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To: Clients and Friends
From: John Gorman and Jean LeMasurier
Date: March 31, 2009
Re: Gorman Health Group 2010 Final Call Letter Summary

On March 30, 2009 CMS issued the Final Call Letter for 2010. The Final Call Letter summarizes legislative and operational changes to Medicare Advantage, Part D, and cost plan programs that will apply in 2010. Plan Sponsors will face considerable challenges in meeting new and more stringent requirements that are intended to increase program transparency, reduce discriminatory pricing, facilitate informed beneficiary choice of plans and increase plan accountability.

The Final Call letter signals additional CMS oversight and audits that will apply in 2010 with appropriate corrective action as necessary. Further requirements are under consideration for future rulemaking. The Final Call Letter also changes several provisions in the Draft Call Letter to reduce the administrative burden on plans.

Changes from the February 23, 2009 Draft Call Letter

- **Medical Loss Ratios (MLR)** - CMS asked for comments on calculating Medical Loss Ratios for potential public release. The final Call Letter does not include a requirement for public release of MLRs. Given the complexity of this issue, CMS will evaluate methodologies for possible future implementation.
- **Multiple and Low Enrollment Plans** – In the Draft Call Letter CMS encouraged MA Organizations to eliminate plans with low enrollment and duplicative plan designs and asked for comments on whether regulations should be issued to limit benefit designs (e.g. two) in a service area. The Final Call Letter states that it is CMS' expectation that MA Organizations will offer no more than three distinguishable benefit plans in a market area. CMS will consider a future regulation to limit plans to no more than a specific number of benefit designs and require consolidation of plans with low enrollment.

- **Discriminatory Pricing** – CMS asked for comments on three criteria in the Draft Call Letter that will guide their review of plan benefit packages to determine if pricing is discriminatory and whether regulations should be adopted to mandate an Out-of-Pocket cost sharing maximum. The final Call Letter keeps the three criteria included in the Draft Call Letter and does not address whether future regulations will be considered for a mandatory Out-of-Pocket Maximum.
- **Transparency of Benefit Plan Designs** – CMS asked for suggestions to increase the transparency of benefit plan designs (e.g. improved Part D labeling). The Final Call Letter keeps the program improvements that were outlined in the draft Call Letter (e.g. use of CMS gap coverage level descriptions) and clarifies that plans should use their unique denominators and determine separate levels for generic and brand drugs covered in the gap.
- **Data Auditing** – In the Draft Call Letter, CMS introduced a new requirement that plan sponsors must conduct a comprehensive audit of all main performance measures that plans submit to CMS. In the Final Call Letter CMS changes the data validation audit requirement to a phased in audit. For 2010 plans must conduct a data validation audit on the following measures:
 - **Part C** – benefit utilization, grievances, organization determinations/redeterminations, agent compensation structures
 - **Part D** – grievances, exceptions and appeals, drug benefit analyses

In 2009 CMS will conduct a pilot study with a sample of plan sponsors on the data validation specifications and upon completion will offer a two week comment period on the approach and specifications for the data audit validation. The Final Call letter provides other clarification on the implementation of the audit including the requirement that plans use external auditors to conduct that validation.

- **Mandatory Use of the On Line Enrollment Center (OEC)** – The Final Call Letter clarifies that SNPs and Religious Fraternal Benefit plans have the option to use the OEC provided they obtain the additional eligibility information that is not collected by the OEC. MSAs, 800-series Employer Group Plans and cost plans may not use the OEC for processing enrollments.
- **Including the Evidence of Coverage (EOC) and Formulary in Case Files-** In the Draft Call Letter, CMS required that all plan sponsors include complete copies of the EOC and Formulary on a CD for every case file that is sent to an Independent Review Entity (IRE). In the Final Call Letter, for 2010 CMS will keep the current policy that “strongly recommends” that plans submit complete copies of the EOC and formulary to the IRE. CMS indicates that failure to submit complete documentation could result in unfavorable appeals decisions.
- **Transitioning C-SNP Enrollees** – In the Final Call Letter, CMS clarifies its policy regarding plans that non-renew in 2010 or where beneficiaries do not have the SNP status of the 2010 plan. CMS will consider requests for passive enrollment when the beneficiary rights are protected.

- **DE SNPs**– The Final Call Letter requires finalized state Medicaid contracts to be submitted by October 1, 2009 and clarifies the definition of Medicaid subset.
- **LIS Reassignment** – CMS asked for comments on how to improve the reassignment process for LIS beneficiaries. CMS will keep the current processes and work with plans that lose LIS members to communicate with beneficiaries regarding their option to remain in their plan with additional premium liability.
- **PFFS Network Requirements** – CMS will issue guidance on network requirements and beneficiary transitions in advance of the deadline for the Notice of Intent to apply for 2011.
- **PFFS Prior Notification** – The Draft Call Letter requested comments on whether CMS should prohibit benefit structures that include lower cost sharing for prior notification. The Final Call Letter requires that differential cost sharing for voluntary prior notification must be included in the CMS approved bid and states that CMS is considering rule making prohibiting prior notification.
- **Bids for Plans in Puerto Rico** – Based on comments, CMS has revised its direction for bids from plans in Puerto Rico if Plantino benefit requirements are not final by the CMS bid deadline of June 1. The policy in the Final Call Letter will provide better financial protection for the plans.
- **PFFS Quality Reporting** – The Final Call Letter makes some technical clarifications for PFFS quality reporting.
- **Health Outcomes Survey** – The Final Call Letter clarifies that this reporting also applies to 1876 cost plans with open enrollment and MSA contracts.
- **Specialty Tier Threshold** – The Final Call Letter states that CMS will carefully evaluate sponsors' formularies to ensure that they do not discourage enrollment by certain classes of beneficiaries and will evaluate the need for further regulations in this area.
- **Formulary Exceptions Tier** – The Final Call Letter clarifies that CMS will allow a second less expensive level of cost sharing for formulary exceptions for generic drugs provided that the cost exception is associated with an existing formulary tier and is applied uniformly to all formulary exceptions for generic drugs. PBP submissions should include the more expensive cost sharing level of the two tiers and this amount will appear as the exceptions tier on marketing materials and the Prescription Drug Plan Finder.
- **Website Postings** – The Final Call Letter clarifies that website posting of “all” UM criteria includes UM applied to formulary drugs including quantity limit amount, quantity limit days supply, prior authorization criteria and step therapy criteria.

- **MTM Programs** – The Final Call Letter clarifies that plan sponsors can use the end of the year analysis that identifies participants who will continue to meet the eligibility criteria to auto enroll beneficiaries early in the next program year to provide less interruption. Part D plan sponsors may not include discriminatory exclusion criteria and CMS will monitor sponsors’ movement to more restrictive criteria. Further plan sponsors are encouraged to target additional diseases beyond the minimum requirements to improve outcomes. MTM services may be provided by pharmacists or other qualified providers.
- **Reference-Based Pricing** – The Final Call Letter clarifies that employer group plans may also not use reference based pricing.
- **Retroactive Enrollment of DEs** – The Final Call Letter clarifies that the single demonstration contractor will only handle claims for retroactive auto-enrollment periods and immediate need point-of-service claims for unenrolled LIS eligibles. Full benefit DEs will continue to be randomly assigned/facilitated for prospective periods to standard LIS PDPs.
- **Claims for Drugs from Excluded Providers** – CMS will develop a model letter for sponsors to use to notify the beneficiary of excluded providers and will work with the National Council for Prescription Drug Programs regarding electronic messaging to inform pharmacies.
- **Medicare Secondary Payer (MSP)** – The Final Call Letter provides clarification on new data elements related to Workers’ Compensation Medicare Set-aside Arrangements and Part D conditional payments. CMS plans rulemaking on options to handle retroactive payment recoveries.
- **E-Prescribing** - In the Draft Call Letter, CMS required the Prescription Origin Code on all PDEs. Based on industry comment, CMS is requiring the Prescription Origin Code only on PDEs for new prescriptions submitted in Standard format. The code will remain optional for refills submitted in the Standard format and all PDEs submitted in the Non-Standard Format.
- **Audit** – The Final Call Letter clarifies that CMS intends to assess the effectiveness of MAO and Part D sponsors’ internal compliance programs including internal monitoring and auditing.

Key Programmatic Changes for 2010 Retained in the Final Call Letter

- **MIPPA changes** – The law made substantial changes to the program structure for SNPs, PFFS and MSA plans; included new cost sharing protections for dual eligible beneficiaries and outpatient mental health services; standardized plan names in marketing and added new prompt payment requirements for Part D plans.
- **New operational requirements** – MA and Part D plans must audit performance data submitted to CMS; face new scrutiny over benefit designs that are potentially discriminatory; accept on-line enrollments; meet new performance standards for complaint resolution; assure that Part D drugs have FDA approval; meet new reporting requirements including enhanced electronic prescribing codes, and meet new marketing requirements (including a clarification that referral fees must be treated as part of compensation).

Part D plans must extend transition requirement when they change utilization management review of formulary drugs year to year and use CMS thresholds to describe coverage in the gap. PFFS plans face enhanced standards for voluntary prior notification programs.

- **New or revamped programs** – MA plans can offer a limited preventive services incentive program and a Medicare specific OTC benefit; SNP plans can offer selected multi-condition plans; Part D plans must enhance and expand their Medication Therapy Management programs and Quality Assurance programs; and plans must modify their beneficiary COB survey procedures.
- **Compliance** – The Call Letter sends out a clear message that CMS will take strong enforcement action against plans that circumvent Medicare rules, particularly in the marketing area. CMS will continue enhanced surveillance of plan marketing activities and increase resources to monitor marketing activities in high risk geographic areas and plans.

Based on concerns about non-compliance in some plans, CMS will conduct focused audits on C-SNP eligibility verification processes. CMS is also tightening up the contracting process by enforcing timelines, enhancing oversight of bids, formulary and Utilization Management submissions, and emphasizing their willingness to take compliance action for plans that do not meet regulatory requirements.

The CMS 2010 Call Letter can be found at:

www.gormanhealthgroup.com/download/CMS2010CallLetter.pdf

Summary of Final Call Letter Provisions

- **Contracting Process** – CMS is taking steps to tighten up the contracting process and enforce timelines and other requirements more stringently. Several of the changes for 2010 include:
 - Limiting MA Plans – Plans that are substantially duplicative in terms of cost sharing, provider networks and benefit designs must be eliminated and low enrollment plans should be consolidated
 - Part D Bids – CMS will consider the completeness and accuracy of the submission as a factor in meeting the submission deadline
 - Bids – MA and PDP plans that request corrections after bids are submitted will receive a corrective action warning letter. Further once a bid is approved it cannot be altered including changes to exclude referral and/or prior authorization requirements.
 - Part D Applications – CMS will deny applications with blank documents or blank spreadsheets
 - Part D Formulary Submissions – CMS will not accept formularies that use last year's Formulary Reference File, that include only one drug in the majority of categories and classes and that are outliers in terms of the number of drugs on the formulary (significantly lower than all other plans). As part of the bid, this will be not considered timely and there will be no contract and no appeal. Further contracts not linked to a timely formulary will be considered not timely and may be non-renewed

- **Cost Sharing** – The Call Letter identifies three criteria where coinsurance will not be considered discriminatory: 1) plan has an overall out of pocket (OOP) maximum of \$3,400, 2) the coinsurance for renal dialysis, Part B drugs, psychiatric hospitalization and skilled nursing facility services does not exceed coinsurance in original Medicare and 3) the plan does not exclude any Part A/B service for the OOP maximum.

- **On-line Enrollments** – MA plans (other than SNPs, employer plans, and cost plans) and PDPs must accept on-line enrollments through the online enrollment center and can no longer opt out. Plans must download pending enrollments at least once every business day.

- **Audited Data** – All MA and PDPs must audit C and D data reported to CMS for CY 2010 using a CMS sampling methodology and CMS technical specifications. For 2010 the following measures must be audited by plans using external auditors to conduct the validation:
 - **Part C** – benefit utilization, grievances, organization determinations/redeterminations, agent compensation structures
 - **Part D** – grievances, exceptions and appeals, drug benefit analyses

In 2009 CMS will conduct a pilot study with a sample of plan sponsors on the data validation specifications and upon completion will offer a two week comment period on the approach and specifications for the data audit validation. Organizations must report overall results of their audit and any measures with “not pass”. Corrective actions will apply for plan failure to submit data, follow technical specifications, or to pass.

- **Grievances and Appeals** – MA and PDPs strongly recommends that complete EOC and formularies on a CD with case files submitted to the Independent Review Entity.
- **Cost Sharing for Duals Eligibles in MA Plans** – Plans must implement the new MIPPA and regulatory requirements to limit cost sharing for all dual enrollees in MA and SNP plans to Medicaid amounts, modify provider contracts, and educate providers.
- **SNPs** – SNPs must meet a number of new MIPPA and regulatory requirements including initial and annual assessments, use of interdisciplinary teams, expanded models of care requirements, and care management requirements.
- **SNP Quality Improvement (QI) and Chronic Care Improvement Programs (CCIP)** – CMS recommends that SNPs incorporate one or more of the 13 components of their models of care into their CCIP and/or QIP as a consolidated activity to evaluate their care management model. Specific examples are included in the Call Letter. In 2009 CMS will contract with an entity with quality improvement expertise to assist SNPs develop their CCIP and QIP activities.
- **Institutional SNPs (I-SNPs)** – Beginning January 1, 2010, I-SNPs must use a state tool to assess the level of care (LOC) of beneficiaries who reside in the community. CMS will monitor I-SNPs to assure they are using the state appropriate tool, which will be different for each state. Additionally, plans must use an independent party which may not be an employee to conduct the assessments and may not pay a bonus or differential payment for qualifying members of the SNP. MAOs must use individuals or parties with professional credentials to administer the LOC assessment or contract with the entity that performs the assessment for the state.
- **Dual SNPs** – Under MIPPA, new dual SNPs or current SNPs that are expanding their service area must have a contract with its respective state Medicaid agency in the 2010 contract year. These contracts are due October 1, 2009. CMS is seeking a contract to assist states with Dual SNP contract related issues in 2009.
- **Chronic Care SNPs (C-SNPs) Targeting More Than One Condition** - MIPPA requires C-SNPs to meet specifically designated chronic conditions to be eligible for a C-SNP contract as of January 1, 2010. A CMS convened panel identified 15 single condition severe or disabling chronic conditions for 2010 contract eligibility and required that C-SNPs have specially designed benefit designs to meet the specific needs of their enrollees.

The Call Letter supersedes previous guidance which precluded multiple condition C-SNPs by allowing certain chronic conditions that are commonly co-morbid and clinically linked under two scenarios:

- One of Five CMS-designated groupings: (1) diabetes mellitus and chronic heart failure; (2) chronic heart failure and cardiovascular disorders; (3) diabetes mellitus and cardiovascular disorders; (4) diabetes mellitus, chronic heart failure, and cardiovascular disorders; (5) stroke and cardiovascular disorders. Beneficiaries must have *at least one* of the qualifying conditions.
 - MAO developed multi-condition groupings of the 15 conditions selected by the panel. Beneficiaries must have *all* qualifying conditions in the combination.
- **C-SNP Eligibility Verification** – CMS plans to conduct focused audits in the next year to assure that plans are verifying that enrollees have the SNP condition for which their product is designed and that policies and operations are in compliance with CMS requirements.
 - **Transition of C-SNP Enrollees from 2009 Plans to 2010 Plans** - The Call Letter provides preliminary guidance on transition from a 2009 C-SNP to a 2010 C-SNP in the following scenarios:
 - A 2009 C-SNP continues as one of the 2010 SNP plans offered by the organization
 - A 2009 C-SNP targets more than one chronic condition, but for 2010 disaggregates into separate plans for each condition
 - A 2009 C-SNP covers a condition that is subsumed into a larger category or into one of the five commonly co-morbid and clinically linked groups in the 2010 plan

CMS will consider other proposals to passively enroll individuals in different plans in 2010 only if the targeted plan is appropriate for the individual, e.g. when a 2009 SNP will not be renewed in 2010 or when an enrolled individual does not have the condition of the 2010 SNP. Affected beneficiaries would have a SEP to choose a different plan.

- **MA Preventive Services Incentives** – A limited preventive services incentives program will be allowed for 2010 that must meet 16 criteria (including a requirement that the program cannot be used in pre-enrollment advertising, payment of incentives cannot be connected to a specific health outcome, incentives cannot be connected to specific providers, may not be cash/monetary rebates/gift cards, may not waive or lower copays, and must be of nominal value \$10 per item/\$50 aggregate).
- **Complaint Tracking Module** – MA and Part D plans must meet new case resolution time requirements beginning January 1, 2010 as follows: 95% resolution of Immediate Need complaints within 2 days; 95% resolution within 7 days for Urgent Need complaint and 95% resolution within 30 days for all other complaints.

- **Part C Supplemental Over the Counter (OTC) Benefits** – CMS has developed its own list of OTC categories (included in the Call Letter) that must be available at a wide variety of chains and stores using identical payment methods. Guidance has been expanded on catalogs, e.g. postal costs must be included as part of the benefit.
- **Outpatient Mental Health Cost-Sharing** – Beginning in CY2010, the MIPPA phase out of cost sharing for outpatient psychiatric services will begin with the coinsurance in original Medicare reduced to 45.2 percent.
- **Home Infusion Bundled Services** – For Part D home infusion services bundled under a Part C mandatory supplemental service in 2010 CMS will also waive the definition of a part D drug to improve the coordination of home infusion therapy between Part C and Part D provided there is \$0 cost sharing for the bundled service. Additional policy clarifications are provided, for example the bundle must also include the services and supplies associated with their infusion.
- **CAHPS and HOS Survey Administration** – MA and Part D plans will conduct the Consumer Assessment of Health Plans Survey (CAHPS) survey following the Health of Seniors (HOS) and Hospital CAHPS process. In late 2010, MA and PDPs plans select an approved vendor to administer the 2011 survey for which plans will begin to pay.
- **Quality Improvement Programs** – Effective in January 2010, as required in MIPPA, PFFS and MSA plans that meet eligibility requirements must implement on an annual basis quality improvement projects, chronic care improvement programs and participate in CMS and HHS quality improvement initiatives. Also PFFS and MSA plans must collect, analyze and report data to measure health outcomes and other indices of quality. For 2010, PFFS and MSA plans must report all administrative HEDIS measures based on claims data related to health outcomes and quality. While PFFS and MSA plans are required to report data from direct contract, deemed and non-contract providers, CMS indicates that they will not use the data from deemed and non-contract providers for evaluation or enforcement purposes since these data are only collected for one year.
- **PFFS Payment and Access Requirements** – CMS has received numerous complaints that PFFS plans are not paying deemed providers equivalent to FFS rates. In the Call Letter, CMS reminds PFFS plans of their responsibilities and its expectation that PFFS plans will cooperate with the new CMS contracted independent review entity for provider payment disputes.

The Call Letter provides additional requirements for PFFS voluntary prior notification programs when reduced cost sharing is offered, for example the PFFS plan must assure that the beneficiary knows they have access to medically necessary services without prior notification at a higher cost. Plans must also include the differential cost sharing in the bid.

As provided in MIPPA, PFFS plans that meet access requirements based on signed contracts for a particular category of provider must have contracts or agreements with a sufficient number to meet the access requirements for that category of provider effective January 1, 2010. For January 1, 2011, PFFS plans that operate in a “network area” and all employer group PFFS plans must have a contracted network that meets access requirements for all providers. CMS announced the “network areas” in the 45 day Advance Notice issued on February 20, 2009.

- **MSA Plans** – MSA plans must submit to CMS their proposed approach to provide cost and quality information.
- **Bonuses and Penalties** – MAOs must decide whether or not to pay the PQRI or e-prescribing incentive payments to contracted physicians (other than PFFS plans with deemed providers who must pay the bonus). MAOs must pay non-contracting eligible physicians and practitioners who have provided professional services to plan enrollees or met the e-prescribing standards the applicable bonuses during a reporting period. CMS will provide a file to MAOs of the PQRI and e-prescribing bonuses that will be due and payments for claims incurred in a given year are payable the following year in a lump sum. With regard to Hospital Quality Initiative penalties, the PC Group/Pricer already incorporates the correct payment amount, so additional MAO action is not necessary.
- **Special rule for Puerto Rico Plantino Bids** – If the Plantino benefit package for 2010 is not announced by May 1, 2009, MAOs should determine what mandatory supplemental bids to include in the bid and if necessary separately negotiate a supplemental premium with Puerto Rico outside the scope of the Medicare bid. Part D bids should only reflect basic benefits and should not include any Part D supplemental benefits that would be covered under a separate supplemental premium paid by the Commonwealth of Puerto Rico.
- **Cost Plans** – MIPPA extended the competition requirement until 2010. Beginning January 1, 2010 no cost plan can apply for a SAE mid-year.
- **PDE Submissions** – Beginning January 1, 2010, CMS is planning to reject PDE submissions with NDC codes that do not have FDA regulatory approval. CMS is requiring the Prescription Origin Code only on PDEs for new prescriptions submitted in Standard format. The code will remain optional for refills submitted in the Standard format and all PDEs submitted in the Non-Standard Format.
- **2010 Formulary Reference File (FRF)** – Moving to the RxNorm drug nomenclature in 2010 will result in deleting some duplicate or obsolete drug records that were included in the 2009 reference file. CMS has posted a FRF.
- **LTC Transition Notices** – Part D sponsors will have a new option to send the transition fill notices to network LTC pharmacies and have the pharmacy send notices to enrollees in lieu of sending notices directly to enrollees. In order to access this option, plans must document the LTC pharmacy willingness to be delegated the responsibility for transition notices; the plan must maintain electronic communication with the LTC pharmacy and the LTC pharmacy must

document that the notice is provided within 3 days. All of these conditions must be in place prior to the start of the plan year.

- **Transition Across Contract Years** – The Call Letter clarifies that transition requirements apply both to drugs that are removed from a sponsor’s formulary from one contract year to the next as well as to formulary drugs that remain on formulary but to which a new prior utilization or step therapy restriction is added from one contract year to the next.
- **UM Criteria** – For 2010, plans must flag new or modified UM criteria as part of their HPMS submission. CMS will be reviewing submissions to assure that P&T Committees have actually reviewed the criteria; that all FDA labeled indications are covered; that the first step is not limited to “off-label” drugs; that criteria are specific and readily understood by prescribers; and that criteria are not overly burdensome (e.g. require use of more than two formulary alternatives without support in the clinical literature). Criteria that are not submitted according to instructions will be rejected.
- **Website Posting** – Plans must post on their websites “all” UM criteria applied to formulary drugs including quantity limit amount, quantity limit days supply, prior authorization criteria and step therapy criteria.
- **PACE Plan Formularies** – If a PACE plan elects to use a formulary, it must meet all of the Part D formulary requirements.
- **Part D Benefit Information** – Effective in 2010, **pre-enrollment** materials that discuss Part D benefit coverage, e.g. the Summary of Benefits and the PBPs submitted to CMS must identify gap coverage for both generic and brand drugs using CMS defined thresholds:
 - All – 100%
 - Many – 65% - 99%
 - Some – 10% - 64%
 - Few – 1 - 9% and greater than 15 products
 - No Gap Coverage – 0% or 15 or fewer products
- **Medication Therapy Management (MTM)** – For 2010, CMS is establishing more specific requirements for MTM programs for all Part D plan sponsors (except PFFS plans) impacting enrollment, targeting, intervention and outcomes-reporting including:
 - Only use of an opt-out method of enrollment
 - Target beneficiaries at least quarterly with multiple chronic diseases (2 or 3) that include at least four of seven specified core chronic conditions
 - Target beneficiaries taking multiple (2 to 8) Part D drugs with costs that are projected to exceed a lowered threshold of \$3,000
 - Offer interventions for both beneficiaries and providers with an interactive annual comprehensive medication review, written plan and targeted quarterly medication reviews

- Report numbers of: comprehensive medication reviews, targeted reviews, and provider interventions as well as the change in therapy resulting from interventions

CMS has awarded a MTM monitoring contract through 2010 to evaluate MTM programs.

- **Elimination of Reference Based Pricing** – CMS will eliminate Reference Based Pricing used to promote generic drugs in 2010 due to difficulties in calculating projected out of pocket costs.
- **Formulary Exceptions Tier** – The Final Call Letter clarifies that CMS will allow a second less expensive level of cost sharing for formulary exceptions for generic drugs provided that the cost exception is associated with an existing formulary tier and is applied uniformly to all formulary exceptions for generic drugs. PBP submissions should include the more expensive cost sharing level of the two tiers as the exceptions tier and this amount will appear as the exceptions tier on marketing materials and the Prescription Drug Plan Finder.
- **Federal Disaster or Public Health Emergency** – Additional guidance is provided on procedures for emergencies, for example when plans may resume normal operations.
- **Retroactive Auto-Enrollment of DE** – Effective January 1, 2010 CMS will implement a demonstration to assign new full benefit dual eligible individuals with retroactive coverage to a single contractor for those retroactive periods.
- **Medicare Secondary Payer (MSP) Edits** – Part D plans must have the ability to participate in the new MMSEA mandatory reporting of beneficiaries who have coverage under group health plan (GHP) arrangements and who receive payments from non-GHP insurers including liability insurance (including self-insurances), no-fault insurance or workers compensation. Effective in 2010 Part D plans must have:
 - Ability to respond to new CMS notifications on MSP conditions
 - Prospective claims processing edits in place to capture new group and non-group MSP reporting.
- **COB Survey** – For 2010, CMS will revise the annual beneficiary survey process. Under the new approach, Part D sponsors will provide each beneficiary with payer information reflected in the COB file from CMS and ask the beneficiary to report only changes to the sponsor. If no changes are reported, plans can assume CMS information is correct.
- **COB User Fees** – CMS is decreasing the user fees for 2010 to \$1.89 per enrollee per year.
- **Drugs Prescribed by Excluded Providers** – If Part D plan sponsors identify situations where claims have been paid to excluded providers, they should notify the MEDICs and beneficiaries, however they do not need to reverse the claim or adjust PDE data.

- **Part D Reporting** – CMS expects to add the following *new* reporting sections: network pharmacy support of electronic prescribing; prompt payment to pharmacies; fraud, waste and abuse compliance programs; enrollment and employer/union-sponsored group health plan sponsors. *Changes* to existing reports will include: adding the new MTM data and streamlining grievance reporting.
- **Part D Quality Assurance (QA)** – New expectations for QA programs include:
 - Concurrent Drug Utilization Review (cDUR) – Detailed policies and procedures should explain cDUR checks, system logic, thresholds, and pharmacy messaging, including information on how these elements were developed and validated. Policies should also include information on pharmacy override use.
 - Retrospective Drug Utilization Reviews (rDUR) – Written policies should include objectives, claims data for review, evaluation periods and criteria and proposed interventions.
 - Medication Error Identification and Reduction (MEIR) – The internal MEIR process must be documented including the types of medication errors to be collected and sources of reported errors (e.g. beneficiaries and operational components). Periodic evaluations should be completed as part of an error reduction program and corrective actions should be initiated. Appropriate staff should be trained to identify potential reportable medication errors and to report to appropriate authorities (e.g. FDA, DEA) if necessary.
- **Prompt Payment** - Effective January 1, 2010, MIPPA prompt payment of retail pharmacy claims go into effect. Contracts with retail pharmacies LTC pharmacies, other providers and first tier and downstream entities must reflect the new timeframes.
- **Out of Network Pharmacy Payment** – CMS will not enforce the 72 hour deadline for determining payment for out of network payment requests. CMS is assessing other options, but in the interim effective January 1, 2009, plans must process and submit reimbursement or a denial letter within 14 calendar days after receipt of the request. If the plan sponsor notifies the beneficiary of a favorable determination within 72 hours, the sponsor has 30 days to mail the payment.
- **Auto-Enrollment Readiness Audits** – CMS will conduct audits (on –site or self-audit) of plans’ readiness to accept auto-enrolled dual eligibles in August or September 2009. The audits will focus on plans that are qualified for auto-enrollments for the first time, plans whose eligibility will expand to new regions, plans under a CAP or with performance problems. The audit will include 4Rx data, LIS matching, call center performance, beneficiary notifications, transition policy, point-of-sale claims adjudication, systems testing, and best available evidence.

- **Mid-Year Enrollment by State Pharmaceutical Assistance Programs (SPAP)** – CMS will monitor large mid-year enrollments from SPAPs which have disrupted Part D plan sponsor operations and budgets, and disrupted beneficiary care in the past. If problems occur, CMS may find that a SPAP has failed to meet the regulatory definition of an SPAP in the statute.
- **Electronic Prescribing** – Effective January 1, 2010 Part D plans must obtain the Prescription Origin Code via the NCPDP5.1 option field 419 DJ and report this on for new prescriptions in the standard format on their PDE submissions. Voluntary reporting can begin in 2009.
- **Employer-Union Direct PDP Contracts** – CMS will no longer approve terminations by mutual consent as a substitute for the prescribed non-renewal process.
- **Marketing Oversight** – CMS states will take very strong action against contractors and related third party entities that violate the marketing rules and guidelines. CMS has increased surveillance activities and issued over 40 compliance letters at the end of the Annual Election Period. Organizations that were outliers on marketing misrepresentation complaints were required to investigate and report their response to CMS on a monthly basis. CMS will continue similar surveillance efforts in the future and will focus increased resources on high risk geographic areas and organizations.
- **Payment of Agents and Referral Fees to Agents** – For 2009, CMS recommends that plans pay agents the renewal rate and then adjust the fee upward when CMS sends a report that they were entitled to an initial compensation amount for some beneficiaries.

CMS is clarifying policy that agent compensation policies and limitations apply to fees paid to agents for enrollment as well as fees paid for referrals. CMS equates these referral fees as “finder’s fees” that are specifically included in the definition of compensation included in the regulations. The Call Letter states that some entities have treated the referral fees as outside the compensation guidelines to circumvent the limits and that this practice must cease immediately.

- **Multiple Organization Marketing Pieces Created by Agents** – CMS will not review materials that are generic in nature and do not include specific plan benefits, cost-sharing or plan names.
- **Marketing - Standardization of Plan Name Type** – To meet the MIPPA requirement that MA and PDPs plans include their type in the plan name, CMS will auto-populate the plan type label at the end of each plan name in HPMS. The standardized terminology is included in the call letter. Plans must display the plan name and type in the same format on all marketing and advertising materials.

- **Marketing Materials** – Changes include:
 - Part D plan sponsors must update abridged and comprehensive printed formularies with any CMS approved non-maintenance formulary changes, e.g. through errata sheets
 - Part D plans can indicate OTC drugs for which they pay administrative costs in a new OTC section
 - Part D Sponsors are encouraged to indicate which network pharmacies support e-prescribing in their pharmacy directories
 - MA plans are encouraged to indicate which participating physicians or physician practices support e-prescribing
 - Part D plans must designate which tier is their “exceptions tier”, i.e. the tier where they adjudicate all formulary exceptions
 - Plans must notify beneficiaries when prescriptions are transferred from network retail pharmacies to network mail-order pharmacies
CMS will modify model materials to incorporate these changes.

- **New Model Evidence of Benefits** – CMS will issue additional guidance in the spring on the timing of implementing changes.

For questions related to specific elements of the CMS 2010 Call Letter, please contact Gorman Health Group at 202-264-8283 or via e-mail at ghg@gormanhealthgroup.com.