VIA Electronic Submission to http://www.regulations.gov

February 25, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6041-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-6041-NC; Medicare Program: Solicitation of Comments Regarding Development of a Recovery Audit Contractor Program for the Medicare Part C and D Programs

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on CMS's information collection request regarding the development of a recovery audit contractor (RAC) program for the Medicare Part C and D programs. As CMS considers promulgating a proposed rule regarding the Medicare Part C and D RAC program, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

The National Community Pharmacists Association (NCPA®) represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. Focusing on the Medicare Part C and D programs, NCPA members are a primary access point for prescription medications for millions of Part C and D beneficiaries and NCPA members comprise a critical piece of the Part C and D prescription drug distribution system.

As key suppliers of Part C and D prescription drugs, NCPA members strive to do their part to help maintain the integrity of the Medicare Part C and D programs. In fact, NCPA members are not a major source of fraud, waste and abuse problems within Medicare. From January, 2009 through July, 2010, only 0.2% of pharmacists and pharmacy owners were added to the OIG's list of excluded suppliers.[1]

Given NCPA members' track record, NCPA and its members strongly support CMS's efforts to strengthen the integrity of the Medicare Part C and D programs and to fight against

[1] Compiled using data from the United States Department of Health & Human Services, Office of Inspector General, List of Excluded Individuals/Entities.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

fraud, waste and abuse within the Medicare Part C and D programs through appropriate audits. While supporting CMS's efforts, NCPA also urges CMS to fight fraud, waste and abuse in a manner that is fair and not unduly burdensome to community pharmacies, and does not lead to the auditors perpetrating abuses of their own for potential financial gain. Therefore, NCPA urges CMS to develop a Medicare Part C and D RAC Program that discourages auditors from engaging in abuses of the auditing system and provides for transparency and fairness for those being audited. We offer the following suggestions.

Impose limits on the Part C and D RAC contingency fee arrangements

While NCPA understands that the payment of contingency fees to Part C and D RACs is statutorily mandated, NCPA contends that paying auditors on a contingency fee basis encourages auditors to be unreasonably aggressive and to develop a "bounty-hunter" mentality. The contingency fee arrangement creates a financial incentive for RACs to identify as many overpayments, technical and otherwise, as possible, while placing less emphasis on equally important underpayments. Moreover, such a system can encourage RACs to go after borderline overpayments and incentivize RACs to make adverse audit findings against those being audited, rather than to achieve a reasonable and proper outcome. As a result, the provider bears the substantial burden to justify and support otherwise appropriate claims.

Overly aggressive RACs, spurred on by contingency fees, create two interconnected concerns. First, the required response to large numbers of audit claims imposes an undue burden on independent community pharmacies. It forces independent community pharmacies, with small staffs, to expend additional time, money and human resources to search through extensive prescription records or make repeated but unsuccessful attempts to urge physicians to provide backup for verbal orders, and to needlessly pursue drawn out appeals processes. Unlike hospital and physicians' offices, small independent community pharmacies lack large office staffs to devote toward responding to audits. Second, given the time, money and effort involved, the audit response process negatively and disproportionately impacts the patients that independent community pharmacies serve. The process takes time away that pharmacies could be devoting to Medicare Part C and D patient care, thereby potentially hindering Part C and D patient access to needed drugs.

Given NCPA's concerns regarding overly aggressive RAC auditors, NCPA urges CMS to incorporate within the Part C and D RAC program a number of provisions that CMS has proposed for the Medicaid RAC program. NCPA believes that the following proposals from the proposed Medicaid RAC program will deter the "bounty hunter" mentality referenced above.

- CMS should require that payments to Part C and D RACs may not exceed the total amounts recovered by the RACs.
- Payments to RACs should not be based on amounts identified, but not recovered, or amounts that are initially recovered, but subsequently must be repaid due to appeal outcomes against the auditor.
- CMS should require Part C and D RACs to refund their contingency fee if they lose at any level of the appeal process.

- Although not contained within the proposed Medicaid RAC program, CMS should adopt a reasonably low maximum contingency fee rate for Part C and D RACs.

NCPA believes that suggestions above, if adopted, will result in Part C and D RACs not being as likely to target those overpayment claims for which they have a weak overpayment case. The RACs will thus have a disincentive to go after borderline overpayments.

Prohibit statistical extrapolation in the Part C and D RAC program

While the CMS RFI is silent on the issue of statistical extrapolation, NCPA urges CMS to adopt language prohibiting Part C and D RACs from using extrapolation or other statistical expansion techniques in calculating the amount of any recoupment or penalty resulting from an audit overpayment finding. Extrapolation is already a controversial and often dubiously deployed statistical technique for overpayment recovery. If not performed correctly, the extrapolation is not statistically valid and can be used to over magnify total recoupments based on very small samples of claims. In other words, extrapolation can be misused to arrive at a questionably inflated number of discrepancies and corresponding penalties. In fact, Arkansas,[2] Florida[3] and Georgia[4] have all passed statutes prohibiting Pharmacy Benefit Manager ("PBM") auditors from using statistical extrapolation to determine recoupment amounts and/or penalties.[5]

Given the questionable soundness of the statistical extrapolation methods and the resulting heavy penalties being calculated, the use of statistical extrapolation against a small independent community pharmacy in an audit can be financially devastating. Moreover, independent community pharmacies, with limited resources, bear a substantial burden in terms of money and time in appealing statistical extrapolation decisions. As discussed above, such time could be much better spent improving Part C and D beneficiary access by providing valuable counseling and other clinical services to Part C and D beneficiaries.

Incentivize Part C and D RACs to pursue underpayments

As with the proposed Medicaid RAC program, NCPA encourages CMS to adopt an underpayment identification methodology that adequately incentivizes the detection of underpayments. CMS should further develop a plan for monitoring the implementation of the methodology and the underpayment payment amounts paid to the Part C and D RACs to ensure that the Part C and D RACs are adequately incentivized to identify underpayments. NCPA encourages CMS to vigorously monitor the underpayment payment system to ensure that Part C and D RACs fairly target underpayments, as well as overpayments within the Part C and D RAC program.

[2] § 17-92-1201, et.seq.
[3] § 465.188.
[4] § 26-4-118.
[5] These state prohibitions against extrapolation do not apply in cases of fraud.

Require Part C and D RACs to coordinate their audits with other auditors

CMS should require Part C and D RACs to coordinate their audit efforts with those of other program integrity or audit initiatives or programs. CMS should further develop a plan for such coordinated efforts, as well as a plan for monitoring such efforts. Such measures will minimize overlapping audits, except when necessary, and avoid overburdening Part C and D providers. CMS needs to ensure that Part C and D providers do not face duplicative and repetitive audits of submitted claims. Generally, there is no reason why Part C and D providers should be burdened with responding to audits of the same claims by multiple auditors. Such a practice is wasteful and unduly burdensome upon Part C and D providers.

NCPA further requests that CMS promulgate regulatory provisions that penalize those who engage in duplicative wasteful audits and who fail to coordinate their efforts with other auditors. If there are no negative consequences to wasteful, duplicative audits, then the burdens of those audits upon independent community pharmacies will likely negatively impact patient access. Any time spent responding to wasteful, duplicative audits is time not spent providing valuable patient counseling services to the vulnerable Part C and D patient population.

Adopt additional anti-abusive auditing provisions in the Part C and D RAC program

NCPA urges CMS to adopt for the Part C and D RAC program a number of anti-abusive auditing provisions. Part C and D plans already employ a number of abusive and overly aggressive auditing measures against pharmacies, which are excessively burdensome upon those pharmacies and, at times, result in erroneous recoupment of reimbursements. NCPA believes that it is important to deter such abusive and overly aggressive tactics. Accordingly, to the extent that Part C and D RACs audit individual pharmacies, NCPA urges CMS to take efforts to ensure that Part C and D plans do not use the RACs to further engage in overly aggressive auditing practices against pharmacies and ensure that the RACs' auditing procedures stay within the confines of the Part C and D RAC program requirements.

NCPA encourages CMS to adopt audit provisions similar to those already proposed within the Medicaid RAC program. First, CMS should require that Part C and D RACs employ licensed pharmacists to review Part C and D claims. Second, CMS should establish strict requirements regarding the nature of the documentation of good cause required for a Part C and D RAC to review a claim and should promulgate specific guidance with respect thereto. Third, CMS should develop a system for monitoring potential organizational conflicts of interest with regard to Part C and D RACs and should take affirmative steps to identify and prevent any such conflicts of interest.

Along with these elements from the proposed Medicaid RAC program, NCPA also urges CMS to adopt the following provisions:

- The Part C and D RAC audit look back period should not exceed one year from the date the claim being audited was submitted or adjudicated.
- The RAC should be required to accept the records of a hospital, physician or other authorized practitioner that are made available by the pharmacy to validate pharmacy

records and prescriptions with respect to confirming the validity of filled Medicare Part C and D claims in connection with prescriptions, refills, or changes in prescriptions.

Phase-in the Part C and D RAC program

NCPA encourages CMS to use a phase-in approach for the development of Part C and D RACs. As stated above, there is a potential for Part C and D RACs to be overly aggressive and to abuse their auditing powers to the detriment of providers, and ultimately, patients. Accordingly, a slow phase-in of Part C and D RACs will allow CMS to fine tune the program and develop the appropriate delicate balance between cutting fraud and waste out of the Part C and D programs, while also ensuring that RAC audits are fair to Part C and D pharmacies and not unduly burdensome and unnecessarily harmful to those pharmacies.

Establish a Part C and D RAC oversight entity

NCPA supports CMS's proposal to establish an oversight entity or review board for Part C and D RAC issue approval. Given the potential for Part C and D RACs to be overly and unfairly aggressive in their pursuit of overpayments and to the extent that the review board would provide a check on this potential "bounty hunter" approach, NCPA supports the proposal. NCPA also urges CMS to install licensed providers, such as physicians or pharmacists, on the review board in order to provide professional medical input into the RAC issue approval process, along with any law enforcement input provided by other board members.

As CMS indicated in the RFI, an oversight board would play an important role in determining whether a Part C or D RAC can proceed with a proposed review on certain complex issues. Assuming the board is intended to provide a check on overly aggressive RAC audits, the establishment of such a board will provide more assurance that the Part C and D RACs pursue only concrete overpayment issues, as opposed to pursuing more borderline cases on the basis of the Part C or D RAC's profit-based motive.

Prohibit Part C and D plans from using in-house RACs

NCPA contends that allowing Part C and D plans to use RACs within their own plans is a potentially dangerous proposition. NCPA fears that in an effort to maximize plan profits, Part C and D plans will encourage and incentivize these in-house RACs to be as aggressive as possible and to recoup as many payments as possible. On the surface, there does not appear to be a disincentive or check on in-house RACs to prevent them from being unduly aggressive. While NCPA opposes this idea, to the extent that CMS adopts this in-house RAC plan, NCPA urges CMS to impose the same checks and restrictions on in-house RACs as it plans to impose on the Part C and D RACs. Moreover, CMS should also vigorously maintain oversight over and monitor the actions of the in-house RACs, given that the incentives of the in-house RACs and Part C and D plans are aligned to recoup whenever possible in an effort to maximize profits.

Conclusion

In conclusion, NCPA and its members enthusiastically support CMS's efforts to strengthen Part C and D program integrity, but we also want to ensure that Part C and D RAC auditors do not engage in abusive audit practices, that audited community pharmacies are treated in a fair manner and that audits do not hinder Part C and D beneficiary access to community pharmacies. Accordingly, NCPA requests that CMS adopt the following suggestions:

- Appropriately constrain and place limits on the Part C and D RAC contingency fee arrangements;
- Prohibit Part C and D RACs from using statistical extrapolation for determining recoupment amounts;
- Equally incentivize Part C and D RACs to pursue underpayments, as well as overpayments;
- Require Part C and D RACs to coordinate their auditing efforts with other auditors and for CMS to monitor and provide oversight over such coordination efforts;
- Adopt a series of audit best practices provisions designed to prohibit audit abuses and ensure a fair audit process for community pharmacies;
- Slowly phase-in the Part C and D RAC program;
- Create an oversight board to approve or disapprove of Part C and D RAC proposals to pursue certain complex or borderline auditing cases; and
- Prohibit Part C and D plans from creating in-house RACs.

NCPA appreciates the opportunity to comment on CMS-6041-NC, CMS's RFI regarding Solicitation of Comments Regarding Development of a Recovery Audit Contractor Program for the Medicare Part C and D Programs. Please do not hesitate to contact me by email at chris.smith@ncpanet.org, or by telephone at (703) 600-1185, if you have any questions.

Sincerely,

Christopher R. Smith

Christopher R. Smith, J.D.
Director of Public Policy and Regulatory Affairs