



FEB 10 2012

Dear 340B Program Participant:

President Obama has challenged the entire Federal Government to improve our efforts to eliminate improper payments and reduce the risk of waste, fraud, and abuse. In responding to the President's challenge and to improve the way the U.S. Department of Health and Human Services (HHS) fulfills its critical mission to protect the health of all Americans and provide essential human services, Secretary Sebelius has established an HHS-wide Program Integrity Initiative. HHS defines program integrity as:

"The operation of HHS' programs, by both HHS and our external partners, in an effective and efficient manner, in accordance with applicable laws and regulations, and without conflict of interest or the appearance of conflict of interest, in accordance with applicable laws and regulations. In line with HHS program goals and objectives, the intended recipients are provided the proper payments, services and benefits while ensuring quality, safety and access."

The Program Integrity Initiative is designed to target the greatest risks of fraud, waste and abuse; reduce those risks by enhancing existing program integrity operations; share new and best program integrity practices; and measure the results of our efforts.

In addition, the Government Accountability Office (GAO) in a September 2011 report (GAO-11-836) recommended that the Health Resources and Services Administration (HRSA) conduct selective audits of 340B covered entities to provide additional program oversight, monitor for program violations and prevent diversion and duplicate discounts. The purpose of this message is to inform you of HRSA's efforts toward strengthening program integrity in the 340B Program.

HRSA recognizes the importance of strengthening oversight of both participating covered entities and manufacturers to ensure compliance with program requirements. Below are some of the actions HRSA will take in Fiscal Year 2012 to strengthen 340B Program oversight:

- 1) Conduct selective and targeted audits of 340B covered entities to provide additional program oversight, monitor for program violations and prevent diversion and duplicate discounts. These audits will help HRSA and all participating covered entities identify and mitigate program risk as well as identify best practices regarding program compliance.
- 2) Increase efforts to ensure that covered entities are not being overcharged through additional oversight of manufacturers.

- 3) Issue policy releases to all 340B stakeholders in order to provide increased transparency into the processes and procedures already in place by HRSA and to ensure program integrity and compliance. HRSA has already issued policy letters restating its policies on penny pricing, non-discrimination, and manufacturer audit protocols and intends to issue policy letters on hospital eligibility criteria and use of the Medicaid Exclusion File. They can be found at www.hrsa.gov/opa/policyreleases.
- 4) Verify that all covered entities continue to meet the statutory requirements for program participation and make improvements on HRSA's processes to ensure 340B Program eligibility. On a quarterly basis HRSA will continue to: (1) verify the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private, for-profit hospitals are not participating; (2) monitor Disproportionate Share Hospital (DSH) adjustment percentages and remove hospitals from the program if they fall below the DSH percentage for eligibility; and (3) monitor Federally Qualified Health Center (FQHC) status to ensure organizations are still eligible to participate in the 340B Program.
- 5) Recertify the eligibility of all covered entities on an annual basis. This recertification process will enable HRSA to verify that all covered entities continue to meet the statutory requirements for 340B Program participation. In addition to providing information for recertification, each participating entity must contact HRSA with any changes or updates to its existing 340B profile to remain in compliance with 340B Program requirements. HRSA will issue a policy letter to clarify that covered entities must ensure accuracy of their profiles and comply with eligibility requirements.

Two of the most important responsibilities we have are to ensure that our programs are free of fraud, waste, and abuse and that we do everything we can to maximize the positive impact of every dollar we spend. HRSA is fully committed to strengthening 340B program integrity efforts and ensuring that our management and oversight supports the program's continued success. I appreciate your support and participation in the 340B program.

Sincerely,



Mary K. Wakefield, Ph.D., R.N
Administrator