

1997. Lab and outpatient services (which one Intermediary reports accounts for 30 to 40 percent of the revenue for critical access hospitals) for some of these entities were reimbursed on a cost basis with applicable coinsurance and deductible amounts, while some of these entities were paid under a fee schedule with no reimbursement for bad debts. As of November 29, 1999, coinsurance and deductibles were eliminated from lab services for critical access hospitals. We expect that this action will significantly reduce the amount of bad debt incurred by these facilities.

The following is the individual estimate of the economic impact of this rule between provider types (in \$millions):

Fiscal year	SNF	ESRD	Net impact
2003	-20	20	0
2004	-30	20	10
2005	-70	20	50
2006	-90	20	70
2007	-100	20	80

The impact on all other provider types would round to \$0. For both SNF and ESRD facilities, these savings or costs represent only a small portion (about 0.5%) of the total Medicare payments for those facilities.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. Although this rule would impact some small rural hospitals, including critical access hospitals, most hospitals have already been subject to the 30 percent reduction implemented by statute. We believe this rule would not have a significant impact on the operations of a substantial number of small rural hospitals and the impact would be mitigated by implementing the rule gradually over a 3-year period.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million annually. Intermediaries and carriers are not considered to be small entities.

Small rural hospitals of fewer than 100 beds, rural health clinics, community mental health centers, freestanding ESRD facilities, and hospital-based ESRD facilities would be affected by this rule. There are approximately 352 critical access hospitals, and all of these facilities would be small rural hospitals. To the extent that they incur bad debts, they would be affected. It is very difficult to assess the impact on these facilities because the impact, if any, on a facility would be influenced by the amount of bad debts the facility incurs. However, the elimination of coinsurance and deductible amounts for lab services rendered by critical access hospitals should substantially reduce the amount of bad debt that these small hospitals incur. Any Medicare participants that are currently receiving full (that is, uncapped) reimbursement for their bad debts would see a reduction in payment.

Based on current data, there are approximately 3,528 freestanding and 787 hospital-based ESRD facilities. Although we are not certain how many of these facilities are small rural hospital-based, most ESRD facilities would benefit from this rule as they would be allowed to claim and receive reimbursement for more of their Medicare bad debts, allowing them to claim bad debts over their unrecovered costs. Costs are difficult to estimate because, as discussed above, not all uncapped ESRD bad debts were reported. We welcome all comments that would assist us in determining the possible impact of this rule on any of the above-mentioned entities.

Specific provisions of this proposed rule have already been applied in part to those ESRD facilities affected by the above-mentioned *Kidney Center* court settlement. These provisions, whether implemented as a result of the court settlement or the rule, were achieved through modifications made to the bad debt settlement portion of the cost report.

We do not believe that the changes made in a final rule will affect beneficiary access to care, as affected providers will continue to be reimbursed for services provided to Medicare beneficiaries, including, where allowable, for Medicare bad debt. By reducing the amount of bad debt reimbursement from 100 percent to 70 percent, this rule will fairly compensate providers, while providing an incentive for them to make reasonable efforts to collect unpaid deductibles and coinsurance.

The analysis indicates that some small, rural providers may experience an additional burden in the form of

reduced payments for bad debts. However, our analysis points out that a number of factors will mitigate the impact on small rural hospitals and that payments to ESRD facilities will increase because of the removal of the cap on allowable bad debts claimed. It is impossible to determine the significance of the impact or the number of entities that may be adversely affected. We invite comments on our analysis.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies perform an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule does not impose any mandates on State, local or Tribal governments, or on the private sector, as defined by section 202. Entities such as hospitals, SNFs and ESRD facilities will continue to receive Medicare reimbursement for services provided to beneficiaries, including, where allowable, bad debt reimbursement.

For purpose of analysis, we considered two alternatives to this policy, (1) maintaining the existing Medicare bad debt policy, or (2) eliminating bad debt reimbursement, where we had authority to do so. However, we believe that the Medicare bad debt policy proposed in this rule is equitable across provider types and ensures that providers have the incentive to make reasonable efforts to collect bad debts without affecting beneficiary access to care. In addition, the removal of the cap on bad debt reimbursement for ESRD facilities is also in accordance with the ruling in *The Kidney Center of Hollywood, et al. v. Shalala*.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and record-keeping requirements.

For the reasons set forth in the preamble, CMS proposes to amend 42