Justification for Emergency PRA Clearance
For the Revised Form CMS-367

Subject: CMSO is requesting that the Paperwork Reduction Act (PRA) package for the revised manufacturer reporting requirements under the Medicaid Drug Rebate Program (forms CMS-367a, CMS-367b, CMS-367c and CMS-367d) be processed under 5 CFR 1320.13(a)(2)(i) for emergency clearance. The reason for this emergency request is: 1) The regular process will cause a statutory or court ordered deadline to be missed. Section 6001 of the Deficit Reduction Act of 2005 (DRA) added a monthly data collection requirement for labelers to supply information within 30 days after the end of each calendar quarter and month on each drug's average manufacturer price (AMP). In addition, that section of the DRA added nominal price as another quarterly data element reported by manufacturers; however, the submission of quarterly nominal price will be voluntary until a final regulation is issued. The DRA established an effective date for both of these new collections of January 1, 2007; therefore, in order to meet that deadline, CMS must begin collecting the first monthly submission from manufacturers on **February 1, 2007** and the first revised quarterly collection as of **April 1, 2007**.

Background: Section 1927 of the Social Security Act (the Act) requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal government for States to receive funding for drugs dispensed to Medicaid recipients. In order for payment to be made under Medicaid, the drug labeler must complete and sign a drug rebate agreement and must submit required price information in accordance with Section 1927(b)(3) of the Act. The DRA modified this section of the law by requiring that manufacturers submit a monthly AMP in addition to the quarterly AMP that they currently submit. In addition, the DRA added nominal price as another quarterly data element submitted by manufacturers. Although the proposed regulation (CMS-2238-P) states that customary prompt pay discounts and a DRA Baseline AMP will also be collected from manufacturers, there are no plans to collect those additional fields at this time. Instead, those additional collections will be addressed in the final regulation and a subsequent PRA package.

Justification: We request this PRA clearance under an emergency approval process to accommodate the timelines under the DRA. If those timelines are not met, manufacturers will not submit the pricing information that states need in order to potentially revise their prescription drug reimbursement methodologies. As the Office of the Inspector General (OIG) has concluded from previous audits, current state reimbursement methodologies, which typically are a calculation of a percentage off of the Average Wholesale Price (AWP), result in drastic overpayment to pharmacy providers. The June 2005 OIG Report (OEI-05-05-00240) found that, on average, AMP is 70% lower than AWP for generic drugs, and AMP is up to 28% lower than AWP for brand drugs. The OIG report estimated that using AMP as a basis for prescription drug reimbursement as set forth in the DRA rather than AWP would result in a savings of $15.1 billion over the next ten years.

Therefore, any delay in the collection of the monthly AMP will result in continuance of pharmacy provider overpayment by State Medicaid Agencies and, in turn, reduces the resources for payment of drugs and services to the Medicaid beneficiary population

Earlier delays in submitting this package were caused by changes in policy and general counsel opinion. The language in the DRA pertaining to the drug data collection was found by OGC to be ambiguous. CMSO Policy, working with OGC, prepared, cleared and submitted a technical amendment to the DRA in an attempt to clarify the ambiguity. Sometime in June 2006, draft technical amendments were being circulated to address the ambiguity, and Policy worked with OGC to submit a change to a technical amendment. In mid-June, we worked with Policy to try and determine what data would be collected based on the draft regulation which at that time was to be published July 1. In July, we worked on getting emergency approval for a Sample AMP Collection necessitated by the DRA (received approval in early August). In mid-August, we worked with Policy again to determine what data collection elements were going to be proposed in the reg. In September, we prepared our initial OMB clearance package for the revised 367, and again sought clarification from Policy on what was going to be proposed for collection in the reg and what needed to be collected pre-reg (the NPRM was delayed and not published until December 22). In late October, we were still waiting for that clarification. The OMB package was signed in early November, and went forward to OSORA for Federal Register publication. On November 20, we informed OSORA that the OMB package should be put on hold pending clarification of additional changes to the collection requirements brought to our attention by Policy. We sought independent clarification from OGC in late November on two specific data elements that were still pending a final decision so that we could finalize our OMB package. OGC issued an opinion in early December, and we believed that the data collection requirements were settled at that time. We revised the OMB package and the Center Director signed the revised package on December 8. Policy took issue with the OGC decision previously issued in regard to the collection of one data element. Meetings were held, and the decision was made to retract the second signed OMB package on January 5. Changes were made once again, and the current package was signed by the Center Director and forwarded to OSORA on January 10. To the best of our knowledge, all policy changes have now been addressed.

We are requesting OMB approval by February 1, 2007 so that the manufacturers can begin to report the January 2007 monthly AMP (due to CMS by March 2, 2007). In order to obtain OMB approval by February 1, 2007 we would need to have a shortened FR notice comment period of approximately 7-10 days or for OMB to possibly waive publication at this time.

Requested and Proposed Timelines

Date	Activity
1/12/2007	Submit emergency justification to OSORA
1/16/2007	OSORA submits emergency justification to OMB
1/26/2007	Publication in the Federal Register Document
1/31/2007	Beginning of 6- day public comment period and OMB review
1/31/2007	End of public comment period
2/1/2007	Requested date of OMB approval
2/1/2007	Federal statute requires manufacturers to submit monthly AMP data to CMS for use in Federal Upper Limit calculation and for state reimbursement