intent (NOI) to apply. The final rule clarifies that failure to submit an application after submitting a NOI will not result in any compliance consequences.

Applications must be complete in order to be considered and to be approved must meet “all” (and not “substantially all”) requirements. Supplemental information cannot be submitted after the notice of intent to deny 10 day grace period or during an appeal. CMS will not allow a change in service area during this grace period. CMS may deny an application from an organization that fails during the previous 14 months to comply with Part C and D requirements or a corrective action plan

The rule includes a technical amendment to clarify that appeal rights for initial applications involve the right to a hearing (rather than right to reconsideration).

Bids and Premiums – Benefit packages and plan costs submitted with bids must reflect meaningful differences from other plans of its type with respect to premiums, benefits, cost sharing or formulary structures. The rule changes the transition period from 3 years to 2 years for a sponsor with recent acquisitions or mergers to ensure substantially different benefit designs. MA plans are required to submit an actuarial certification with bids consistent with the requirement for Part D plans.

Discriminatory Cost Sharing - Cost sharing for A and B services cannot exceed levels annually determined by CMS to be discriminatory. In the preamble, CMS states it will initially focus on service categories used in prior years (inpatient, SNF, home health, Part B drugs, and DME). The annual cost sharing limits will distinguish between plans that adopt the higher mandatory MOOP and the lower voluntary MOOP. In addition, CMS will implement the new PPACA law which limits cost sharing for chemotherapy administration services, renal dialysis services and skilled nursing care to FFS levels.

Part D tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. Prior year bids; types of cost sharing and other factors, e.g. number of Part D tiers will be used to determine cost sharing outliers.

Compliance – To assure effective compliance programs, the regulations strengthen the seven core elements of a compliance plan by adding increased specificity to demonstrate effective operation of the compliance program.

Key among these is the new requirement for the compliance officer and the compliance committee to provide periodic reports directly to the Board of

Directors and for the Board of Directors to exercise reasonable oversight on the implementation and operation of the compliance program.

The rule specifies that the Compliance Officer must be an employee of the MA Organization, parent company or a corporate affiliate. Downstream entities that have met FFS FWA certification requirements are deemed to have met the FWA training and educational requirements.

The General Contract provisions also provide that a plan may be determined to be out of compliance for failure to meet performance standards including an organization being scored as an outlier relative to the performance of other MA organizations.

Data Validation – Plans must conduct an annual validation of data used for Part C and Part D reporting through an independent audit. In the preamble to the final rule, CMS noted that they have recently reduced the number and frequency of Part C and D measures to be reported, thus reducing the burden of the data validation requirement.

Corrective Action Process (CAP) and Contract Terminations – CMS will no longer require the submission of CAPs for CMS approval before implementation. CMS will provide an opportunity of at least 30 calendar days to develop and implement a CAP. CMS will use an outcome oriented approach to review the effect of the CAP although some CAPs may require longer periods for correction due to the complexity of technology or other technical problems.

Except for cases where enrollee health is in jeopardy, the CAP process will occur before CMS sends a notice of termination or non-renewal. Consequently, this will apply to any deficiency finding that could result in termination or non-renewal.

CMS may require plans to disclose to enrollees and potential enrollees the organization's performance and contract compliance deficiencies in a manner specified by CMS.

The regulation clarifies procedures regarding hearings to assure that the request is sent to the appropriate CMS officials. The notice of contract determination or intermediate sanction will specify the process and the request for a hearing must be filed within 15 days after receipt of the notice and the hearing within 30 calendar days of the notice.

Formal discovery is eliminated and alternate procedures are added, including revised procedures to request a review by the Administrator. The regulation allows CMS and the plan to request an extension of the hearing date.

Burden of Proof – CMS is deleting the “substantial compliance” standard of review for contract determinations and intermediate sanctions. The regulation also removes the “earliest of” date because it creates unworkable timeframes for an organization to demonstrate it has met CMS standards.

It clarifies the standard of proof to include “preponderance of evidence”; specifies different standards for Part C or D contract application qualifications; those involving termination or non-renewal; and intermediate sanctions.

The regulation changes the deadline for notice of a failure to qualify for a contract to September 1 (from July 15).

The rule amends procedures for expedited contract terminations that impose imminent or serious risk to health to assure that CMS has the authority to terminate a plan experiencing severe financial difficulty, fails to make services available risking health or when there is credible evidence the organization committed or participated in false, fraudulent, or abusive activities.

Deeming – The regulation clarifies the list of deemable requirements and deletes the authority to deem FWA. The regulation clarifies that CMS retains enforcement and other oversight authority over organizations that are deemed. While the regulations address Part D, there is currently no approved Part D deeming program.

Non-Renewal Notification – The rule changes the 60-day notification of beneficiaries to “at least 90 days” in advance by mail or outbound calls. The rule allows plans to provide a written list of all MA, MA-PD and PDP options or to make outbound calls to all affected enrollees with information and resources on how to identify the plans. The rule removes the requirement for non-renewing plans (in voluntary nonrenewal situations) and CMS to publish a notice in one or more newspapers concerning the impending non-renewal.

Termination of Contract – The rule adds continuous low enrollment as a ground for nonrenewal of a MA or PDP contract.

The final rule modifies the language on the bases for termination and adds two new circumstances where CMS may impose a termination: (1) failure to comply with the regulatory requirements and (2) failure to meet performance standards (e.g. outlier analysis).

The regulation extends the two year ban on the licensed legal entity on entering into new contracts after a termination by mutual consent.

Involuntary Disenrollment for Nonpayment of Premium –The rule changes the Part C and D provisions to provide a grace period of at least 2 months for beneficiaries to pay past due premiums in full. The grace period begins on the later of the first day of the month for which the premium is unpaid or the first day of the month when premium payment is requested. The rule clarifies how this policy will work for visitor/traveler benefits.

Marketing – The rule includes a definition of communication materials to current members that are not considered marketing materials, e.g. materials about claims processing and other operational activities and ad hoc customized or situational enrollee communications. CMS reserves the right to review these materials separately from marketing materials.

The rule clarifies that materials about “membership activities”, e.g. membership rules and procedures, and EOB templates are considered marketing materials.

Model Notices – The final rule requires Part C and Part D plan sponsors to use standardized marketing material language and formats without modification in every instance it is provided.

Consumer Surveys – MA coordinated care plans, cost contractors and Part D plans with 600 or more members in July of the prior year must contract with approved CAHPS survey vendors and conduct and submit data according to CMS specifications. Beginning in 2011, plans would pay for the surveys.

Privacy and Security – The rule strengthens current requirements for Part C and Part D plans and extends the term “facilities” to the sponsor’s computer and electronic systems, including information generated by downstream and related entities.

COB – The regulation codifies current policy that Part C and Part D plan sponsors must report other creditable coverage information (new or changes) to the COB contractor that is inconsistent with existing information on the COB file. The final rule establishes a 3 year limit on Part D COB from the date the prescription was filled.

Part D

LIS Eligibility –The rule amends the length of time an individual is re-deemed eligible for the full low income subsidy to conform with manual guidance, e.g. if the individual is deemed between July 1 and December 31 of a calendar year they will be deemed subsidy eligible for the remainder of the calendar year and the next calendar year.

LIS Enrollment and SEP– The rule codifies the facilitated enrollment policy for LIS beneficiaries who are not full subsidy eligible to be consistent with the process for full subsidy duals. The rule also extends the SEP for full benefit duals to all LIS-eligible beneficiaries.

LIS Retirees in an Employer RDS Plan – After beneficiary notice, CMS automatically enrolls full benefit duals that are currently in an employer plan receiving the RDS subsidy in a Part D plan with an option to decline that enrollment before the enrollment is effectuated.

PDE Reporting – The rule provides authority for collection of all elements unrelated to payment included in all drug claims (e.g. point of sale rebates, vaccine administration, prescription origin code) beyond the 37 elements currently reported. The new elements would be released under the same process as the payment elements (e.g. minimum necessary, encryption, aggregation of costs). The final rule permits disclosure of unencrypted data to HHS grantees.

Access Standards – The regulation clarifies that the access standards are determined at the “plan sponsor” level and not the plan as erroneously included in the current regulation.

Formulary and Transition Policy – The regulation clarifies the 90 day transition process for enrollees who are on drugs not on formulary, e.g. new enrollees or individuals that switch from one plan to another or current enrollees remaining in the plan who are affected by formulary changes from one contract year to another.

The rule clarifies that the transition policy applies to non-formulary drugs as well as drugs that require prior authorization or step therapy. Non-compliance will be considered discouraging enrollment or re-enrollment. The rule codifies policy for a one-time temporary supply of non-formulary drugs in outpatient settings of at least 30 days, unless written for fewer than 30 days in which case multiple fills up to 30 days must be allowed.

The rule allows a temporary fill for new enrollees in a LTC facility for non-formulary drugs for up to 93 days in 31 day increments with refills unless a lesser amount is prescribed.

The regulation specifies the process to notify beneficiaries of the transition process, including use of first class mail within 3 business days of adjudication of the temporary fill and includes a requirement for plans to make reasonable efforts to notify prescribers.

Protected Classes – The final rule codifies the 6 protected classes. The final rule retains two exceptions to the inclusion of all drugs – drug products determined to be therapeutic equivalents under the FDA’s Orange Book; and edits that limit the quantity of drugs due to safety. Other exceptions to permit Part D sponsors to exclude or limit drugs in the protected classes or to add new protected classes will be made through notice and rulemaking. Since PPACA deleted the two criteria included in MIPPA to identify protected classes, the final rule deletes the provisions in the proposed rule defining the MIPPA criteria.

P & T Committee and UM – The proposed rule will change the current policy which allows the plan and not the P&T committee to establish UM criteria after the P&T committee reviewed the appropriateness of the plan policies that guide UM.

Under the final rule, P&T committees would be required to review and approve all clinical PA criteria, step therapy protocols and quantity limit restrictions for each Part D drug.

MTMPs – The regulation codifies the changes included in the 2010 Call Letter e.g. requiring opt out enrollment methods, targeting of beneficiaries at least quarterly, establishing a minimum level of MTM services for the beneficiary and prescriber. The regulation specifies that the maximum number of multiple chronic diseases for targeted enrollment be no more than three and that eight Part D drugs be the maximum number required for targeted enrollment. Beneficiary interventions cannot be only passive and must include an annual comprehensive medication review conducted in person (except LTC). The final rule adopts a \$3,000 incurred cost threshold for targeting beneficiaries which is indexed by the annual increase in Part D costs (rather than the Initial Coverage Limit included in the proposed rule).

Gross Covered Prescription Drug Costs – The rule modifies the definition to read “share of actual costs” (rather than share of negotiated prices). This is a technical change to assure that the definition includes costs for out of network pharmacies which are typically usual and customary prices.

Generic Equivalent Disclosure – The regulation waives long term network pharmacies from the requirement to disclose generic equivalent information since the current policy which uses the EOB is operationally unworkable.

Claims Adjudication – The rule requires that effective January 1, 2011 plans contractually require network pharmacies to submit claims electronically to the Part D sponsor or intermediary unless a beneficiary requests otherwise (e.g. lower cash price). The rule codifies current policy that plan sponsors use HIPAA standard electronic transactions. Plan sponsors and their intermediaries are required to establish and use unique RxBIN or RxBIN/RxPCN combinations to identify Medicare Part D member claims as well as to assign unique RxID identifiers to individual Part D beneficiaries effective January 1, 2012.

Retroactive Claims and COB – Plans must have a process to account for retroactive claims adjustments, refunds and over payment recoveries. The rule retains the current policy that plan sponsors must make adjustments and refunds involving pharmacies and beneficiaries within 45 days of receipt of information necessitating the adjustment. COB must be completed within 3 years of the fill date (currently no deadline).

Coverage Determinations – The rule adds a new provision to clarify the method for filing requests for standard organization determinations. The regulation requires Part D plan sponsors to accept a request orally and in writing, except for standard requests for payment which must be in writing (unless the plan voluntarily adopts a policy of accepting oral payment requests.) Plans must document oral requests.

In addition, the regulation modifies the timeframe for a Part D plan to notify the enrollee of a standard payment determination. Instead of the current 72 hours notification after receipt and payment within 30 days, the final rule would require sponsors to process payment requests and notify beneficiaries of the decision no later than 14 calendar days after receipt and make full or partial payment in the same time period (no later than 14 calendar days after receipt).

Plan sponsors must send written notices of fully favorable decisions to enrollees that explain conditions of approval in an understandable manner. As an option, plans can provide an initial notice orally followed by a written notice in 3 calendar days.

The regulation codifies a requirement that plan sponsors issue adverse standard and adverse expedited coverage determination decisions using CMS approved language and forms.

Absence from the Service Area – The rule allows beneficiaries to be out of the service area for 12 months before mandatory disenrollment.

Enrollment by SPAPs– The rule prohibits mass enrollment of by SPAPs mid-year. This prohibition will prevent beneficiary disruptions and financial disparities for plan bids.

Novation Agreements – The regulation clarifies that novations are approved only when the sponsor's entire line of PDP business is included (i.e. all contracts held by the legal entity).

Uniform Benefits – The rule clarifies the current regulation to more clearly specify that Part D plan sponsors apply uniform premiums and cost sharing to each enrollee within the plan's service area.

Cost Contracts

Marketing and Cost Contracts – MA marketing requirements are extended to 1876 cost contracts with HMOs and CMPs.

Nonrenewal of Cost Contracts – Consistent with MA, CMS will provide written notice of appeal rights to a cost HMO or CMP when a contract is terminated.

Intermediate Sanctions and CMPs for Cost Plans – MA intermediate sanctions and CMPs are extended to cost contracts. However, the amount of CMPs is governed by section 1876(i)(6)(B) and (C).

Apportionment of Administrative and General Costs – The rule requires the HMOs and CMPs to document personnel costs for each administrative task and the rate of pay assuring that skill level matches task. The rule identifies items that must be excluded from administrative costs e.g. donations, fines and penalties, lobbying activities, entertainment.

HCPPs –The rule includes a technical correction to extend the appeals procedures to Comprehensive Outpatient Rehabilitation Facility services.

For specific questions, contact Gorman Health Group at 202-364-8283 or at ghg@gormanhealthgroup.com.