

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C1-22-06  
Baltimore, Maryland 21244-1850



**PROGRAM COMPLIANCE AND OVERSIGHT GROUP**

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May 17, 2010

**VIA FEDERAL EXPRESS DELIVERY**  
**E-MAIL [drnkhan@qualityhealthplans.com](mailto:drnkhan@qualityhealthplans.com)**  
**AND FACSIMILE (813) 961-3154**

Dr. Nazeer Khan  
Chief Executive Officer  
Quality Health Plans, Inc.  
4010 Gunn Highway, Ste 220  
Tampa, FL 33618  
Phone Number: 813-574-1640 Ext. 123

Re: Notice of Intent to Impose Intermediate Sanctions (Suspension of Enrollment and Marketing) – Medicare Advantage Organization Contact Number H2773, H5402 and Prescription Drug Plan Contact Number S8475

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Dear Dr. Khan:

Pursuant to 42 C.F.R. §422.756 and 42 C.F.R. §423.756, the Centers for Medicare & Medicaid Services (CMS) is hereby providing notice to Quality Health Plans, Inc. (QHP) of the intent to impose intermediate sanctions for contract numbers H2773, H5402 and S8475. These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries (42 C.F.R. §422.750(a)(1), 42 C.F.R. §423.750(a)(1)) and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. §422.750(a)(3), 42 C.F.R. §423.750(a)(3)). This determination to impose intermediate sanctions will be effective 15 calendar days after the date of this notice, or on June 2, 2010, and will remain in effect until CMS is satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur.

**Summary of Noncompliance**

QHP has demonstrated a persistent and substantial failure to comply with CMS' requirements for the proper administration of its Medicare Advantage Prescription Drug Plan (MA-PD) and Prescription Drug Plan (PDP) contracts. QHP's noncompliance has resulted in significant

administrative and contract management deficiencies in the areas related to billing procedures and practices; administration of QHP's formulary benefit; development and implementation of an adequate compliance plan; proper administration, management and oversight of QHP's pharmacy benefit manager (PBM); and compliance with appeals and grievance procedures. Based on the serious nature of these deficiencies and QHP's failure to correct many of these issues, CMS determined that intermediate sanctions in the areas of enrollment and marketing are necessary.

In September 2009 CMS began receiving numerous complaints from QHP enrollees who were concerned about high premium invoices that they received from QHP. After investigating the matter, QHP admitted that it had not sent bills for monthly premiums to a portion of its previous and current enrollees since January 2008. QHP informed CMS that beginning in August 2009 QHP billed enrollees for the total amount of monthly premiums due since January 2008. QHP sent premium invoices to 5,470 of its previous and current Prescription Drug Plan (PDP) enrollees and 398 of its previous and current Medicare Advantage-Prescription Drug (MA-PD) enrollees and requested that they pay the total amounts within 30 days. The majority of affected enrollees received premium invoices with individual totals of approximately \$330, while there were other enrollees who received invoices for as much as and in excess of \$1,000. At the time these invoices were sent to enrollees, QHP had approximately 5,100 PDP enrollees and 13,500 MA-PD enrollees.

At the same time that CMS received complaints regarding the high premiums, CMS also noticed that there were complaints from QHP enrollees who were being denied coverage for Part D prescription drugs. In order to ensure that these denials were not related to enrollees' inability to pay their total premiums, in December 2009 and January 2010, CMS asked QHP for documentation on denied claims for enrollees who received the premium invoices. Although CMS concluded that the denials for prescription drugs were not related to the premium issue, a review of the documentation led CMS to conclude that QHP was denying coverage for prescription drugs that were on its CMS approved formulary and conversely covering prescription drugs that are considered to be excluded drugs (such as drugs for sexual dysfunction).

In response to these areas of noncompliance, CMS decided to conduct an on-site audit of QHP to obtain additional information on the extent of the improper premiums invoices and the inappropriate denial of prescription drugs. The site visit was conducted from January 27- 29, 2010, at QHP's headquarters in Tampa, Florida (hereinafter "on-site audit"). CMS also sent an audit team to Envision, QHP's PBM subcontractor, in Twinsburg, Ohio. CMS' audit focused on QHP's billing practices, formulary administration, compliance plan, and appeals and grievances processes. Based on the information obtained by CMS during the site visit, CMS determined that QHP had failed to meet other compliance requirements in addition to the initial failure to bill premiums and inappropriate denial of prescription drugs.

### *Premium Billing*

According to 42.C.F.R. §422.262 (b)(1) and §423.293 (a)(1), MA-PD and PDP sponsors must charge enrollees a consolidated monthly MA premium or prescription drug (Part D) premium. Pursuant to 42 C.F.R. §422.262 (e) and §423.293(a)(2), MA-PD and PDP sponsors are required to permit payment of monthly premiums on a monthly basis. During the on-site audit, QHP assured CMS that it had corrected its billing errors and was currently billing premiums on a monthly basis. However, after reviewing documentation provided by QHP, CMS determined that QHP continued to fail to meet requirements to correctly issue monthly premium invoices. By the end of January 2010, QHP had sent only one additional premium invoice to enrollees and that notice, sent in November 2009, was an invoice for three months of premiums. QHP's conduct represents a significant incident of non-compliance. By not billing its enrollees their monthly premiums and then sending a request for immediate repayment of several months of unpaid premium, QHP did not meet the CMS regulatory requirement to permit its enrollees to pay their premiums on a monthly basis.

In addition to its failure to bill premiums, QHP also failed to offer enrollees the required repayment options to satisfy their premiums in arrears. In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, QHP is required to offer the enrollee the option of payment either by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and QHP. (See 42 C.F.R. §422.262(h) and §423.293(a)(4)). Instead the premium notices required enrollees to pay the entire lump sum within 30 days. Based on information obtained from CTM complaints, many enrollees feared that they would be disenrolled from QHP if they did not pay the entire amount within that timeframe afforded by QHP. Additionally, approximately seventy five percent (75%) of QHP's enrollees are Low Income Subsidy (LIS) members, which means they are receiving assistance for medications due to their financial status. In 2009 QHP's premiums rose substantially making it an above the benchmark plan. Due to the increase in premiums, many of the LIS members have expressed concerns with their inability to pay the unpaid premiums.

Pursuant to 42 C.F.R. §422.262(g) and §423.293(e), QHP must not bill any enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security check. Prior to the on-site audit, CMS discovered that several enrollees, who were sent an invoice for premiums, had elected to have their premiums withheld from their Social Security checks and therefore these enrollees were billed twice. During the on-site audit, CMS confirmed 38 enrollees, who were on premium withhold, were incorrectly billed twice for their premiums in violation of 42 C.F.R. §422.262(g) and §423.293(e).

### *Formulary Administration*

Pursuant to 42 C.F.R. §423.104(a), QHP must provide its enrollees with qualified prescription drug coverage. An MA-PD or PDP sponsor that uses a formulary under its qualified prescription drug coverage must meet certain requirements, including the requirement that the formulary be

reviewed and approved by CMS pursuant to 42 C.F.R. §423.120(b)(2)(iv). Administration of a formulary in a manner inconsistent from what was approved by CMS is in direct violation of CMS' requirements. During the on-site audit, CMS reviewed a sample of denied claims and confirmed that 46 enrollees were denied certain formulary Part D drugs, such as medications to treat Alzheimer's disease, cardiovascular disorders, and pain. QHP denied these Part D medications by coding them as non-formulary, when in fact these drugs were on the CMS approved formulary.

CMS also confirmed that QHP was covering excluded prescription drugs for members enrolled in QHP's Part D plan S8475-001. This specific plan does not provide for enhanced alternative coverage consistent with 42 C.F.R §423.104(f), which permits the coverage of drugs that are specifically excluded as Part D drugs. QHP has one plan under contract S8475 that did provide for enhanced alternative coverage, however, QHP did not explain this to their PBM subcontractor. Consequently, QHP's PBM subcontractor incorrectly covered excluded drugs for all QHP plans, including ones that did not provide for enhanced alternative coverage.

In addition, during the on-site audit, CMS found that QHP was incorrectly applying requirements with respect to Part D drugs that fall within the six protected classes. Pursuant to 42 C.F.R. §423.120(b)(2)(v), QHP's formulary must include substantially all drugs that fall within the six protected classes as determined by CMS. QHP may not implement prior authorization (PA) or step therapy (ST) requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a protected class drug. (*See Medicare Prescription Drug Benefit Manual, Pub. 100-18, Chapter 6, §30.2.5 of Chapter 6*). During the on-site audit, CMS reviewed a sample of denied claims and found that QHP improperly denied a protected class drug(s) for 22 enrollees who had a change in drug strength. Those enrollees were denied their Part D drugs because there was an incorrect trigger for the application of prior authorization (PA) or step therapy (ST) criteria to re-fill prescriptions for a change in drug strength. Since these enrollees were currently taking a protected class drug, QHP should not have implemented PA or ST requirements.

Finally, CMS also confirmed that QHP failed to apply its Part D transition policy correctly. Pursuant to 42 C.F.R. §423.120(b)(3), QHP must provide for an appropriate transition process for new enrollees to receive prescribed Part D drugs that are not on its Part D plan's formulary. An appropriate transition process also applies to current enrollees whose Part D drugs are no longer on the formulary. (*See Medicare Prescription Drug Benefit Manual, Pub. 100-18, Chapter 6 §30.4.5*). During the on-site audit, CMS found that QHP failed to ensure that their PBM subcontractor properly coded all drugs that were subject to a formulary change between 2009 and 2010. Therefore, enrollees who were eligible to receive a transition fill during the first part of 2010 were incorrectly denied their Part D medications. During the on-site audit, CMS reviewed a sample of denied claims and confirmed that there were 128 enrollees who were improperly denied Part D drugs due to QHP's failure to provide the required transition fill for those enrollees.

### *Contract Administration and Management*

Pursuant to 42 C.F.R. § 422.504(i)(4)(i) and §423.505(i)(4)(i), MA-PD and PDP sponsors are required to have adequate written arrangements which specify delegated activities and reporting responsibilities for their first tier, downstream and related entities. Additionally, pursuant to 42 C.F.R. § 422.504(i)(4)(iii) and §423.505(i)(4)(iii), the written arrangements must specify that the MA-PD and PDP sponsors, on an ongoing basis, monitor the performance of these entities.

During the on-site audit, CMS determined that QHP failed to send the correct Benefit Specification Form to Envision, its PBM subcontractor, thus causing Envision to incorrectly administer the drug benefits on behalf of QHP. Also, while both QHP and Envision could produce copies of this form for 2009 and 2010, the copies were not signed by either QHP or Envision. Additionally, QHP has no monitoring activities, such as quality audits, in place to ensure claims are adjudicated according to the benefit designs for the MA-PD and PDP contracts and no documented quality audits in place to ensure transition fills are processed.

### *Compliance Plan*

An effective compliance plan is required to be developed and implemented by all MA-PD and PDP sponsors pursuant to 42 C.F.R. §422.503(b)(4)(vi) and §423.504(b)(4)(vi). During the on-site audit, CMS determined that QHP did not have an effective compliance plan that met CMS requirements.

QHP's Compliance Program Policies and Procedures state that there is a Compliance Committee, however, during the on-site audit, it was determined that QHP does not have any Compliance Committee as required by 42 C.F.R. §422.503(b)(4)(vi)(B) and §423.504(b)(4)(vi)(B). Additionally, QHP's compliance officer also serves as the organization's chief operating officer and chief financial officer. Sponsors must ensure its compliance officer does not hold other responsibilities that could lead to self-policing of his/her activities (e.g., the compliance officer should not also be or be subordinate to the chief financial officer (CFO)) (*See Medicare Prescription Drug Benefit Manual, Pub. 100-18, Chapter 9 §50.2.2.1*). This arrangement compromises the independence necessary for an individual to perform effectively as a compliance officer and violates the requirement that the compliance officer is accountable to senior management as required by 42 C.F.R. §422.503(b)(4)(vi)(B) and §423.504(b)(4)(vi)(B).

QHP must also have effective lines of communication between the compliance officer, members of the compliance committee, the organization's employees, managers and directors, and the organization's first tier, downstream and related entities. (See 42 C.F.R. §422.503(b)(4)(vi)(D) and §423.504(b)(4)(vi)(D)). Although, QHP's policy indicated that all reported or detected potential compliance violations will be logged, QHP does not have any internal system to track potential compliance issues other than a hotline which mostly resolved human resources complaints.

QHP's compliance plan does not include any auditing or monitoring activities as required by 42 C.F.R. §422.503(b)(4)(vi)(F) and §423.504(b)(4)(vi)(F). This lack of compliance oversight is

demonstrated by QHP's failure to exercise proper contract administration and oversight of its PBM subcontractor, as detailed above. Additionally, QHP did not have any procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as required by 42 C.F.R. §422.503(b)(4)(vi)(G) and §423.504(b)(4)(vi)(G). Specifically, QHP does not have any formal tracking system for its complaints or issues of potential non-compliance. Since QHP has no tracking system, CMS was unable to determine whether QHP promptly responded to detected offenses.

Finally, MA-PD and PDP organization must enforce compliance standards through well-publicized disciplinary guidelines. (See 42 C.F.R. §422.503(b)(4)(vi)(E) and §423.504(b)(4)(vi)(E)). Although QHP's policy provided disciplinary actions for employees who violate the Code of Ethics, QHP did not follow this policy. QHP's policy stated that violations of the Code of Ethics will be escalated to the Compliance Committee. However, as detailed above, QHP did not have a Compliance Committee. Additionally, QHP was not consistent with its disciplinary actions for the same offenses.

#### *Appeals and Grievances*

The CMS on-site audit also found that QHP substantially failed to comply with CMS requirements by failing to properly process grievances and appeals. These deficiencies included, but are not limited to, a lack of oversight with Prescription Drug Plan (Part D) appeals performed by QHP's subcontractor; QHP's failure to develop policies and procedures to ensure grievances are handled appropriately; QHP's failure to substantiate timely notification and disposition of Medicare Advantage (Part C) and Part D grievances, in violation of 42 C.F.R. §422.564 and §423.564; QHP's failure to substantiate timely notification and effectuation of Part D redetermination decisions, in violation §423.590(a); QHP's failure to correctly distinguish between Part C organization determinations, grievances, and appeals, in violation of §42 C.F.R. §422.561, §422.564, §422.566 and §422.580; and QHP's failure to forward Part C adverse claims reconsiderations to the IRE in a timely manner, in violation of 42 C.F.R. §422.590.

In 2008, CMS conducted an audit of QHP's contract H5402, which found many of the same deficiencies in the processing of grievances and appeals. CMS required QHP to submit a corrective action plan (CAP) for these deficiencies, which was accepted by CMS on October 15, 2009. QHP's repeated deficiencies in grievances and appeals demonstrate that QHP has longstanding and persistent compliance failures in these areas which must be corrected.

#### **Basis of Proposed Intermediate Sanctions**

CMS has determined that QHP's compliance deficiencies, as described above and further detailed below, provide sufficient basis for intermediate sanctions (42 C.F.R. §422.752(b) and 42 C.F.R. §423.752(b)). CMS' determination to impose intermediate sanctions is based on the following regulatory violations, each of which provides an independent basis for the imposition of an intermediate sanction, and which are supported by examples of QHP's noncompliance, as described below:

***QHP failed substantially to carry out the terms of its Medicare Advantage (MA) and Prescription Drug Plan (PDP) contracts with CMS and is carrying out its contracts with CMS in a manner that is inconsistent with the effective and efficient implementation of the program. (42 C.F.R. §422.510(a)(1) and (2), 42 C.F.R. §423.509(a)(1) and (2)).***

- QHP failed to bill enrollees for monthly premiums on a monthly basis, thus causing enrollees to unknowingly incur large balances in unpaid premiums. This failure continued even after QHP was notified and asked to correct this deficiency.
- QHP sent premium invoices to beneficiaries who had already paid their premiums through premium withhold (i.e. Social Security checks).
- QHP failed to give enrollees the option of paying their premiums in arrears either by lump sum, by equal monthly installments spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and QHP.
- QHP failed to have adequate contracts or written agreements with its PBM contractor and failed to adequately oversee its PBM contractor.
- QHP covered prescription drugs for members enrolled in QHP's Part D plan, S8475-001, which is a non-enhanced plan that did not provide for excluded prescription drug coverage.
- QHP failed to develop and implement an effective compliance plan.
  - QHP failed to designate a compliance committee and failed to hold the compliance officer accountable to senior management.
  - QHP failed to have effective lines of communication between the compliance officer, members of the compliance committee, the organizations employees, managers and directors, and the organizations first tier, downstream and related entities.
  - QHP failed to implement disciplinary guidelines for enforcement of compliance standards.
  - QHP failed to develop and implement procedures for internal monitoring and auditing.
  - QHP failed to develop and implement procedures for ensuring prompt responses to detected offenses and to develop corrective action initiatives relating to QHP's contracts.

***QHP substantially failed to comply with the service access requirements in 42 C.F.R. §423.120 (42 C.F.R. §423.509(a)(8)).***

- QHP failed to properly administer its benefits package as approved by CMS pursuant to 42 C.F.R. §423.120(b)(2)(iv). QHP's failure resulted in the inappropriate denial of Part D drugs that were on QHP's approved formulary.
- QHP failed to apply Part D benefit transition policy correctly. QHP's failure resulted in the inappropriate denial of Part D drugs for beneficiaries who were eligible to receive a transition fill during the first part of 2010.
- QHP failed to properly adhere to the policy governing the adjudication of claims for Part D drugs that fall within the six protected classes. QHP's failure resulted in the

inappropriate denial or delay of Part D drugs for beneficiaries who were not required to have prior authorization or step therapy criteria.

***QHP substantially failed to comply with the requirements in subpart M of Part 422 and Part 423 related to appeals and grievances (42 C.F.R. §422.510(a)(6), 42 C.F.R. §423.509(a)(6)).***

- QHP failed to conduct proper oversight of QHP's contractor who was responsible for Part D appeals.
- QHP failed to develop policies and procedures to ensure grievances are handled appropriately.
- QHP failed to provide documentation to substantiate compliance with CMS requirements regarding the timely notification and disposition of Part D grievances.
- QHP failed to provide documentation to substantiate compliance with CMS' requirements regarding timely notification and effectuation of Part D redetermination decisions.
- QHP failed to correctly distinguish between Part C organizational determinations, grievances and appeals.
- QHP failed to provide timely notification and disposition of Part C grievances and appeals.
- QHP failed to properly forward adverse claims reconsiderations to the independent review entity (IRE) for independent review.
- QHP inappropriate processed the waiver of liability for Part C appeals.

**Opportunity to Respond to Notice**

Pursuant to 42 C.F.R. §422.756(a)(2) and 42 C.F.R. §423.756(a)(2), QHP has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or on May 28, 2010. If the 10<sup>th</sup> day falls on a weekend or federal holiday, you have until the next regular business day to provide a written rebuttal. Please note that CMS considers receipt as the day after the notice is sent by fax, e-mail, or overnight mail, or in this case, May 18, 2010. If you choose to submit a rebuttal, please send it to the attention of Brenda J. Tranchida at the address noted below.

**Right to Request a Hearing**

QHP may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§422.660 through 684 and 42 C.F.R. §§423.650 through 662. Pursuant to 42 C.F.R. §422.756(b) and 42 C.F.R. §423.756(b), your written request for a hearing must be received by CMS within 15 calendar days of your receipt of this notice, or by June 2, 2010. Please note, however, a request for a hearing will not delay the date specified by CMS when the sanction becomes effective. If the 15<sup>th</sup> day falls on a weekend or federal holiday, you have until the next regular business day to submit your request. Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

Dr. Nazeer Khan  
May 17, 2010  
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QHP must submit a request for hearing to the following CMS official:

Brenda J. Tranchida  
Director, Program Compliance and Oversight Group  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
MAIL STOP: C1-22-06  
Baltimore, MD 21244  
Email: [brenda.tranchida@cms.hhs.gov](mailto:brenda.tranchida@cms.hhs.gov)  
FAX: 410-786-6301

You must also send a courtesy copy of your request by e-mail to the CMS Hearing Officer on the date you mail your request. CMS will consider the date the Office of Hearings receives your e-mail or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of your request. Your request for a hearing must include the name, fax number and e-mail address of the contact within your organization (or the attorney who has a letter of authorization to represent your organization) with whom you wish us to communicate regarding the hearing request. The request for a hearing must be sent to the CMS Hearing Office at the following address:

Benjamin Cohen  
CMS Hearing Officer  
Office of Hearings  
ATTN: HEARING REQUEST  
Centers for Medicare & Medicaid Services  
2520 Lord Baltimore Drive, Suite L  
Mail Stop LB-01-22  
Baltimore, MD 20244-2670  
Phone: (410) 786-3169  
E-Mail: [Benjamin.Cohen@cms.hhs.gov](mailto:Benjamin.Cohen@cms.hhs.gov)

Please note that we are closely monitoring your organization and QHP may also be subject to other applicable remedies available under law, including the imposition of additional sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O. For all the deficiencies cited in this letter, QHP must develop and implement its corrective action plan pursuant to the procedures and timeframes stated in 42 C.F.R. §422.510(c) and §423.509(c). If, after a reasonable opportunity to correct, CMS determines that the deficiencies which formed the basis for this intermediate sanction remain uncorrected and/or are likely to recur, CMS may consider taking action to terminate QHP's contracts.

If you have any questions about this determination, please do not hesitate to contact Jennifer Smith directly at (410) 786-1404 or [Jennifer.Smith2@cms.hhs.gov](mailto:Jennifer.Smith2@cms.hhs.gov).

Dr. Nazeer Khan  
May 17, 2010  
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Sincerely,

/s/

Brenda Tranchida  
Director  
Program Compliance and Oversight Group

cc: Mr. Jonathan Blum, CMS/CPC  
Mr. Timothy Hill, CMS/CPC  
Ms. Jennifer M. Smith, CMS/CPC/PCOG  
Ms. Cynthia Tudor, CMS/CPC/MDBG  
Ms. Jennifer Shapiro, CMS/CPC/MDBG  
Ms. Judith Geisler, CMS/CPC/MDBG  
Ms. Danielle Moon, CMS/CPC/MCAG  
Ms. Heidi Arndt, CMS/CPC/MCAG  
Ms. Cheri Rice, CMS/CPC/MPPG  
Mr. Randy Brauer, CMS/CPC/MPPG  
Ms. Michele Edmondson-Parrott, CMS/CPC/MEAG  
Ms. Mary A. Laureno, CMS/OBIS  
Mr. Peter Ashkenaz, CMS/OEA  
Ms. Laurie McWright, CMS/OL  
Mr. Greg Jones, CMS/OL  
Ms. Kimberly Brandt, CMS/OFM/PI  
Mr. James Kerr, CMS/OA/CMHPO  
Ms. Gloria Parker, CMS/CMHPO/Region IV  
Ms. Julia Shake, CMS/CMHPO/Region IV  
Ms. Colleen Carpenter, CMS/CMHPO/Region IV  
Ms. Carol Bennett, DHHS/OGC  
Ms. Leslie Stafford, DHHS/OGC  
Ms. Jill Abrams, DHHS/OGC  
Ms. Nancy Brown, DHHS/OIG/OCIG  
Mr. Paul Collura, CMS/CMHPO  
Mr. Benjamin Cohen, CMS/OA  
Mr. Gerald T. Walters, CMS/OFM