

## **Section 1. Short Title.**

### *Explanation of Provision*

This Act may be cited as the “QI Program Supplemental Funding Act of 2008”.

## **Section 2. Funding For The Qualifying Individual (QI) Program.**

### *Current Law*

Certain low-income individuals who are aged or have disabilities, as defined under the Supplemental Security Income (SSI) program, and who are eligible for Medicare are also eligible to have their Medicare Part B premiums paid for by Medicaid under the Medicare Savings Program (MSP). Eligible groups include Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QI-1s). QMBs have incomes no greater than 100% of the federal poverty level (FPL) and assets no greater than \$4,000 for an individual and \$6,000 for a couple. SLMBs meet QMB criteria, except that their incomes are greater than 100% of FPL but do not exceed 120% FPL.

QI-1s meet the QMB criteria, except that their income is between 120% and 135% of poverty. Further, they are not otherwise eligible for Medicaid. The QI-1 program is currently slated to terminate June 2008.

In general, Medicaid payments are shared between federal and state governments according to a matching formula. Unlike the QMB and SLMB programs, federal spending under the QI-1 program is subject to annual limits. Expenditures under the QI-1 program are paid 100 percent by the federal government (from the Part B Trust fund) up to a state’s allocation level. States are required to cover only the number of people which would bring their annual spending on these population groups to their allocation levels. For the period beginning on January 1, 2008, and ending on June 30, 2008, the total allocation amount was \$200 million.

### *Explanation of Provision*

The provision would authorize an additional \$45 million for the QI program.

## **Section 3. Mandatory Use of State Public Assistance Reporting Information System (PARIS) Project**

### *Current Law*

The federal government pays a share of every state’s spending on Medicaid services and program administration. In order to receive Medicaid federal matching funds for

reimbursement of state costs for automated data systems used for the administration of the Medicaid state plan, states must have mechanized claims processing and information retrieval systems that meet certain requirements.

The Public Assistance Reporting Information System (PARIS) is a voluntary computer data matching and information exchange system administered by the Administration for Children and Families (ACF) to provide States with a tool to improve program integrity in the administration of public and medical assistance programs. Most States voluntarily participate in the system. The PARIS project is designed to match State enrollment data from the Temporary Assistance to Needy Families (TANF) Program, the Food Stamp Program, and Medicaid, with data from other participating States and from a selected group of Federal databases PARIS provides information to States regarding possible duplicate interstate public assistance payments (AFDC/TANF, Medicaid, Food Stamps, SSI and other Federal and State public assistance programs) of active cases.

#### *Explanation of Provision*

In order to receive Medicaid federal matching funds for reimbursement of state costs for automated data systems used for the administration of the Medicaid state plan, the provision would require states to have in operation a Medicaid eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) (or any successor system), including matching with medical assistance programs operated by other states.

This provision would take effect October 1, 2009. States that require state legislation to come into compliance with the requirements of this provision would not be regarded as failing to comply solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. In the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

#### **Section 4. Incentives for the Development of, and Access to, Certain Antibiotics**

##### *Current Law*

In the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress moved antibiotics from Section 507 to 505 (new drugs) because the separation did not make sense. Congress added language to ensure that old antibiotics approved under Section 507 would not be able to double dip on Hatch-Waxman benefits due to their new status under Section 505. The language said that any application for an antibiotic that was submitted to the Secretary could not “double dip.” As a result, companies have no access to Hatch-Waxman incentives to develop drugs based on active ingredients of the old antibiotics submitted to the Food and Drug Administration (FDA).

The FDAMA language also impacted generic drug companies' ability to gain approval of and market generic equivalents of antibiotics approved under Section 507.

#### *Explanation of Provision*

This provision says that any antibiotic that was the subject of an application submitted to the FDA but not approved (before FDAMA), can get the 3 year and/or 5 year Hatch Waxman exclusivity OR a patent term extension. According to Food, Drug, and Cosmetic Act lawyers, approximately 10 antibiotics fit this category of submitted but not approved and about half of those could never be approved because of issues with the active ingredients. Due to guidance from a CRS legal expert who said that the Patent Act would apply to this language, language was added to the proposal giving companies the option to choose the data exclusivity route OR the patent term route. Given that the affected antibiotics are all "old" antibiotics, it is highly unlikely any drug sponsor of such antibiotics would choose the patent term option.

The provision also includes language clarifying the ability of generic drug companies to gain approval of and market generic equivalents of antibiotics approved under Section 507.

This provision was included in Senate-passed S. 1082, the Food and Drug Administration Revitalization Act, and was agreed upon in Senate-House conference negotiations. Due to a lack of funding in H.R. 3580, the Food and Drug Administration Amendments Act, the House pulled this provision before passage of H.R. 3580 (P.L. 110-85).

### **Section 5. Amendment to the Medicaid Integrity Program**

#### *Current Law*

The Deficit Reduction Act of 2005 (DRA, P.L. 109-171) established a Medicaid Integrity Program (MIP) with an appropriation reaching \$75 million annually for audits; identification of overpayments; education of providers of services, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care; and other purposes. It also provided an additional \$25 million in each of FY2006 – FY2010 for Medicaid activities of the HHS Office of Inspector General and an appropriation reaching \$60 million annually for an expanded Medicare-Medicaid data match project (referred to as Medi-Medi) that analyzes claims from both programs together in order to detect aberrant billing patterns.

Under the DRA provision, the Secretary of HHS enters into contracts with eligible entities to carry out the program's activities, which include: (1) review of the actions of individuals or entities furnishing items or services for which a Medicaid payment may be made, (2) audit of claims for payment for items or services furnished or for administrative services rendered, (3) identification and recovery of overpayments to individuals or entities receiving federal funds under Medicaid, (4) education of service

providers, managed care entities, beneficiaries, and other individuals with respect to payment integrity and benefit quality assurance issues.

#### *Explanation of Provision*

The provision would expand the education activities under the MIP to provide education or training, including at such national, state or regional conferences as the Secretary may establish, of state or local officers, employees, or independent contractors responsible for the administration or supervision of the administration of the state Medicaid plan. In addition, the provision permits the Secretary to use the appropriated funds for the MIP to pay for transportation and travel expenses for attendees at education, training, or consultative activities. These amendments would take effect as if included in DRA. The bill also requires CMS to post on a publicly available website the total amount of funds expended for each conference conducted and the amount of funds expended for each such conference that were for transportation and for travel expenses.

### **Section 6. Funding for the Medicare Improvement Fund**

#### *Current Law*

The Secretary established a Medicare Improvement Fund available to the Secretary to make improvements under the original fee-for-service program under Parts A and B for Medicare beneficiaries. The Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275, MIPPA), together with a provision in the Supplemental Appropriations Act, 2008 (P.L. 110-252), makes \$2.22 billion from the Part A and B Trust Funds available for services furnished during FY2014 and an additional \$19.9 billion available for fiscal years 2014 through 2017.

For purposes of carrying out the provisions of, and amendments made by MIPPA in addition to any other amounts provided in such provisions and amendments, additional funds will be made available to CMS. For fiscal years 2009 through 2013, the Secretary of Health and Human Services will transfer \$140 million from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund to the CMS Program Management Account. The amounts drawn from the funds will be in the same proportion as for Medicare managed care payments (Medicare Advantage), that is, in a proportion that reflects the relative weight that benefits under part A and under part B represent of the actuarial value of the total benefits.

#### *Explanation of Provision*

The provision would make \$2.294 billion available to the Fund for expenditures from the Fund for services furnished during FY 2014. The \$74 million is unspent savings from the offset identified in section 3.