DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 401, 403, 405, 410, 411, 413, 447, 466, 473, and 493

[HCFA–1719–P]

RIN: 0938–AD95

Medicare Program; ''Without Fault'' and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This rule would amend the Medicare regulations governing liability for overpayments to eliminate application of certain regulations of the Social Security Administration and to replace them with HCFA regulations more specific to circumstances involving Medicare overpayments. The following specific changes are included in this rule.

Explicit criteria and the circumstances under which a provider or supplier can be relieved of liability for an overpayment on the basis of being ''without fault'' with respect to the overpayment.

Specific criteria and circumstances of the conditions under which a waiver of recovery for Medicare overpayments would apply to individuals.

A provision to ordinarily consider it inequitable to recover an overpayment from a without-fault individual when an overpayment is made to a without-fault provider.

Specific provisions that enable Medicare intermediaries and carriers to determine without fault in Medicare overpayments resulting from Medicare secondary payer conditional payments.

Provisions that grant Peer Review Organizations the authority to make without-fault determinations.

Provisions for an administrative appeals process for providers and suppliers with regard to a ''not-without-fault'' determination.

We expect this rule would prevent some providers and suppliers from claiming without-fault status. This could reduce the number of overpayment liabilities passed on to individuals and result in a slight increase in the amount of money recovered.

DATES: To ensure consideration, comments must be mailed or delivered to the appropriate address, as provided below, and be received by 5 p.m. on May 26, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1719–P, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1719–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT: David Walczak (410) 786–4475.

SUPPLEMENTARY INFORMATION:

I. Background

In any large organization that makes payments to a substantial number of individuals, providers, and suppliers, excesses in payment amounts may occur. Medicare overpayments are Medicare funds an individual, provider, or supplier has received that exceed amounts due and payable under the Medicare statute and regulations. (The Medicare rules at § 400.202 define a ''supplier'' as ''a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.'' Therefore, in this preamble, we have used the term ''supplier'' to include a physician.)

Overpayments generally result when payment is made by Medicare for noncovered items or services, when payment is made that exceeds the amount allowed by Medicare for an item or service, or when payment is made for items or services that should have been paid by another insurer (Medicare secondary payer obligations). Once a determination and any necessary adjustments in the amount of the overpayment have been made, the remaining amount is a debt owed to the United States Government.

Section 1870 of the Social Security Act (the Act) provides a framework within which liability for Medicare overpayments is determined and recoupment of overpayments is pursued. This framework prescribes a certain flow of events (that is, a decisionmaking process) that must be followed when pursuing the recoupment of Medicare overpayments.

Specifically, section 1870(a) of the Act provides that a payment to a provider or a supplier is considered to be a payment to the individual who received the items or services. Therefore, all overpayments (with the exception of certain aggregate overpayments described later in this preamble) are considered to be an individual's overpayments. However, under section 1870(b) of the Act, if payment was made to a provider or supplier, Medicare looks first to recover any associated overpayment from the provider or supplier unless: (1) The provider or supplier is ''without fault'' with respect to the overpayment, or (2) the Secretary determines that the overpayment cannot be recouped from the provider or supplier. Section 1870(b) of the Act also specifies that, in the absence of evidence to the contrary, without fault is administratively presumed for a provider or supplier when an overpayment is discovered after the third calendar year following the year in which notice of the payment was sent to the provider or supplier.

In accordance with section 1870(b) of the Act, if an overpaid provider or supplier is determined to be without fault or the overpayment cannot be recouped from the provider or supplier or the individual was paid directly by the Medicare program, the individual is liable for the overpayment, and Medicare seeks recovery from the individual. In the case of an individual who is liable for an overpayment, section 1870(b) of the Act provides for recovery by adjusting cash benefits by

decreasing subsequent title II payments (social security retirement, survivors, and disability cash benefits) or railroad retirement benefits to which the individual (or other person if the individual dies before the adjustment has been completed) is entitled.

Under section 1870(c) of the Act, adjustment (or any other type of recovery of an overpayment against the individual) is waived if the individual is without fault with respect to the overpayment and if the adjustment or recovery would ''defeat the purposes of title II or title XVIII'' (Medicare Part A and Part B benefits) of the Act or would be ''against equity and good conscience.'' Section 1870(c) of the Act also specifies that adjustment or recovery is deemed to be against equity and good conscience if the overpayment resulted from expenses incurred for items or services for which payment may not be made under Medicare by reason of the provisions of section 1862(a)(1) or (a)(9) of the Act (not reasonable and necessary or custodial care), and if the Secretary's determination that the payment was incorrect was made after the third year following the year in which notice of that payment was sent to the individual.

II. Current Regulations and Instructions Dealing with Overpayments

The provisions of section 1870(a) through (d) of the Act are incorporated in our regulations in §§ 405.350 to 405.359 (''Liability for Payments to Providers or Suppliers and Handling of Incorrect Payments''). Specifically, § 405.350 (''Individual's liability for payments made to providers and other persons for services furnished the individual'') provides that an individual is liable for an overpayment if the overpayment cannot be recouped from the provider or supplier or if the provider or supplier is without fault with respect to the overpayment. Section 405.350(c) further specifies that, in the absence of evidence to the contrary, a provider or supplier is deemed to be without fault if the overpayment determination was made after the third year following the year in which a payment notice was sent to the provider or supplier.

In accordance with § 405.350, we look first to recoup an overpayment from the provider or supplier unless: (1) We determine that the overpayment cannot be recouped from the provider or supplier, or (2) the provider or supplier is without fault with respect to the overpayment. Currently, there are no criteria in our regulations pertaining to when a provider or supplier is without fault, nor do our regulations make reference to Social Security Administration (SSA) regulations with respect to provider or supplier fault. However, criteria are listed in section 3708 of the Medicare Intermediary Manual and in section 7103 of the Medicare Carrier Manual that incorporate the principles employed in the SSA regulations.

Under these manual instructions, a provider or supplier is without fault if it exercised reasonable care in billing for and accepting payment. Exercising reasonable care means that the provider or supplier disclosed all material facts and, based on available information, including but not limited to, the Medicare regulations and instructions, had a reasonable basis for assuming that the payment was correct. However, if the provider or supplier had reason to question the payment, it must have promptly brought the question to the attention of the appropriate Medicare contractor (intermediary or carrier).

If the intermediary or carrier, acting on behalf of HCFA, determines that the provider or supplier is liable for the overpayment according to § 405.350 and the applicable manual instructions, we recoup the overpayment from the provider or supplier. If the intermediary or carrier, acting on behalf of HCFA, determines that the provider or supplier is not liable for the overpayment, liability rests with the individual, regardless of whether the individual was without fault. Whether an individual was without fault is not relevant to his or her liability for the overpayment, but is considered in deciding whether to waive adjustment or recovery of the overpayment.

Under § 405.355 (''Waiver of adjustment or recovery''), adjustment or recovery against the individual is waived if the individual is without fault with respect to the overpayment and if recovery would cause substantial financial hardship so that the purposes of title II or title XVIII of the Act would be defeated or if recovery would be against equity and good conscience. Section 405.356 (''Principles applied in waiver of adjustment or recovery'') specifies that the principles applied in determining waiver of adjustment or recovery are the applicable principles found in SSA regulations at 20 CFR 404.506 through 404.509, 20 CFR 404.510(a), and 20 CFR 404.512. These regulations, in part, define ''fault'' (as used in without fault) and explain the conditions for waiver of the adjustment or recovery if an incorrect payment has been made under title II or title XVIII of the Act. (Before we were established as a separate agency, SSA was responsible for both the social security cash benefit program and the Medicare program. Consequently, the two programs have many identical regulations that embody SSA's understanding of the terms used in the overpayment recoupment process.)

Under § 405.356 of our regulations, intermediaries and carriers, acting on behalf of HCFA, currently determine if an individual is without fault, based on SSA regulations at 20 CFR 404.507 (''Fault''). Under 20 CFR 404.507, the following three elements are considered in determining fault:

- Whether the overpayment resulted from an incorrect statement made by the individual that he or she knew or should have known to be incorrect.
- Whether the overpayment resulted from the individual's failure to furnish information that he or she knew or should have known to be material.
- Whether the overpayment resulted from acceptance of a payment that he or she either knew or could have been expected to know was incorrect. These criteria provide the foundation for making individual waiver of adjustment or recovery decisions.

Under § 405.355, we may waive all or part of a recovery against an individual who is found to be without fault if recovery would defeat the purposes of title II or title XVIII of the Act or would be against equity and good conscience. We currently use as a basis for making these determinations the definitions for these terms found in SSA regulations at 20 CFR 404.508 (''Defeat the purpose of title II'') and 20 CFR 404.509 (''Against equity and good conscience; defined'').

Under 20 CFR 404.508, ''defeat the purpose of title II'' means to deprive a person of income required for ordinary and necessary living expenses. Ordinary and necessary expenses, as specified in 20 CFR 404.508, include the following:

- Living expenses, such as food and clothing, rent, mortgage payments, utilities, maintenance, insurance (for example, life, accident, and health insurance including premiums for supplementary medical insurance benefits under title XVIII), taxes, and installment payments.
- Medical, hospitalization, and other similar expenses.
- Expenses for the support of others for whom the individual is legally responsible.
- Other miscellaneous expenses that may reasonably be considered as part of the individual's standard of living.

Using these criteria, 20 CFR 404.508(b) specifies that adjustment or recovery will defeat the purpose of title II, for example, if the person from whom recovery is sought needs substantially all of his or her current income

(including social security monthly benefits) to meet current ordinary and necessary living expenses.

Under 20 CFR 404.509, recovery of an overpayment is against equity and good conscience in the following circumstances:

- Because the individual relied on a notice that payment would be made, or actually received the erroneous payment, the individual—
  - * Changed his or her position for the worse; or
  - * Relinquished a valuable right.
- The individual was living in a separate household from the overpaid person at the time of the overpayment and did not receive the overpayment.

That section further specifies that the individual's financial circumstances are not material to a finding of against equity and good conscience.

HCFA, through its intermediaries and carriers, currently makes determinations of without fault with regard to providers and suppliers. Intermediaries and carriers also coordinate the waiver process if the individual is liable for the overpayment. When an overpayment consists of both Medicare Part A and Part B claims, the lead intermediary or carrier, that is, the one that has paid the most in benefits, is responsible for coordinating the without-fault determinations and the waiver request process. The lead intermediary or carrier coordinates Medicare's activities with all parties, including the intermediary or carrier, the individual or his or her representative(s), the liability insurer or tort-feasor (in Medicare secondary payer cases), and the HCFA regional office, to ensure that the overpayment situation is resolved in accordance with our guidelines.

III. Problem Areas Within the Framework of the Current Regulations and Our Proposed Revisions to the Regulations

A. Without Fault

1. Differences Between the Social Security and Medicare Programs

The proposed regulations regarding without fault will clarify circumstances unique to the Medicare context because the social security regulations do not consider the different roles played by the individual within the social security and Medicare programs. These roles that an individual plays in obtaining benefits from each of the programs are significantly diverse. As a social security claimant, the individual (or his or her representative) receives a cash benefit directly from SSA, generally with no third party involved. As a result, the individual has a very proactive role in providing accurate information to obtain this benefit and has a direct degree of responsibility in accepting the SSA payment each month.

The individual entitled to Medicare, on the other hand, generally receives items or services from a provider or supplier that, in turn, directly bills and accepts payment from the Medicare contractor on behalf of the individual. (There are exceptions to this arrangement, as described later in this preamble.) The information furnished by the individual with respect to the Medicare claim is minimal; most claim-related information is furnished by the provider or supplier. Therefore, the individual entitled to Medicare, in obtaining and accepting Medicare benefits, does not have the same role as a social security claimant.

Because of these role distinctions, the SSA regulations are not always clearly transferable to Medicare overpayment situations. For example, the term ''fault,'' as described in the SSA regulations, focuses on the individual's disclosure of accurate information. This element is emphasized because a social security claimant is in control of all of his or her financial information (for example, receipt of benefit checks and employment information) that often determines the outcome of the claim. SSA relies primarily on the claimant's own self-reporting and disclosure. A social security claimant receives a benefit payment directly and is in a position to know if he or she received more than the correct payment due under title II of the Act.

In contrast, Medicare relies largely on information received from providers and suppliers to determine payment amounts. The individual entitled to Medicare does not have the same control that a social security claimant has in the outcome of a claim. Under most circumstances (with the exception of cases involving unassigned Part B claims and certain Medicare secondary payer situations), the individual entitled to Medicare receives no actual payment and does not know if the payment made under Medicare is correct. Generally, the information generated by a provider or supplier, not information provided by the individual, causes the overpayment to be made. The SSA regulations do not take into account the significant difference between the role an individual plays in receiving social security cash benefits and in receiving Medicare benefits and, therefore, the social security regulations are not always transferable to Medicare overpayment situations.

2. Differences Resulting From Provider and Supplier Involvement

In addition, the SSA regulations do not take into consideration the role that a provider or supplier plays in administering Medicare benefits. While 20 CFR 404.507 describes what constitutes fault (as it relates to without fault) on the part of an overpaid individual, it makes no specific reference to without fault as it pertains to a provider or supplier and does not adequately provide for situations when a determination regarding without fault must be made for providers or suppliers.

While the criteria in 20 CFR 404.507 can generally be applied to all recipients of payments, they do not specifically consider substantive differences between an individual and a provider or supplier billing for and accepting Medicare payment. (Generally, the recipient of a Medicare payment is a provider or supplier. However, in the case of unassigned claims, the recipient is the individual.) Because of Medicare provisions that require all providers and suppliers to submit claims on behalf of individuals, the individual entitled to Medicare does not participate in the actual claim filing process in a significant way. Also, in most instances, it is the provider or supplier, not the individual, that actually receives the Medicare payment. This is because most providers and suppliers agree to bill Medicare directly and to accept the payment amount as determined under the applicable payment system (prospective payment, reasonable cost method, fee schedule, or reasonable charge method) as total payment for covered services. For providers, this is accomplished by entering into a Medicare provider agreement. Suppliers accomplish this either by agreeing to accept assignment on an individual claims basis or by entering into a Medicare participation agreement. Under these circumstances, the individual is responsible for providing the entity with the correct insurance information and authorizing the claim by signing the claim form; however, he or she plays no direct role in the claim filing process and receives no direct payment.

In the case of a supplier that does not accept Medicare assignment, the individual pays the supplier directly. The claim is submitted to the Medicare contractor by the supplier, and the Medicare contractor pays the individual directly. Although in these situations the individual receives payment directly, he or she normally has no way of knowing if the Medicare payment

amount for the item or service he or she received is correct.

These differences raise questions as to whether the same criteria should be applied both to the individual and to the provider or supplier when determining without fault with regard to an overpayment. In particular, determining if the recipient of the payment knew, or could reasonably be expected to know, that the payment amount was incorrect depends on determining the level of information available to the recipient.

The information available to a provider or supplier is more extensive than that available to an individual. We furnish instruction manuals to providers, and intermediaries and carriers send detailed instructions, such as newsletters, to suppliers. This direct access to Medicare payment information should impart a degree of knowledge and responsibility to both providers and suppliers that does not apply to individuals.

For example, a provider or supplier that receives an unusual payment amount for a routinely billed service should be in a better position than the individual to question and determine whether the payment amount is correct. This is because of the information available to a provider or a supplier (for example, a physician should know the Medicare physician fee schedule payment amount for a particular service). Although the individual may directly receive a Medicare payment, an Explanation of Medicare Benefits or a Notice of Utilization showing that Medicare payment has been made, the individual normally has no way of knowing if the Medicare payment amount for a particular covered service or item is correct.

Thus, we propose revisions to the regulations that consider the substantive differences between an individual accepting a Medicare payment and a provider or supplier billing for and accepting a Medicare payment.

3. Revisions Proposed to Reflect Circumstances Unique to Medicare

a. Without Fault as it Applies to Individuals Entitled to Medicare. In this rule, we propose to add regulations that are specifically applicable to individuals entitled to Medicare for determining without fault in Medicare overpayment situations. We propose that an individual be considered to be without fault with respect to a Medicare overpayment if he or she exercises reasonable care in requesting Medicare payment and in accepting Medicare payment.

Under these proposed regulations, an individual exercised reasonable care if he or she accepted a payment that he or she did not know, or could not reasonably have been expected to know, was incorrect; accepted a payment that, on the basis of information available, he or she could reasonably assume was correct; or accepted payment because of reliance on erroneous written information on the interpretation of a pertinent provision of the Act or implementing regulations from an official source within HCFA, SSA, or a Medicare contractor.

Conversely, we propose that an individual is not without fault when the individual: (1) Receives prior written notice that a particular item or service was not covered by Medicare; (2) makes an incorrect statement or withheld information to obtain benefits that were not due him or her; (3) accepts a payment that he or she knew or should have known was not due; or (4) receives a prior determination of liability under the limitation on liability provisions in section 1879 of the Act for the specific items or services for which a without-fault determination is being made.

Criteria to be considered in deciding whether an individual was without fault would include the cause of the overpayment, the individual's ability to realize that the payment was incorrect (based on his or her age, education, and physical or mental state), and whether the individual could reasonably be expected to have taken action to prevent the overpayment from occurring.

b. Without Fault as it Applies to Providers and Suppliers. We propose to incorporate in regulations criteria that currently exist in the Medicare Intermediary Manual, the Medicare Carrier Manual, and 20 CFR 404.506.

Under these proposed regulations, providers or suppliers are ''not without fault'' unless they exercise reasonable care in billing for and accepting Medicare payments and either: (1) Did not know, and could not reasonably have been expected to know, that Medicare payment exceeded amounts payable under the Medicare statute and regulations and, therefore, accepted payment based on a reasonable assumption that the payment was correct; or (2) did know, or could reasonably have been expected to know, that Medicare payment exceeded amounts payable under the Medicare statute and regulations but questioned the appropriate intermediary or carrier in writing, within 60 days of receipt of the excess payment. If, after questioning the appropriate intermediary or carrier, the provider or supplier relied on a written response from the intermediary or carrier that stated that the Medicare payment was correct, or failed to receive a response from the intermediary or carrier within 120 days of the intermediary's or carrier's receipt of the written inquiry, the provider or supplier is without fault.

We propose that the exercise of reasonable care in billing includes making full disclosure of all material facts and complying with each applicable provision specified in subpart C (''Claims for Payment'') of part 424, including the supplying of all the necessary information on the billing form, to ensure correct payment by the intermediary or carrier. We further propose criteria for determining that a provider or supplier knew, or could reasonably have been expected to know, that Medicare payment exceeded amounts payable under the Medicare statute and regulations. Under these proposed criteria, a provider or supplier is considered to have known that Medicare payment exceeded amounts payable under the Medicare statute and regulations if any one of the following conditions is met:

- It had knowledge that payment exceeded amounts payable under the statute and regulations based on experience, actual notice, or constructive notice, including (except in very limited circumstances described later in this preamble) final publication of payment amounts in official source documents; receipt of HCFA notices including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or Peer Review Organizations; or experience with Medicare payment amounts for similar or reasonably comparable items or services. Under this criterion, final publication of payment amounts in official source documents includes correction notices that are published after the initial publication.
- It received prior notice from the peer review organization, intermediary, or carrier of the correct Medicare payment for the items or services furnished or for similar or reasonably comparable items or services.
- It gave the individual prior notice of the correct Medicare payment for the items or services furnished or for similar or reasonably comparable items or services.

These proposed criteria are similar to those contained in § 411.406 (''Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary''). Those criteria are used to determine if a provider or supplier is liable for payment of an item or service

under the limitation on liability provisions in section 1879 of the Act because of knowledge that Medicare payment for the item or service would be denied.

Because the criteria we propose in the without fault regulations is based, in part, on the limitation on liability provisions, we propose that a provider or supplier that has already been determined liable under the limitation on liability provisions in section 1879 of the Act for a specific item or service cannot be found without fault with regard to the overpayment for that specific item or service.

c. Without Fault as it Applies to Peer Review Organization Responsibilities. Because this proposed rule would furnish providers and suppliers with appeal rights for determinations that the provider or supplier must repay an overpayment because the provider or supplier is not-without-fault (discussed later), we are considering expanding the responsibility for making without-fault determinations to peer review organizations. Although our final decision may be that intermediaries and carriers make the without-fault determinations for overpayments resulting from peer review organization determinations, we want to provide as much flexibility as possible in exploring this issue. Therefore, we propose revising our regulations to provide peer review organizations with the authority to make without-fault determinations. However, it should be noted that intermediaries, carriers, and peer review organizations that make determinations are acting on behalf of HCFA.

d. Without Fault as it Applies to the Prospective Payment System. Under section 1886(d) of the Act, effective with hospital cost reporting periods beginning on or after October 1, 1983, we established a system of payment for acute inpatient hospital stays under Medicare Part A (Hospital Insurance), based on prospectively-set rates. Under this prospectively-set rate system (the prospective payment system), Medicare payment is made at a predetermined, specific rate for each hospital discharge. All discharges are classified according to a list of diagnosis-related groups. The regulations governing the inpatient hospital prospective payment system are located at 42 CFR part 412.

Regarding payments under the prospective payment system, we are required, under section 1886(e)(5)(B) of the Act, to publish by September 1 of each year a list of diagnosis-related group categories and provide instructions on calculating proper Medicare payment amounts. Thus, hospitals paid under the prospective payment system generally have a way to determine whether a payment is correct or incorrect. Accordingly, these hospitals are generally liable for refunding Medicare overpayments they receive under the prospective payment system because, under most circumstances, they cannot be found to be without fault since they have an independent means of conclusively determining whether the prospective payment system payment they accept is correct.

However, under our proposed rule, a provider may be found to be without fault for payments under the prospective payment system in the event of an error in our prospective payment system publication in the **Federal Register**, relating to the diagnosis-related group for which the hospital was overpaid. In these circumstances, a hospital that can show, based on criteria specified in these proposed regulations, that it did not know and could not reasonably have been expected to know that a Medicare payment based on an erroneous published schedule of payment amounts exceeded amounts payable under the Medicare statute and regulations is considered to be without fault for the overpayment that resulted from the erroneous published schedule of payment amounts. We note, however, that this rule would not apply if a correction notice containing the correct schedule of payment amounts has been published in the **Federal Register** after the initial publication of the erroneous schedule of payment amounts. In this instance, the correction notice imputes the same responsibility for knowledge of the overpayment as a correct published schedule of payment amounts.

If the hospital is without fault, liability shifts to the individual under section 1870(b) of the Act. However, under these circumstances, an individual will also be without fault because there is nothing to indicate that the overpayment resulted from the individual not exercising reasonable care in requesting and accepting Medicare payment, as specified in our regulations. In addition, recovery from the individual may be waived on the basis of ''equity and good conscience'' with respect to Medicare overpayments of this type.

The same rules would also apply for Medicare payment for inpatient hospital capital-related costs. In a final rule published on August 30, 1991 (56 FR 43358), a new subpart M was added to 42 CFR part 412 to provide for a prospective payment system for hospital inpatient capital-related costs. Previously, hospital inpatient operating costs were the only costs covered under the prospective payment system. However, section 1886(g)(1) of the Act now requires that capital-related costs be paid under the prospective payment system effective with cost reporting periods beginning after September 30, 1991, for hospitals paid under the prospective payment system. Implementing regulations are found at § 412.300.

e. Without Fault and Aggregate Overpayment Issues. Under section 1870 of the Act, if a provider is found to be without fault for an overpayment, the individual who received the service for which payment was made is liable for the overpayment. Therefore, application of the without fault provision in section 1870 of the Act is limited to overpayments for individual claims for which lability can ultimately be shifted to a specific individual.

Consequently, the without fault provisions under section 1870 of the Act do not extend to aggregate overpayment issues, such as Medicare cost report errors, because liability for an individual claim cannot be shifted to a specific individual. For certain providers, aggregate overpayments result from payments under a reasonable cost payment methodology in which payment is made on an interim basis throughout the year, with appropriate adjustments made upon settlement of annual cost reports. Because Medicare cost report errors are not directly associated with specific services, liability cannot be shifted from a specific provider to a specific individual.

Thus, the without fault provisions of this proposed rule would not apply to overpayments resulting from aggregate payment issues, such as cost report errors. These overpayments are addressed in section 1878 of the Act, which contains provisions relating to the Provider Reimbursement Review Board and the circumstances under which a provider may obtain a hearing with the Board.

f. Without Fault as it Applies to Payment Under the Medicare Physician Fee Schedule. A major change in Medicare physician payment rules was enacted as part of the Omnibus Budget Reconciliation Act of 1989, (OBRA 1989), Public Law 101–239. Section 6102 of OBRA 1989 added to the Act a new section 1848, ''Payment for Physicians' Services.'' The new section contains three major elements: (1) A new fee schedule for physicians' services based on a Resource-Based Relative Value Scale to replace the reasonable charge payment mechanism; (2) a Medicare volume performance

standard for the rates of increase in Medicare expenditures for physicians' services; and (3) limits on the amounts that nonparticipating physicians submitting unassigned claims can charge individuals for covered services.

We issued a final rule on November 25, 1991, (56 FR 59502) to implement section 1848 of the Act. (The physician fee schedule regulations are set forth at 42 CFR part 414, subpart A.) Section 1848 requires that the fee schedule include national uniform relative values for all physicians' services. The fee schedule is being phased in over 4 years, beginning in 1992, with the new rules fully effective in 1996. During 1992 through 1995, transition provisions generally blend the old payment amount with the fee schedule amount.

At the end of each calendar year, we send each physician and other supplier a schedule of the next year's physician fee schedule amounts. In addition, the fee schedule is published in the **Federal Register** each year. Therefore, all physicians and other suppliers paid under the physician fee schedule are generally in a position to determine whether a payment is correct. Accordingly, physicians and other suppliers are generally liable for refunding Medicare overpayments they receive under this payment system because, under most circumstances, they cannot be found to be without fault since they have an independent way of conclusively determining whether the payment they accept is correct.

However, under our proposed rule, a physician or other supplier may be found to be without fault if an error in the annual fee schedule for the services for which the physician or supplier was overpaid is published in the **Federal Register**. In these circumstances, a physician or other supplier is considered to be without fault for an overpayment resulting from the erroneous schedule if the physician or supplier can show, based on criteria specified in these proposed regulations, that he or she did not know and could not reasonably have been expected to know that a Medicare payment based on an erroneous schedule of payment amounts exceeded amounts payable under the Medicare statute and regulations. We note, however, that this would not be the case if a notice correcting the erroneous schedule has been published.

If the physician or other supplier is found to be without fault, liability shifts to the individual under section 1870(b) of the Act. However, under these circumstances, the individual will also be without fault under our proposed regulations because there is nothing to indicate that the overpayment resulted from the individual not exercising reasonable care in requesting and accepting Medicare payment. In addition, recovery from the individual may be waived on the basis of equity and good conscience with respect to Medicare overpayments of this type.

g. Without Fault As It Applies to Medicare Secondary Payer Obligations. A large proportion of Medicare overpayments results from Medicare secondary payer situations. Because the nature of Medicare secondary payer obligations is somewhat different from other types of Medicare overpayments, in that Medicare secondary payer situations involve a conditional payment and a third party payer, the current regulations addressing without fault pose particular problems for the recovery of Medicare secondary payer obligations.

For example, if a conditional Medicare payment becomes a de facto overpayment (that is, a primary payer pays after Medicare payment) as a result of an individual's action that is unrelated to the filing of a Medicare claim, direct application of the SSA regulations can be difficult. The SSA regulations predate the Medicare secondary payer provisions and, therefore, do not provide for them. Under the current regulations, when an Medicare secondary payer obligation results from a conditional Medicare payment for an individual who is injured in an automobile or other accident, and who subsequently receives a settlement or damage award, the individual is generally considered to be without fault. This is because, within the framework of the SSA regulations, the obligation does not result from failure to supply information because even if the individual informs us of a pending suit we frequently make a conditional payment for the claim.

Thus, when applying the SSA regulations, few circumstances will ever arise when the individual could be found to be at fault in causing an overpayment of this type. This de facto without-fault finding, when coupled with financial or equity considerations, could result in waiving recovery from the individual in the majority of cases, even though the individual may have been instrumental in causing the overpayment.

We do not believe this to be an appropriate outcome in Medicare secondary payer contexts because, under our current operating procedures, all individuals entitled to Medicare receive a Notice of Utilization or an Explanation of Medicare Benefits showing that Medicare has paid for services. Therefore, individuals are informed that Medicare has made a conditional payment. We believe that, because this information is available, a degree of responsibility should be imputed to the individual or the individual's representative. We believe that the individual who elects to pursue subsequent settlement or damage awards for injuries from liability or no-fault insurers or, in some cases, tort-feasors, should be responsible for notifying us of this intent and protecting the proceeds until the Medicare claim is satisfied. If the individual does not take this responsibility, he or she should be found not without fault once a liability insurance payment is made and we seek to recover our conditional payment.

All too often, we are not aware of an individual's liability suit until a liability insurance payment is about to be made, or thereafter. At that point, it is more difficult to assert Medicare's interest, despite the fact that under the Medicare secondary payer statute, Medicare has a priority right of recovery. The Congress intended that Medicare payment would be available to individuals to pay for their covered medical expenses to avoid their having to pay for their medical expenses out-of-pocket. Since Medicare conditionally paid for these medical expenses, Medicare is entitled, under the statute, to reimbursement, as opposed to the individual collecting twice for the same loss—first in the form of a benefit payment and then in the form of a cash settlement.

We propose adding regulations that are specifically applicable to determining without fault for Medicare overpayments resulting from Medicare secondary payer conditional payments. We propose that a provider or supplier will generally be not-without-fault with respect to a Medicare payment in a Medicare secondary payer situation unless the provider or supplier complied with all of the claims filing requirements specified in 42 CFR part 411 and, in the case of providers, the provider agreement provisions in 42 CFR part 489. In addition, we are specifying in these regulations that the without fault provisions do not apply to third party payers or other non-Medicare entities involved in a Medicare secondary payer case.

With regard to individuals in Medicare secondary payer cases, we propose that an individual would not be considered to be without fault if the facts show that the individual failed to notify Medicare within 30 days of the receipt of a payment from an entity that is primary to Medicare or the overpayment resulted because the

individual failed to file a proper claim, as required in regulations, with an entity that is primary to Medicare; made an incorrect statement or withheld information to obtain benefits that were not due him or her; or accepted a payment that he or she should have known was not due.

In some cases we seek recovery of Medicare secondary payer obligations from group health plans as a result of the data match in section 1862(B)(5) of the Act and other procedures. In those situations, it would ordinarily be considered inequitable to recover from the individual, and we will not recover the incorrect Medicare payment from the individual unless the Medicare payment was made to the individual.

In the past, we have required written notification when an individual requests a waiver of recovery of an overpayment. However, on July 10, 1995, we published a proposed rule (60 FR 35544) offering the option of requesting by telephone a review of Part B initial claim determinations. Consequently, we are also proposing in this document that an individual may request to be found without fault and may request waiver by telephoning the contact listed in the notice from the carrier, intermediary, or HCFA.

We also propose to require that, if the individual or the individual's representative received an Explanation of Medicare Benefits or a Notice of Utilization that Medicare made a payment, and the individual subsequently elects to pursue a liability settlement or damage award for an illness or for injuries sustained in an accident, he or she must notify the Medicare contractor within 60 days of filing a suit or a claim with the insurer. Otherwise, he or she cannot be considered to be without fault. Thus, when Medicare is billed for services furnished to an individual, and the individual (or his or her estate) pursues a liability or damage award or payment from another source, he or she must notify the Medicare contractor both when a suit or claim is filed and when payment is received from any source other than Medicare. This notice requirement does not apply in MSP group health plan situations. Failure to furnish the Medicare contractor with both notices will result in the individual (or his or her estate) being ''at fault'' with respect to any resulting Medicare secondary payer obligation.

To ensure that beneficiaries realize their obligation to notify the Medicare contractor as proposed above, we would include these requirements in general program information furnished to Medicare beneficiaries, as well as in material (such as, pamphlets) that are targeted to Medicare secondary payer situations. Also, we would include these new requirements in any notice or communication we send to beneficiaries in connection with potential liability situations.

B. Not-Without-Fault Determinations and the Appeals Process

Under current regulations (405.704(b)(14)), determinations concerning the waiver of adjustment or recovery of overpayments are considered initial determinations, for purposes of the Medicare appeals process, under Medicare Part A and Part B with respect to individuals. These determinations are often based on not-without-fault findings. However, we do not have regulations that address not-without-fault determinations made for providers or suppliers. We believe that our regulations need to be revised to afford providers and suppliers an explicit right to appeal determinations made under section 1870(b) of the Act that they are not without fault and, therefore, that they must repay an overpayment.

Although the Medicare statute does not specifically provide for appeal rights for providers and suppliers regarding a not-without-fault determination, we believe that the administrative appeals process should include that issue. This process will ensure that, when a not-without-fault determination is made, the adversely-affected party has a due process right of appeal that is expressly recognized by regulation.

Therefore, we propose to revise the Medicare appeals regulations to state that, if a provider or supplier that is not without fault receives an initial determination that an overpayment must be refunded, the issue of without fault would also be appealable.

C. Defeats the Purposes of Title II or Title XVIII of the Act and Equity and Good Conscience

If it is determined that an individual entitled to Medicare is without fault, we may waive all or part of a recovery against that individual according to SSA regulations at 20 CFR 404.508 (''Defeat the purpose of title II'') or 20 CFR 404.509 (''Against equity and good conscience; defined''). SSA's definitions of these terms and the examples cited in which they arise reflect SSA's assessment of how this principle applies to recovery from a social security claimant when the claimant has received more than the correct payment due under title II of the Act. There are no illustrations that explain how to apply this principle to a Medicare overpayment situation. As previously noted, an individual entitled to Medicare and a social security claimant are in distinguishable positions with respect to overpayments. For example, the social security claimant is actually receiving a cash benefit. However, the individual entitled to Medicare, in most cases, receives no direct payment. Consequently, the SSA rules are not always directly transferable to a Medicare overpayment situation and provide no clear guidelines for their application to Medicare situations.

In particular, in the case of a Medicare secondary payer overpayment, transferring the SSA regulations for granting a waiver based on financial hardship or equity and good conscience poses a specific problem. Because the SSA regulations predate the existence of the Medicare secondary payer provisions, they were not written with Medicare secondary payer situations in mind and contain no specific illustrations applying to Medicare secondary payer recoveries. In principle, in the Medicare secondary payer context, there is no basis for the existence of financial hardship because the individual either knows or may reasonably be expected to know from the inception of a claim that Medicare has a priority right of recovery (that is, that we can recover our conditional payments directly from the primary payer or from any entity that received payment, directly or indirectly, from the primary payer).

The facts of a particular circumstance, however, do not always support this position. For example, suppose an individual entitled to Medicare has received a cash settlement as a result of a liability suit after receiving Medicare payment. Subsequently, the individual spends the settlement proceeds without repaying Medicare. Within the framework of the SSA regulations, the overpayment does not result from failure to supply information since Medicare pays even if the individual makes us aware of a pending suit. Therefore, the individual passes the first test of being without fault.

The final settlement payment received by the individual as a result of this liability suit could be small enough that an individual could contend that reimbursing Medicare would cause economic hardship or would be inequitable. Thus, it is possible that the individual would not be required to repay Medicare for this type of overpayment because of the application of the SSA regulations addressing without fault coupled with the SSA definitions of ''defeats the purposes of title II or title XVIII'' and ''against equity

and good conscience.'' We believe that the current Medicare overpayment regulations should be revised to not preclude recovery of an overpayment in Medicare secondary payer situations, but be written in a way that does not unfairly disadvantage the individual or the Medicare program.

Additionally, a 1990 Court of Appeals decision indicates that SSA's definition of against equity and good conscience may be too narrow for SSA or Medicare issues. In the court case, a social security claimant challenged SSA's waiver denial determination that, although he was without fault in causing the overpayment, recovery would not defeat the purpose of title II or be against equity and good conscience. In an unreported decision, the District Court for the Western District of Washington upheld the waiver denial. However, the Court of Appeals for the Ninth Circuit reversed the decision, holding that requiring the plaintiff to repay the overpayment would be against equity and good conscience. (*Quinlivan* v. *Sullivan,* 916 F.2d 524 (9th Cir. 1990)).

The Court indicated that, although the Act does not define the phrase against equity and good conscience, the Secretary has interpreted it, in 20 CFR 404.509, to be narrowly limited to situations when (1) the claimant changed his or her position for the worse, (2) relinquished a valuable right, or (3) lived in a separate household from the overpaid person at the time of the overpayment and did not receive the overpayment.

The Court was of the opinion that the Congress intended to broaden the availability of the waiver (*id*. at 526). Accordingly, the Court concluded that ''the meaning of the phrase, 'against equity and good conscience,' cannot be limited to the three narrow definitions set forth in the Secretary's regulations. The Congress intended a broad concept of fairness to apply to waiver requests, one that reflects the ordinary meaning of the statutory language and considers the facts and circumstances of each case'' (*id*. at 527). The Court favored the against equity and good conscience interpretation used by the Department of Veterans Affairs (VA) in its regulations at 38 CFR 1.965 (July 1, 1988 edition), published on July 19, 1974 (39 FR 26400) (*id*. at 526 and 527, n.2).

The cited VA regulation indicates that the application of the standard, ''equity and good conscience,'' will be applied when the facts and circumstances in a particular case indicate a need for reasonableness and moderation in the exercise of the Government's rights. Under the VA regulations, equity and good conscience means arriving at a fair decision between the obligor and the Government that is not unduly favorable or adverse to either side.

In making a determination of equity and good conscience, the VA regulation specified that consideration should be given, but should not be limited, to the following elements: (1) Fault of the debtor; (2) balance of faults; (3) undue hardship; (4) defeats the purpose for which benefits were intended; (5) unjust enrichment; and (6) changed position to one's detriment. In applying this single standard for all areas of indebtedness, the VA regulation further indicates that consideration should be given to the elements of (1) fraud or misrepresentation of a material fact, (2) material fault, and (3) lack of good faith; any one of which, if found, would preclude the granting of a waiver.

Because the *Quinlivan* case related to a social security claimant, we are not bound to follow that decision. However, a 1993 District Court decision found that we were not using broad concepts of fairness in reviewing waivers in Medicare secondary payer liability cases, nor had we told our decision makers to ''base the waiver determination on the totality of the circumstances.'' We submitted substantial materials to the court to reflect our actual policies (contrasted with the policies reflected in the SSA regulations) with regard to waiver of recovery in Medicare secondary payer liability cases. However, despite those representations, the court ordered us to formalize these policies by way of written guidelines to ensure their application, instead of the SSA policies, when reviewing whether waiver should be granted under equity and good conscience in Medicare secondary payer liability situations. The court, making reference to the *Quinlivan* case, further ordered that the guidelines incorporate broad concepts of fairness and not limit waivers to the three factual situations listed in 20 CFR 404.509. (*Zinman* v. *Shalala,* Civ. No. 90–20674 (N.D. Cal. September 24, 1993 and November 29, 1993)). The September ruling is reported at 835 F. Supp. 1135 (N.D. Cal. 1993).

As a result of that court ruling, we issued guidelines to all of our regional offices on November 17, 1994. In those guidelines, we incorporated our longstanding interpretation of against equity and good conscience as that principle relates to Medicare overpayments. While the guidelines were issued to apply to Medicare secondary payer liability overpayment situations, we advised that they could also be used as guidance in overpayment situations other than those involving Medicare secondary payer liability cases.

We have always taken the broader view of equity and good conscience that the *Quinlivan* and *Zinman* Courts endorsed. Not only do we find the Courts' reasoning in those cases to be persuasive, we also find the language of the VA regulation to be a useful guide. Accordingly, in formulating standards for applying equity and good conscience to Medicare situations for the guidelines issued in November 1994, we have not only expressed our long-held expansive view of this concept, we have also incorporated, to the extent possible, the VA approach in expressing that policy.

We propose to incorporate into our regulations our current policies regarding when recovery of an overpayment may be waived based on financial hardship. Our current policies are in accordance with SSA's definition of defeat the purposes of title II or title XVIII. Under this proposed regulation, recovery of an overpayment would defeat the purposes of title II or title XVIII when the individual needs substantially all current income and assets to meet ordinary and necessary living expenses.

We propose to consider the individual's current assets and ordinary and necessary living expenses when evaluating requests for waiver based on financial hardship. Ordinary and necessary living expenses would include the following:

- Current living expenses, such as food and clothing, rent, mortgage payments, utilities, maintenance, insurance (for example, life, accident, and health insurance including premiums for Part B Medicare), taxes, and installment payments.
- Current medical, hospitalization, and other related expenses not covered by Medicare or another insurer.
- Expenses for the support of others for whom the individual is legally responsible.
- Other miscellaneous expenses that may reasonably be considered necessary to maintain the individual's current standard of living.

In addition, we propose to include in the regulations examples that demonstrate how the principles of defeat the purposes of title II or title XVIII would be applied in Medicare overpayment situations.

We propose to add regulations that incorporate criteria to be used when determining whether recovery of an overpayment may be waived based on equity and good conscience. Our proposed regulations require that the standard of equity and good conscience would be applied to Medicare

overpayment recoveries using broad concepts of fairness and reviewing the totality of the circumstances in each particular case. We have used as the basis for our proposed regulations both language from the VA regulation on equity and good conscience found at 38 CFR 1.965, which the U.S. Court of Appeals for the Ninth Circuit believes reflects the intent of the Congress, and guidelines that were issued as a result of the Zinman court case (as discussed earlier in this preamble).

Under the proposed regulations, factors to be considered when applying the standard of equity and good conscience include, but are not limited to, the following:

- The amount of the overpayment.
- The size of a liability settlement and the amount the individual would retain if Medicare recovered.
- The degree to which recovery would cause undue hardship for the individual.
- The degree to which Medicare and/or its contractors contributed to causing the overpayment.
- The degree to which the individual contributed to causing the overpayment (even if determined to be without fault in accordance with § 401.355).
- The impact of an accident on the individual, both physically and financially.
- Whether the individual would be unjustly enriched by a waiver of recovery.
- Whether it would be equitable for us to reduce the recovery if the individual is responsible for noncovered accident-related out-of-pocket expenses and/or future accident-related expenses.
- Whether the individual made a personal financial decision based on his or her reliance on erroneous information supplied to the individual by Medicare or SSA, and recovery would change the individual's position to his or her material detriment.

Also, we would provide several Medicare overpayment examples in which waiver of recovery is being sought based on the concepts involved with equity and good conscience to illustrate how those concepts are to be applied.

In some cases an overpayment is made to a without-fault provider or supplier on behalf of a without-fault individual who did not receive the payment. In those situations, we ordinarily would consider recovery from the individual to be inequitable, and would, therefore, waive recovery.

In accordance with section 1870(c) of the Act, we would specify that recovery is deemed to be against equity and good conscience if the overpayment resulted from expenses incurred for items or services for which payment may not be made under Medicare by reason of the provisions of 1862(a)(1) or (a)(9) of the Act (reasonable and necessary or custodial care), and if the Secretary's determination that the payment was incorrect was made after the third year following the year in which notice of that payment was sent to the individual.

The basic concepts embodied in the principle of waiver based on equity and good conscience assume that an individual did not intentionally cause an overpayment. Therefore, we propose that applying the equity and good conscience standard for waiving recovery does not apply if we determine that the individual committed fraud, misrepresentation, or some other action or omission that indicates the individual's lack of good faith in causing an overpayment.

D. Waiver Policy With Regard to Liability Settlement Agreements and Stipulations

In general, Medicare policy requires recovering payments from liability awards or settlements, whether a settlement arises from a personal injury action or a survivor action, without regard to how a settlement agreement stipulates disbursement should be made. This requirement also applies to situations in which the settlements do not expressly address damages for medical expenses. Since liability payments are usually based on the injured or deceased person's medical expenses, liability payments are considered to have been made ''with respect to'' medical services related to the injury even when the settlement does not expressly include an amount for medical expenses. To the extent that Medicare has paid for these services, the law obligates us to seek recovery of Medicare payments.

The only situation in which we recognize allocations of liability payments to nonmedical losses is when the payment is based on a court order on the merits, that is, the court makes a substantive decision on the amounts to be awarded. If the court specifically designates amounts that are for the reimbursement of pain and suffering or other amounts not related to medical services, we will accept the court's designation and not seek recovery from portions of court awards that are designated as payment for losses other than medical services.

Conversely, we do not generally grant waivers if an individual obtains a settlement that is expressly awarded for medical expenses. However, we believe there are circumstances in which waiver could be justified. For example, a situation could arise in which an individual's injury was great but the award of damages was small, or in which the individual incurred bona fide medical expenses (other than deductibles, premiums, and coinsurance) that were not reimbursed by Medicare; that is, out-of-pocket medical expenses. We believe the criteria we propose for equity and good conscience are broad enough that these situations will be taken into consideration when determining whether waiver of recovery should be granted.

E. Waiver Policy With Regard to Estates

Under current law, a deceased individual's estate may request a waiver of adjustment or recovery of an overpayment when the estate (or the now-deceased individual) has effected a liability recovery. Although in these situations an estate (or the now-deceased individual) may be found to have been without fault with respect to notifying us of the third party recovery, it is generally difficult to satisfy the second test for waiver—that recovery from the estate would defeat the purposes of title II or title XVIII or be against equity and good conscience. Because the individual is deceased, he or she does not need the monies to meet ordinary and necessary living expenses or medical expenses. In addition, it is unlikely that the estate would warrant the money based on an argument of detrimental reliance. Therefore, waiver is generally not applied in these situations.

However, when a title II dependent survives a deceased individual (who is without fault), and Medicare's recovery or adjustment of an overpayment from the estate would be made by decreasing payments to the title II dependent, situations could arise in which waiver of adjustment or recovery of the overpayment would be appropriate. Therefore, we propose adding a provision to the regulations that would permit a waiver for an estate if the estate (and the individual) were without fault and the individual had a surviving title II dependent. A waiver would be granted in these situations if recovery from the estate would be made by decreasing payments to the title II dependent and the recovery would defeat the purposes of title II or title XVIII or would be against equity and good conscience.

IV. Provisions of the Proposed Regulations

The existing regulations at §§ 405.301 through 405.359 would be removed.

With the exception of § 405.356, these sections would be replaced by proposed §§ 401.301 through 401.370. The remaining sections of subpart C of part 405 (§§ 405.370 through 405.380) would be redesignated and moved into subpart D of part 401 as §§ 401.375 through 401.396.

These proposed regulations would supersede SSA criteria for Medicare purposes. SSA criteria would no longer have any application to recovering Medicare overpayments.

Generally, this proposed rule clarifies the explicit criteria and circumstances under which a provider, supplier, or individual will be relieved of liability for a Medicare overpayment. Thus, we are proposing no changes to current carrier and intermediary liability in instances when an overpayment results from a carrier or intermediary error. We are aware, however, of the perception that carriers and intermediaries may not be held accountable in instances when an overpayment results from their error. Therefore, we are requesting comments on proposed changes to our current carrier and intermediary standards that might introduce a higher level of accountability when overpayments are the result of carrier or intermediary errors, regardless of whether a provider or supplier was without fault.

As part of the proposed changes to the regulations, we would describe ''recovery'' to include ''adjustment'' as one type of recovery, rather than listing it separately, as in section 1870 of the Act. Under Medicare operations, adjustment is one way we can recover an overpayment from an individual who is found liable for that overpayment. However, we have alternative ways of recovering an overpayment that we often use before adjusting title II or railroad retirement benefits. Therefore, we would include adjustment as one of several ways we may recover from an individual (or his or her estate).

In addition, we would make certain technical changes to the regulations.

Once these proposed regulations are published as final, conforming changes will be made to the appropriate regulations in 20 CFR part 404 to remove references to title XVIII as they relate to without fault.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

However, we believe the information collection requirements referenced in this proposed rule, as summarized below, are exempt from the Paperwork Reduction Act of 1995 for the following reasons:

The requirements in this proposed rule are either facts or opinions obtained or solicited through non-standardized follow-up questions designed to clarify responses to approved collections of information, initiated on an individual basis, and/or are performed in the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or organizations (see title 5 § 1320.3(c), 1320.3(h)(9), and/or 1320.4(a)(2)).

Section 401.352 Waiver of Recovery of Overpayment From Individuals

Section 401.352 requires an individual desiring a waiver of recovery of an overpayment to request the waiver within 60 days from the date on the written notification from HCFA that he or she is liable for the overpayment.

Section 401.364 Without Fault and Medicare Secondary Payer (MSP) Obligations

Section 401.364 requires an individual to give notice of receipt of a payment from an entity that is primary to Medicare and requires an individual desiring a waiver of recovery of an MSP obligation to request the waiver within 60 days from receipt of written notification from HCFA that he or she is liable for the obligation.

Section 411.23 Individual's Cooperation

When HCFA makes conditional payments, § 411.23 requires an individual to notify HCFA of the progress and final outcome of the liability claim. The individual must notify the intermediary or carrier within 60 days of filing a claim with an entity that is primary to Medicare and notify HCFA within 30 days of receipt of payment from an entity primary to Medicare.

Organizations and individuals desiring to submit comments should send them to both the following addresses:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: HCFA–1719–P.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

VI. Regulatory Impact Statement

A. Introduction

This proposed rule clarifies our right and responsibility to recover overpayments, and the conditions under which recovery of overpayments may be waived. Under the Medicare statute, when a Medicare overpayment occurs, and a provider or supplier is found to be without fault, the liability is passed on to the individual. Medicare then seeks recovery from the individual or waives the recovery.

Our present regulations do not clearly differentiate an individual's responsibilities from provider and supplier responsibilities with regard to overpayment liability and recovery. This proposed rule describes the conditions for determining who is at fault for the overpayment; specifies criteria for determining the liability of providers, suppliers, and individuals; and describes the circumstances under which recoveries from individuals can be waived.

In addition, this proposed rule would provide for the administrative appeals process to include determinations when a provider or supplier is found to be at fault in causing an overpayment. Also, this proposed rule more specifically defines without fault with respect to Medicare secondary payer situations as well as the conditions for waiver of adjustment or recovery of Medicare overpayments in Medicare secondary payer situations.

We expect the main effect of this proposal would be to prevent some providers and suppliers from claiming without-fault status. This could reduce the number of overpayment liabilities passed on to individuals and result in a slight increase in the amount of money recovered. We estimate that this proposed rule would result in

additional overpayment recoveries for 5 fiscal years as follows:

ESTIMATED ADDITIONAL RECOVERIES FROM THE MEDICARE PROGRAM PARTS A AND B

[In Millions]

1996	1997	1998	1999	2000
$7	$13	$15	$16	$18

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (5 U.S.C. 601 through 612) we generally prepare a regulatory flexibility analysis unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the Regulatory Flexibility Act, all providers and suppliers are considered to be small entities. Individuals and Medicare contractors are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed 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 Regulatory Flexibility Act. 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 50 beds.

This proposed rule would add regulations that are specifically applicable for determining without fault in general Medicare overpayment situations, as well as for obligations resulting from Medicare secondary payer conditional payments.

Under this proposed rule, a provider or supplier would be required to notify the Medicare contractor in writing within 60 days if any payment exceeds the usual compensation for an item or service under Medicare. A Medicare contractor would be required to respond to a provider or supplier within 120 days of receipt of a written inquiry from the provider or supplier questioning the correctness of a Medicare payment amount.

For Medicare secondary payer situations, an individual pursuing a claim for a liability settlement or damage award for illness or injuries sustained in an accident would be required to notify the Medicare contractor within 60 days of filing a suit or a claim with an insurer. In addition, an individual would be required to notify the Medicare contractor within 30 days of receiving a payment from a liability insurer or, in certain circumstances, direct payment for a tort-feasor.

This proposed rule would not place an unreasonable burden on individuals, providers, suppliers, or Medicare contractors. We believe that the time required for individuals, providers, suppliers, or Medicare contractors to comply with the provisions of this proposed rule would be minimal. As in the past, providers and suppliers would be required to exercise reasonable care in billing for and accepting payment from Medicare.

For these reasons, we have determined that this proposed rule would not result in a significant economic impact on a substantial number of small entities and would not have a significant economic impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for either the Regulatory Flexibility Act or section 1102(b) of the Act.

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

VI. Other Information

A. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. However, we will consider all comments that are received by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 403

Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 466

Grant programs-health, Health care, Health facilities, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 473

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 493

Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended, under the authority of sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), as follows.

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

A. Part 401 is amended by adding a new subpart D to read as follows:

Subpart D—Recovery of Overpayments, Suspension of Payment, and Repayment of Scholarships and Loans

General Provisions

401.301 Basis and scope.
401.303 Definitions.

Liability for Payments to Providers and Suppliers and Handling of Incorrect Payments

401.305 Individual's liability for incorrect payments.

Medicare Debts Arising from an Overpayment to a Provider or to a Supplier that Received Payment on Behalf of an Individual

401.310 Overpayments.

401.320 Liability of a provider or a supplier.
401.323 Determining without fault for a provider or a supplier.
401.326 When a provider or a supplier is relieved of liability.
401.329 Recovery of overpayment from providers or suppliers: General rule.

Medicare Debts Arising from an Overpayment to an Individual

401.340 Liability of an individual.
401.343 Overpayment limitation for the individual.
401.346 Recovery of overpayment from the individual.
401.349 Adjustment against an individual's title II or railroad retirement benefits.
401.352 Waiver of recovery of overpayment from individuals.
401.355 Determining without fault for an individual.
401.358 Defeat the purposes of title II or title XVIII of the Act.
401.361 Equity and good conscience.
401.364 Without fault and Medicare Secondary Payer (MSP) obligations.
401.367 Initial determination.
401.370 Liability of certifying or disbursing officer.

Suspension of Payment to Providers and Suppliers and Collection and Compromise of Overpayments

401.375—401.390 [Reserved]

Interest

401.393 [Reserved]

Repayment of Scholarships and Loans

401.396 [Reserved]

Subpart D—Recovery of Overpayments, Suspension of Payment, and Repayment of Scholarships and Loans

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

General Provisions

§ 401.301 Basis and scope.

(a) *Statutory basis.* This subpart is based on the indicated provisions of the following sections of the Act:

1815—Payment to providers of services (Part A).

1833—Payment of benefits (Part B).

1842—Use of carriers for administration of benefits.

1848—Payment for physicians' services.

1866—Agreements with providers of services.

1870—Overpayment on behalf of individuals and settlement of claims for benefits on behalf of deceased individuals.

1879—Limitation on liability of individual if Medicare claims are disallowed.

1886—Payment to hospitals for inpatient hospital services.

1892—Offset of payments to individuals to collect past-due obligations arising from breach of scholarship and loan contracts.

(b) *Scope.* (1) This subpart sets forth the policies and procedures for processing incorrect payments and recovering overpayments under the Medicare program and for offsetting payments to collect past-due obligations arising from breach of scholarship and loan contracts.

(2) When the term ''HCFA'' is used in reference to making determinations, it includes intermediaries, carriers, or PROs, as appropriate.

§ 401.303 Definitions.

(a) *Person* (for purposes of this subpart) means an individual, a trust or estate, a partnership, or a corporation.

(b) *Supplier* has the meaning given in § 400.202 of this chapter.

Liability for Payments to Providers and Suppliers and Handling of Incorrect Payments

§ 401.305 Individual's liability for incorrect payments.

(a) In accordance with section 1870(a) of the Act, any payment made under title XVIII of the Act to any provider or supplier with respect to any item or service furnished an individual is regarded as a payment to the individual, and recovery is made in accordance with §§ 401.346 through 401.352 if any of the following conditions exists:

(1) More than the correct amount is paid to a provider or supplier and the intermediary, the carrier, or HCFA determines that—

(i) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider or supplier, or

(ii) The provider or supplier was without fault with respect to the payment of the excess.

(2) A payment has been made to a provider for inpatient hospital services furnished to a noneligible individual before notification of noneligibility, in accordance with the provisions described in section 1814(e) of the Act.

(b) For purposes of paragraph (a)(1)(ii) of this section, a provider or supplier is, in the absence of evidence to the contrary, deemed to be without fault if the determination by HCFA, that more than the correct amount was paid, was made after the third year following the year in which notice was sent to the individual that the amount had been paid.

Medicare Debts Arising From an Overpayment to a Provider or to a Supplier That Received Payment on Behalf of an Individual

§ 401.310 Overpayments.

(a) *Definition.* An overpayment consists of Medicare funds a provider, a supplier, or an individual has received in excess of amounts payable under the Medicare statute and regulations.

(b) *Types of overpayments.* Overpayments are of the following types:

(1) Overpayment to a provider that received payment on behalf of an individual (including an overpayment resulting from payment for inpatient hospital services furnished to a noneligible individual before notification of noneligibility in accordance with section 1814(e) of the Act and an overpayment to a provider determined from a cost report under part 413 of this chapter or under the prospective payment systems (PPS) included in part 412 of this chapter).

(2) Overpayment to a supplier that received payment on behalf of an individual.

(3) Direct overpayment to an individual or to a person acting on behalf of an individual.

(c) *Examples of causes of Medicare overpayments.* Examples of how Medicare overpayments occur include, but are not limited to, the following:

(1) Payments made by Medicare for noncovered services.

(2) Medicare payment in excess of the allowable amount for an identified covered service.

(3) Errors and nonreimbursable expenditures in cost reports.

(4) Duplicate payments.

(5) Medicare payment when another entity had the primary responsibility for payment.

(d) *When an overpayment is considered a debt.* (1) *General Overpayments.* Once a determination and any adjustments in the amount of the overpayment have been made, the remaining amount is a debt owed to the United States Government.

(2) *Medicare Secondary Payer (MSP) obligations.* Potential debts arise under the MSP provisions when an individual recovers payment from an entity that had the primary responsibility for payment. Obligations to refund Medicare under the MSP provisions are addressed in part 411, subparts B through F of this chapter and § 401.364.

§ 401.320 Liability of a provider or a supplier.

(a) In accordance with section 1870(b), unless found to be without

fault, as described in this subpart, a provider or a supplier that receives Medicare payment with respect to items or services furnished to an individual is liable for any overpayment resulting from that payment.

(b) HCFA makes determinations whether providers or suppliers are without fault with respect to overpayments.

§ 401.323 Determining without fault for a provider or a supplier.

(a) *General rule.* In accordance with section 1870(b) of the Act, a provider or a supplier is without fault if—

(1) Based on the criteria specified in paragraph (b) of this section, the facts show that the provider or the supplier exercised reasonable care in billing for and accepting Medicare payment; and

(2) Based on the criteria specified in paragraph (c) of this section, the facts show that the provider or the supplier either—

(i) Did not know, and could not reasonably have been expected to know, that Medicare payment was in excess of amounts payable under the Medicare statute and regulations and, therefore, accepted payment based on a reasonable assumption that the payment was correct; or

(ii) Did know, or could reasonably have been expected to know, that Medicare payment was in excess of amounts payable under the Medicare statute and regulations but questioned the appropriate intermediary or carrier in writing, at the correct address, within 60 days of receipt of the excess payment, and—

(A) Relied on a written response from the intermediary or carrier that stated that the Medicare payment was correct; or

(B) Failed to receive a response from the intermediary or carrier within 120 days of the intermediary's or carrier's receipt of the inquiry.

(b) *Exercising reasonable care in billing.* Exercising reasonable care in billing includes—

(1) Making full disclosure of all material facts; and

(2) Complying with each applicable provision specified in subpart C of part 424 of this chapter, including supplying all necessary information on the billing form (or through electronic media), to ensure correct payment by the intermediary or carrier.

(c) *Criteria for determining that a provider or a supplier knew that the payment was an excess payment.* A provider or a supplier is considered to have known that the Medicare payment was in excess of amounts payable under the Medicare statute and regulations if any one of the conditions specified in paragraphs (c)(1) through (c)(3) of this section is met.

(1) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider or the supplier knew, or could have been expected to know, that Medicare payment was in excess of amounts payable under the Medicare statute and regulations on the basis of—

(i) Final publication (including any published correction notice) of payment amounts in official source documents, for example, the **Federal Register** (except in very limited circumstances, as provided for in paragraph (h)(1) of this section);

(ii) Receipt of HCFA notices, either written or electronic, including manual issuances, bulletins or other written guides, or directives from intermediaries, carriers, or PROs; or

(iii) Experience with Medicare payment amounts for similar or reasonably comparable items or services.

(2) *Notice from the PRO, intermediary, or carrier.* Before the items or services were furnished, the PRO, intermediary, or carrier had informed the provider or supplier of the correct Medicare payment for the items or services furnished or for similar or reasonably comparable items or services.

(3) *Notice from the provider or supplier to the individual.* Before the items or services were furnished, the provider or the supplier informed the individual of the correct Medicare payment for the items or services furnished, or for similar or reasonably comparable items or services.

(d) *Intermediary or carrier fault.* Determination of without fault, as specified in paragraph (a) of this section, pertains solely to the liability of the provider or the supplier. Even when HCFA's or an intermediary's or carrier's actions cause or contribute to the overpayment, that fact does not relieve the provider or the supplier from liability for repayment if the provider or the supplier is not without fault.

(e) *Intermediary and carrier action.* (1) The Medicare intermediary or carrier, as appropriate, must provide a written response within 120 days of receipt of a correctly addressed written inquiry regarding the correctness of a Medicare payment amount. If the intermediary or carrier informs the provider or the supplier that the payment amount is correct, or fails to reply within 120 days, the provider or the supplier is without fault even if the intermediary or carrier should later discover that the questioned payment amount was an overpayment.

(2) The 120-day limitation for the response applies only to an evaluation of the correctness of the payment amount. If the evaluation indicates that the payment amount is incorrect, the intermediary or carrier must send a notice to that effect to the provider or supplier within the 120-day period. Once a timely notice has been sent, the intermediary or carrier may determine the precise amount of the overpayment and initiate recovery procedures without regard to the 120-day limitation.

(f) *When a provider or a supplier is considered to be not without fault.* There are some circumstances when a provider or a supplier will never be without fault. A provider or a supplier is not without fault if any of the following conditions exist:

(1) It did not exercise reasonable care in billing for and accepting payment, in accordance with criteria specified in paragraph (b) of this section.

(2) It accepted a Medicare payment that it knew, or could reasonably have been expected to know, was in excess of amounts payable under the Medicare statute and regulations, as determined by criteria specified in paragraph (c) of this section.

(3) It has already been determined, in accordance with the limitation on liability provisions of section 1879 of the Act and § 411.406 of this chapter, that the provider or the supplier knew, or could reasonably have been expected to know, that the specific items or services (for which a without fault determination is being made) would not be paid for by Medicare.

(4) The overpayment resulted from a payment that did not conform to the applicable published schedule payment amount, as explained in paragraph (h)(2) of this section.

(5) The overpayments resulted from payment for noncovered services that were a part of a pattern of billing for similar services that the provider or the supplier knew or should have known were noncovered.

(6) The overpayment resulted from the failure of the provider or the supplier, in making a claim for payment, to comply with a provision of subpart C of part 424 of this chapter.

(7) The overpayment resulted from a payment by a workers' compensation plan, a liability or no-fault insurer, or group health plan for the same service paid for by Medicare.

(8) Fraud or similar fault has been determined. Similar fault includes situations when a provider or supplier obtains a provider number from a carrier

or intermediary while excluded from the Medicare program and when a provider or supplier hires and seeks reimbursement for services performed by excluded individuals.

(g) *Overpayments that result from Medicare provider cost report errors.* The without fault provisions in this section do not apply to overpayments that result from aggregate payment issues, such as Medicare provider cost report errors.

(h) *Special rule for physician fee schedule and prospective payment system (PPS) diagnosis-related group (DRG) schedule and Medicare fee or rate schedule amounts.* HCFA publishes fee schedules that establish payment amounts for physician services and rates of payment for services furnished under the hospital PPS as indicated by a specific DRG. Other fee schedules or rates of payment may be established from time to time. Except as provided in paragraph (h)(1) of this section, the final publication of these payment amounts in official source documents is evidence that a provider or a supplier could have been expected to know that the payment amount was in excess of amounts payable under the Medicare statute and regulations, as specified in paragraph (c)(1)(i) of this section.

(1) In the case of an error in a schedule of payment amounts published in the **Federal Register** (for which no correction notice has been published), a provider or a supplier that can show, based on criteria specified in paragraphs (c)(1)(ii) or (c)(1)(iii), (c)(2), and (c)(3) of this section, that it did not know, and could not have been expected to know, that a Medicare payment based on the erroneous published schedule of payment amounts was in excess of amounts payable under the Medicare statute and regulations, is without fault with respect to the resulting overpayment.

(2) When an overpayment occurs because a payment does not conform to the applicable published schedule, a provider or a supplier is not without fault.

(i) *Without fault presumption: Three-year rule.* In accordance with section 1870(b) of the Act, if HCFA determines that more than the correct amount was paid to a provider or supplier, and this determination was made after the third calendar year following the year in which the notice was sent to the provider or supplier that payment had been made (or, in the case of Part A benefits, approved), the overpaid provider or supplier is considered without fault unless one of the following conditions exist:

(1) The overpayment resulted from a payment that did not conform to the applicable published schedule payment amount, as explained in paragraph (h)(2) of this section.

(2) The overpayment resulted from payment for noncovered services that were a part of a pattern of billing for similar services that the provider or the supplier knew, or should have known, were noncovered.

(3) The overpayment resulted from the failure of the provider or the supplier, in making a claim for payment, to comply with a provision of subpart C of part 424 of this chapter.

(4) The overpayment resulted from a payment by a workers' compensation plan, a liability or no-fault insurer, or group health plan for the same service paid for by Medicare.

(5) The overpayment resulted from fraud or similar fault. Similar fault includes situations when a provider or supplier obtains a provider number from a carrier or intermediary while excluded from the Medicare program and when a provider or supplier hires and seeks reimbursement for services performed by excluded individuals.

§ 401.326 When a provider or a supplier is relieved of liability.

A provider or a supplier is relieved of liability for refunding an overpayment when it is found to be without fault under the criteria in this subpart. When a provider or a supplier is determined to be without fault, liability for the overpayment shifts to the individual. See § 401.340 (concerning the liability of an individual).

§ 401.329 Recovery of overpayment from providers or suppliers: General rule.

When it is determined that a provider or a supplier is liable for an overpayment, HCFA uses the following methods to recover the overpayment:

(a) Direct collection.

(b) Recoupment or offset against any monies that HCFA owes the provider or supplier.

(c) Offset against a Federal tax refund under authority of 31 U.S.C. 3720A.

Medicare Debts Arising From an Overpayment to an Individual

§ 401.340 Liability of an individual.

(a) *Direct payment imputed.* In accordance with section 1870(a) of the Act, a Medicare payment made to a provider or a supplier with respect to any item or service furnished to an individual is considered as if it were a payment to the individual.

(b) *Scope of individual's potential liability.* In accordance with section 1870(b) of the Act, subject to the provisions in §§ 401.346 through 401.352, an individual is liable for an overpayment if any of the following situations occur:

(1) An amount is paid to an individual that is more than the amount payable under the Medicare statute and regulations.

(2) An amount is paid to a provider or a supplier for items or services furnished to the individual that is more than the amount payable under the Medicare statute and regulations, and HCFA determines that—

(i) The overpayment cannot be recouped from the provider or the supplier within a reasonable period of time; or

(ii) The provider or the supplier was without fault, as described in § 401.323, with respect to the overpayment.

(3) Payment was made to a provider for items and services furnished to an individual under the provisions described in section 1814(e) of the Act (''Payment for Inpatient Hospital Services Prior to Notification of Noneligibility'').

§ 401.343 Overpayment limitation for the individual.

If an overpayment has been made to a provider or a supplier, the individual is liable only to the extent that he or she has benefited from that payment, for example, when the Medicare payment exceeds the charges for which the individual was legally responsible.

§ 401.346 Recovery of overpayment from the individual.

If an individual is liable for an overpayment (that is, a payment described in § 401.340(b)), recovery, to the extent of the liability, is made in one of the following ways:

(a) By direct collection against the individual (or his or her estate if the individual has died).

(b) By adjustment of title II or railroad retirement benefits, in accordance with section 1870(b)(3) and 1870(b)(4) of the Act, in one of the following ways:

(1) By decreasing any payment under title II of the Act or under the Railroad Retirement Act of 1974 (45 U.S.C. 231) to which the individual is entitled.

(2) By decreasing, if the individual has died before recovery is completed, any payment under title II of the Act or under the Railroad Retirement Act of 1974 that is based on the individual's earnings record (or compensation) and payable to the individual's estate or to any other person.

(c) By offset against a Federal tax refund under authority of 31 U.S.C. 3720A.

(d) By applying the requirements and procedures that implement the Federal

Claims Collection Act (FCCA) (31 U.S.C. 3711) with respect to Medicare payments and the general FCCA regulations set forth at § 401.387 and subpart F of this part. If HCFA's regulations fail to address a particular issue, refer to 45 CFR part 30.

§ 401.349 Adjustment against an individual's title II or railroad retirement benefits.

(a) *Certification of amount that will be adjusted.* In accordance with section 1870(b) of the Act, as soon as practicable after any adjustment against an individual's title II or railroad retirement benefits is determined to be necessary, HCFA certifies to SSA the amount of the overpayment or payment with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the railroad retirement benefits, the certification is made to the Railroad Retirement Board.

(b) *Procedures for recovery by adjustment of benefits.*

(1) The procedures applied in making an adjustment to title II benefits are the applicable procedures of 20 CFR 404.502.

(2) The procedures applied in making an adjustment to railroad retirement benefits are the applicable procedures of 20 CFR part 367.

§ 401.352 Waiver of recovery of overpayment from individuals.

(a) The provisions of § 401.346 are not applied and there is no recovery of an overpayment made under § 401.340(b) if—

(1) The overpayment has been made with respect to an individual who is without fault, as specified in § 401.355, or the recovery would be made by decreasing payment to which another person who is without fault is entitled, as provided in section 1870(c) of the Act; and (2) The recovery would either—

(i) Defeat the purposes of title II or title XVIII of the Act, as specified in § 401.358; or

(ii) Would be against equity and good conscience, as specified in § 401.361.

(b) An individual desiring a waiver of recovery of an overpayment must request the waiver within 60 days from the date on the written notification from HCFA that he or she is liable for the overpayment.

(c) A waiver granted in accordance with § 401.358 or § 401.361 may be granted partially or in full.

(d) HCFA determines whether waiver of recovery of an overpayment for which an individual is liable under this subpart will be granted.

(e) A waiver of recovery of an overpayment may be granted to a deceased individual's estate if all of the following conditions exist:

(1) The estate and the deceased individual are without fault.

(2) The deceased individual is survived by a title II dependent.

(3) Recovery of the overpayment from the estate would be made by decreasing payments to the title II-dependent. (4) The recovery would defeat the purposes of title II or title XVIII, as defined in § 401.358, or would be against equity and good conscience, as defined in § 401.361.

§ 401.355 Determining without fault for an individual.

(a) *General.* In accordance with section 1870(c) of the Act, a determination of without fault pertains to the liability of the individual. Even when HCFA's actions cause or contribute to the overpayment, that fact does not relieve the individual from liability for repayment if the individual is not without fault. In determining whether a individual is without fault, HCFA considers all pertinent circumstances, including the individual's age, intelligence, education, and physical and mental condition. (See § 401.364(d) for application of without fault for an individual with respect to a Medicare payment in an MSP situation.)

(b) *Reasonable care standard.* An individual is considered without fault with respect to an overpayment made to him or her, or to a provider or a supplier on his or her behalf, if the individual has exercised reasonable care in requesting and accepting Medicare payment. The individual, or other person acting on behalf of the individual, has exercised reasonable care when he or she has—

(1) Accepted a payment that the individual, or other person acting on behalf of the individual, did not know, or could not reasonably have been expected to know, was incorrect;

(2) Accepted a payment because of reliance on erroneous written information from an official source within HCFA, SSA, or a Medicare intermediary or carrier with respect to the interpretation of a pertinent provision of the Act or implementing regulations; or

(3) Made a reasonable assumption, based on available information including, but not limited to, Medicare instructions and regulations, that the payment was correct.

(c) *When an individual is considered to be not without fault.* There are some circumstances in which an individual will never be without fault. An individual is considered to be not without fault for an overpayment when the individual, or other person acting on behalf of the individual, has—

(1) Received prior written notice that a particular item or service was not covered or paid for by Medicare;

(2) Made an incorrect statement or withheld information to obtain benefits that were not due the individual;

(3) Accepted a payment that he or she knew or should have known was not due; or

(4) Received a prior determination, in accordance with the limitation on liability provisions in section 1879 of the Act and § 411.404 of this chapter, that he or she knew, or could reasonably have been expected to know, that the specific items or services (for which a without fault determination is being made) would not be paid for by Medicare.

§ 401.358 Defeat the purposes of title II or title XVIII of the Act.

(a) *General.* The standard of defeat the purposes of title II or title XVIII, contained in section 1870(c) of the Act, means that recovery of all or part of the overpayment frustrates the purposes of benefits under these titles by depriving an individual (or surviving title II dependent) of income required for ordinary and necessary living expenses.

(b) *Ordinary and necessary living expenses.* For purposes of this subpart, an individual's ordinary and necessary living expenses include the following expenses:

(1) Current living expenses, such as food and clothing, rent, mortgage payments, utilities, maintenance, insurance (for example, life, accident, and health insurance, including premiums for Supplementary Medical Insurance benefits under title XVIII and premiums for Medigap insurance), taxes, and installment payments.

(2) Current medical, hospitalization, and other related expenses not covered by Medicare or another insurer.

(3) Expenses for the support of others for whom the individual is legally responsible.

(4) Other miscellaneous expenses that may reasonably be considered necessary to maintain the individual's current standard of living.

(c) *Example.* An individual entitled to Medicare, who was also receiving title II benefits, was injured in a slip and fall accident. He pursued a liability suit and received a settlement. However, after a pro rata share of procurement costs were deducted, he was left with an amount that was smaller than, or close to, Medicare's claim amount. As a result of expenses related to the accident, he has a monthly budgetary shortfall and does not have savings. In

addition, the individual has out-of-pocket medical expenses. If Medicare were to recover the overpayment by adjusting the individual's title II benefit, he would be deprived of income necessary for ordinary and necessary living expenses. Assuming that the individual is without fault, his liability for the overpayment may be waived partially or in full based on financial hardship. (The fact that the individual is left with a settlement amount that is smaller, or close to, what Medicare would recover does not automatically permit waiver of the recovery under this regulation. The final determination would depend on the total amount of the individual's settlement and his other financial circumstances.)

§ 401.361 Equity and good conscience.

(a) *General rule.* The standard of equity and good conscience, contained in section 1870(c) of the Act, is applied to title XVIII overpayment recoveries using broad concepts of fairness and reviewing the totality of an individual's circumstances in each particular case.

(b) *Factors to be considered.* In applying the standard of equity and good conscience, factors to consider include, but are not limited to, the following:

(1) The amount of the overpayment.

(2) The size of a liability settlement and the amount the individual would retain if Medicare recovered.

(3) The degree to which recovery would cause undue hardship on the individual.

(4) The degree to which Medicare and/or its contractors contributed to causing the overpayment.

(5) The degree to which the individual contributed to causing the overpayment (even if determined to be without fault in accordance with § 401.355.

(6) The impact of an accident on the individual both physically and financially.

(7) Whether the individual would be unjustly enriched by a waiver of recovery.

(8) If the individual is responsible for noncovered accident-related out-of-pocket expenses and/or future accident-related expenses, whether it would be equitable for Medicare to reduce its recovery.

(9) Whether the individual made a personal financial decision based on his or her reliance on erroneous information supplied to the individual by Medicare or SSA, and recovery would change the individual's position to his or her material detriment.

(c) *Examples in which waiver of recovery is being sought based on the concepts involved with equity and good conscience.* Assuming that the individual is without fault in accordance with § 401.355, the following examples illustrate situations in which waiver of recovery is sought based on the concepts involved with equity and good conscience and how those concepts are to be applied. The purpose of these examples is to illustrate both the application of the basic principles of the equity and good conscience standard and that each individual case must be evaluated on the basis of its particular facts and circumstances.

Example 1

Facts: As a result of an accident, an individual's leg was amputated below the knee, and he was confined to a nursing home. He filed suit for the injuries and damages he suffered as a result of the accident. The settlement he received was just a few hundred dollars more than Medicare's claim amount (after a pro rata share of procurement costs were deducted). The individual has substantial outstanding medical bills that will not be reimbursed by Medicare or another insurer.

Analysis: In determining whether waiver may be granted on the basis of equity and good conscience, HCFA may take into consideration that the accident has had a significant impact on the individual, both physically and financially, in that he must not only deal with the physical trauma of the leg amputation, but also with being confined to the nursing home with its resultant increased nursing care costs. In addition, the individual will retain only a few hundred dollars of his settlement if Medicare seeks full recovery, and will still have substantial remaining medical bills he will be responsible to pay. This situation could cause undue hardship for the individual.

Action: Given the significant impact that the accident has had on the individual, both physically and financially, HCFA may find that it is against equity and good conscience to recover and may grant a full waiver.

Example 2

Facts: As a result of an accident, a 26-year-old individual is rendered a ventilator-dependent quadriplegic. (The individual was eligible for Medicare prior to the accident because of a disabling condition that occurred several years ago; however, he had been able to care for himself without outside assistance.) The individual pursued a liability claim after the accident and received a settlement that was twice the amount of Medicare's potential claim (after a pro rata share of procurement costs were deducted). The individual needs all of his income and settlement proceeds to finance 24-hour nursing care, upon which he will be totally dependent for the remainder of his lifetime, and to enable him to live independently (outside of an institution). In addition, the individual will have future unavoidable accident-related expenses that will not be reimbursed by Medicare or another insurer.

Analysis: In determining whether waiver may be granted on the basis of equity and good conscience, several factors involved in this case should be considered. The individual's young age should be considered as it relates to the expense of being totally dependent on 24-hour nursing care for the remainder of his lifetime. Moreover, he is a ventilator-dependent quadriplegic. Additionally, although he received a settlement that was twice the amount of Medicare's potential recovery, he has substantial accident-related expenses and is likely to have future out-of-pocket expenses that will not be covered by Medicare or another insurer.

Action: HCFA may find that it is against equity and good conscience to recover, and grant full waiver based on the various factors involved in this case. Although the settlement received by the individual is more than Medicare's potential recovery, consideration must be given to the extent of his disability, his need for lifetime 24-hour nursing care, and the future accident-related expenses he is likely to incur.

Example 3

Facts: After being notified in writing by an SSA official that she was eligible for title II and title XVIII benefits, the individual dropped her existing health insurance based on the prospect of receiving health insurance coverage under Medicare. One year later, it was discovered that, due to an error by SSA, her eligibility status was erroneous because she did not have enough qualifying quarters of covered employment under the Act to obtain the required insured status. During that year, the individual was hospitalized, and a significant amount of Medicare benefits was paid on her behalf. Because the individual dropped her previous health insurance coverage, Medicare was her only source of health care coverage during this time. The individual's financial situation is such that recovery of the overpayment would change her financial position for the worse.

Analysis: In determining whether waiver may be granted on the basis of equity and good conscience, HCFA may consider several factors. The fact that the individual made a personal financial

decision based on her reliance on erroneous information supplied by SSA warrants significant consideration. This, in turn, raises the question of whether recovery would change the individual's position to her material detriment, as well as the degree to which she contributed to the overpayment. Since she did not know that she was not entitled to receive the Medicare services (and, in fact, was told otherwise by SSA), it appears that she did nothing to actually contribute to the overpayment other than avail herself of services to which she believed she was entitled.

Action: In this situation, recovery may be waived as against equity and good conscience because the individual, based on erroneous information provided by SSA, relinquished her right to payment from another source, and recovery would change her position to her material detriment.

Example 4

Facts: An individual sustained injuries in an automobile accident that rendered her incapable of operating a motor vehicle unless the vehicle was modified for use by a handicapped person. Medicare made conditional payments on the individual's behalf. The individual filed suit for the injuries and damages she suffered as a result of the accident and received a settlement that was about equal to the amount of Medicare conditional payments made on her behalf. The individual submitted documentation demonstrating that all of the money she received in the settlement was used to purchase a modified vehicle required as a result of the accident and requested a waiver of recovery of the overpayment.

Analysis: If Medicare seeks full recovery, the individual will likely have to sell her modified vehicle to repay Medicare. This modified vehicle is necessary because of the injuries she sustained in the accident and, like the car in which she had the accident, is her only means of transportation. Selling the modified vehicle to repay Medicare would cause her to be without transportation and would place her in a worse position than before the accident. Based on this consideration, and the significant physical impact that the accident has had on the individual, recovery of the overpayment may be against equity and good conscience.

Action: HCFA may grant a waiver in an amount equal to the cost of the vehicle and, based on the various factors involved in this case, including the fact that all of the money she received in the settlement was used to purchase the modified vehicle, could be justified in waiving an additional amount. If the cost of the modified vehicle were less than the settlement amount, HCFA could grant a partial waiver up to the cost of the vehicle.

Note: Using the settlement money to purchase a vehicle was considered appropriate only because the individual required a modified vehicle as a result of her accident. It would be inappropriate to grant waiver simply because the individual chose to purchase another car from the proceeds.

Example 5

Facts: An individual sustained multiple injuries in an automobile accident that caused him to be away from his job (without pay) for 4 months. His monthly income just equals his monthly expenses. The individual received a liability settlement that was about equal to Medicare's potential claim (after a pro rata share of procurement costs were deducted). However, he incurred significant accident-related out-of-pocket medical expenses.

Analysis: In determining whether waiver may be granted on the basis of equity and good conscience, HCFA may take into consideration that the accident has caused the individual to lose 4 months of income, and, thus, his ability to absorb the out-of-pocket medical expenses has greatly diminished. If the individual repaid Medicare the total amount owed, he would be left with no funds with which to pay his out-of-pocket medical expenses. Because of this, it may be equitable for Medicare to reduce its recovery due to the individual's responsibility for noncovered out-of-pocket expenses. Therefore, it would be against equity and good conscience for Medicare to recoup its entire potential recovery amount.

Action: HCFA may grant a partial waiver up to the amount of out-of-pocket expenses.

Example 6

Facts: An individual was injured in an accident that triggered Medicare conditional payments. Before the accident, he was experiencing monthly financial difficulties due to expenses that were not related to the accident. Medicare's recovery after reduction for procurement costs is significantly less than the total liability settlement received by the individual. The individual has several thousand dollars worth of injury-related out-of-pocket medical expenses.

Analysis: Although the individual has monthly financial difficulties that appears to constitute a financial hardship, it must be noted that this financial hardship existed before the accident. It is important to remember that repaying Medicare must be the circumstance that causes financial hardship. Pre-existing financial hardship alone is not a sufficient reason to grant waiver. Additionally, after repaying Medicare and reimbursing himself for out-of-pocket expenses, the individual will still retain a significant portion of the settlement proceeds. The repayment of Medicare's claim will not cause undue hardship. All of these factors must be taken into consideration when making a waiver decision that is not unduly favorable or adverse to either side, but is fair to both the individual and to HCFA.

Action: Based on the circumstances presented in this case, the likely outcome is to deny waiver. Although the individual has substantial out-of-pocket expenses, he would not be unduly disadvantaged if Medicare seeks full recovery because he will still retain a significant portion of his settlement after the recovery.

(d) *Special Rule: When recovery of an overpayment from an individual is ordinarily considered inequitable.* (1) Except for MSP obligations, recovery of an overpayment from a without-fault individual is ordinarily considered to be inequitable if the individual did not receive the payment.

(2) For MSP obligations, recovery from a without-fault individual is considered to be inequitable only if the recovery involves a group health plan and the individual did not receive the Medicare payment.

(e) *Deemed to be against equity and good conscience.* In accordance with section 1870(c) of the Act, recovery of an overpayment, or of such part of an overpayment as is determined would be inconsistent with the purposes of title XVIII of the Act, is deemed to be against equity and good conscience when either of the following conditions exist:

(1) The overpayment resulted from expenses incurred for items or services for which payment may not be made under title XVIII by reason of the provisions of section 1862 (a)(1) or (a)(9) of the Act (reasonable and necessary, or custodial care).

(2) HCFA did not determine that the payment was incorrect until after the third year following the year in which the notice of the payment was sent to the individual.

(f) *Equity and good conscience deemed inapplicable.* In considering whether recovery of a Medicare overpayment should be waived, the application of the standard of equity and good conscience is deemed inapplicable in either of the following circumstances:

(1) The individual committed a fraud or misrepresented a material fact that resulted, directly or indirectly, in the overpayment.

(2) The individual's actions or omissions indicate a lack of good faith or the absence of an honest intention to abstain from taking an unfair advantage of Medicare.

§ 401.364 Without fault and Medicare Secondary Payer (MSP) obligations.

(a) *MSP debt defined.* In general, an MSP debt is an amount owed to the United States Government, once a determination and any recovery adjustments are made to an obligation, that resulted from a payment made by Medicare for an identified item or service and payment for the item or service has been made, can reasonably be expected to be made, or, in certain circumstances, can reasonably be expected to be made promptly, by another entity that is required or responsible under section 1862(b) of the Act to make primary payment. HCFA's rules that govern MSP obligations are located at part 411, subparts B through F of this chapter.

(b) *Application of without-fault provisions to MSP obligations—third-party payor or other non-Medicare entity.* The without-fault and related provisions specified in §§ 401.323 and 401.326 (with respect to providers and suppliers) and in §§ 401.352, 401.355, 401.358, and 401.361 (with respect to individuals entitled to Medicare) do not apply to MSP obligations for which a third-party payer or other non-Medicare entity is liable. A provision in a contract to which a third-party payer or other non-Medicare entity is a party, or a State law provision that governs the relations between the third-party payer or other non-Medicare entity and an individual entitled to Medicare, that gives or purports to give any right of subrogation to the third-party payer or other non-Medicare entity does not confer a right to without-fault consideration for an obligation for which the third-party payer or other non-Medicare entity is responsible.

(c) *Application of without-fault provisions to MSP obligations—providers and suppliers.* In general, a provider or a supplier is not without fault with respect to a Medicare payment in an MSP situation unless it complied with all of the requirements specified in part 411 of this chapter and, in the case of providers, part 489 of this chapter.

(d) *Application of without-fault provisions to MSP obligations—individuals.* (1) In general, an individual is without fault with respect to a Medicare payment in an MSP situation except when the individual (or the individual's representative)—

(i) Fails to give notice as required by § 411.23(a)(1) of this chapter (that is, notice that a claim has been filed with an entity that may be primary to Medicare) to the intermediary or carrier within 60 days of filing the claim;

(ii) Fails to give notice as required by § 411.23(a)(2) of this chapter (that is, notice of receipt of a payment from an entity that is primary to Medicare) to HCFA within 30 days of receipt of a payment;

(iii) Fails to file a proper claim, as defined in § 411.21 of this chapter, with an entity that is primary to Medicare for the item or service for which no proper claim was filed, subject to the recovery provisions in §§ 411.24(l) and 411.32(c) of this chapter;

(iv) Makes an incorrect statement or withholds information to obtain benefits that are not due him or her; or

(v) Accepts a payment that he or she clearly should have known was not due.

(2) An individual who is without fault according to paragraph (d)(1) of this section may have recovery of an MSP obligation (either by adjustment of his or her social security benefit or by direct recovery) waived if the recovery would either—

(i) Defeat the purposes of title II or title XVIII of the Act, as specified in § 401.358; or

(ii) Would be against equity and good conscience, as specified in § 401.361 (a) through (c), (e), and (f).

(3) An individual desiring a waiver of recovery of an MSP obligation must request the waiver within 60 days from receipt of written notification from HCFA that he or she is liable for the obligation.

(4) HCFA may waive recovery, in whole or in part, in accordance with § 401.358 or § 401.361 (a) through (c), (e), and (f) of this subpart.

§ 401.367 Initial determination.

Each of the following determinations is an initial determination for purposes of §§ 405.704(b), 405.704(c), and 405.803(b) of this chapter, as applicable, and the entities are parties for purposes of §§ 405.708 and 405.805 of this chapter:

(a) A determination that a provider or supplier must repay an overpayment because the provider or supplier is not without fault.

(b) A determination that an individual (or the estate of an individual), does not qualify for waiver of adjustment or recovery of overpayments because the individual is, or the estate and the individual are, not without fault.

(c) A determination, with respect to an individual that is (or an estate and individual that are) without fault, that the individual (or estate) does not qualify for waiver of adjustment or recovery of overpayments on the basis that the purposes of title II or of title XVIII of the Act would be defeated, as described in § 401.358.

(d) A determination, with respect to an individual that is (or an estate and individual that are) without fault, that the individual (or estate) does not qualify for waiver of adjustment or recovery of overpayments on the basis that recovery would be against equity and good conscience, as described in § 401.361.

§ 401.370 Liability of certifying or disbursing officer.

No certifying or disbursing officer is liable for any amount certified or paid by him or her to a provider or supplier in either of the following situations:

(a) The amount is waived under the provisions of this subpart.

(b) Recovery is not completed prior to the death of all persons against whose benefits the recovery is authorized.

Suspension of Payment to Providers and Suppliers and Collection and Compromise of Overpayments

§§ 401.375—401.390 [Reserved]

Interest

§ 401.393 [Reserved]

Repayment of Scholarships and Loans

§ 401.396 [Reserved]

B. Part 401, subpart F, is amended as follows:

Subpart F—Claims Collection and Compromise

1. In § 401.601, paragraphs (d)(2)(ii) and (d)(2)(iii) are revised to read as follows:

§ 401.601 Basis and scope.

* * * * *

(d) *Related regulations.* * * *

(2) *HCFA regulations.* * * *

(ii) Adjustments in railroad retirement or social security benefits to recover Medicare overpayments to individuals are covered in §§ 401.310 through 401.340.

(iii) Claims against providers and suppliers for overpayments under Medicare and for assessment of interest are covered in §§ 401.387 and 401.393.

* * * * *

2. In § 401.607, paragraph (d)(2) is revised to read as follows:

§ 401.607 Claims collection.

* * * * *

(d) *Collection by offset.* * * *

(2) Under regulations at §§ 401.310 through 401.340, HCFA may initiate adjustments in program payments to which an individual is entitled under title II (Federal Old-Age, Survivors, and Disability Insurance Benefits) of the Act or under the Railroad Retirement Act of 1974 (45 U.S.C. 231) to recover Medicare overpayments.

C. Part 405 is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for subpart C continues to read as follows:

Authority: Sections 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

2. The following sections are redesignated as part 401, subpart D as shown in the table below:

Old section—	New section—
405.370	401.375
405.371	401.378
405.372	401.381
405.373	401.384
405.374	401.387
405.375	401.390
405.376	401.393
405.377	401.394
405.378	401.395
405.380	401.396

3. Subpart C, is further amended by removing the undesignated centered headings and §§ 405.301 through 405.359, and subpart C is reserved.

Subpart G—Reconsiderations and Appeals Under Medicare Part A

4. Subpart G is amended as follows:

a. The authority citation for subpart G continues to read as follows:

Authority: Secs. 1102, 1151, 1154, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 1320c–3, 1320c–4, 1395ff(b), 1395hh, 1395ii, and 1395pp).

b. In § 405.704, the section heading and the introductory text of paragraph (c) are revised, and a new paragraph (c)(3) is added, to read as follows:

§ 405.704 Actions that are initial determinations.

* * * * *

(c) *Initial determination with respect to a provider.* An initial determination with respect to a provider is a determination made on the basis of the request for payment filed by the provider under Part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

* * * * *

(3) A determination by HCFA that a provider must repay an overpayment because the provider is not without fault as that term is described in § 401.323 of this chapter.

Subpart H—Appeals Under the Medicare Part B Program

5. Subpart H is amended as follows:

a. The authority citation for subpart H is revised to read as follows:

Authority: Secs. 1102, 1842(b)(3)(C), and 1869(b) of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), and 1395ff(b)).

b. In § 405.803, paragraph (b) is revised to read as follows:

§ 405.803 Initial determination.

* * * * *

(b) An initial determination for purposes of this subpart includes, among others, the following determinations:

(1) Whether the items and services furnished are covered.

(2) Whether an individual deductible has been met.

(3) Whether a receipted bill or other evidence of payment is acceptable.

(4) Whether the charges for items or services furnished are reasonable.

(5) For items or services furnished an individual by a supplier in accordance with an assignment under § 424.55 of this chapter, that are not covered by reason of § 411.15(g) or § 411.15(k) of this chapter, whether the individual or supplier knew, or could reasonably have been expected to know, that the items or services were excluded from coverage.

(6) A determination that a supplier must repay an overpayment because the supplier is not without fault as that term is described in § 401.323 of this chapter.

(7) A determination that an individual, or the estate of the individual, does not qualify for waiver of adjustment or recovery of overpayments because the individual is, or the estate and the individual are, not without fault as that term is described in § 401.355 of this chapter.

(8) A determination, with respect to an individual that is (or an estate and individual that are) without fault, that the individual (or estate) does not qualify for waiver of adjustment or recovery of overpayments on the basis that recovery would defeat the purposes of title II or of title XVIII of the Act, as described in § 401.358 of this chapter.

(9) A determination, with respect to an individual that is (or an estate and individual that are) without fault, that the individual (or estate) does not qualify for waiver of adjustment or recovery of overpayments on the basis that recovery would be against equity and good conscience, as described in § 401.361 of this chapter.

* * * * *

c. Section 405.805 is revised to read as follows:

§ 405.805 Parties to the initial determination.

The parties to the initial determination (see § 405.803) may be any party described in § 405.802(b). A party may also be any supplier as defined at § 400.202 of this chapter that has been determined to be not without fault as that term is described in § 401.323 of this chapter, with respect to that issue only.

D. Part 411 is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 411.23 is revised to read as follows:

§ 411.23 Individual's cooperation.

If HCFA makes conditional payments, the individual must do the following:

(a) Cooperate in notifying HCFA of the progress and final outcome of the liability claim, including, but not limited to—

(1) Notifying the intermediary or carrier within 60 days of filing a claim with an entity that may be primary to Medicare; and

(2) Notifying HCFA within 30 days of the receipt of a payment from the entity that is primary to Medicare.

(b) Cooperate in the recovery action.

3. Section 411.28 is revised to read as follows:

§ 411.28 Waiver of recovery and compromise of claims.

(a) HCFA may waive recovery, in whole or in part, if HCFA determines that waiver is in the best interest of the Medicare program.

(b) General rules applicable to compromise of claims are set forth in subpart F of part 401 of this chapter.

(c) Other rules pertinent to recovery are contained in subpart D of part 401 of this chapter.

E. Part 466 is amended as set forth below:

PART 466—UTILIZATION AND QUALITY CONTROL REVIEW

1. The authority citation for part 466 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 466.86, new paragraph (a)(5) is added to read as follows:

§ 466.86 Correlation of Title XI functions with Title XVIII functions.

(a) Payment determinations. * * *

(5) A finding by the PRO that the provider or supplier is not without fault, as that term is described in § 401.323 of this chapter, with respect to an overpayment, is conclusive for payment purposes.

* * * * *

3. In § 466.94, paragraph (c)(6) is redesignated as paragraph (c)(7), and a new paragraph (c)(6) is added to read as follows:

§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.

* * * * *

(c) Content of the notice. * * *

(6) If applicable, a statement about the without fault determination as that term is described in § 401.323 of this chapter.

* * * * *

F. Part 473 is amended as set forth below:

PART 473—RECONSIDERATIONS AND APPEALS

1. The authority citation for part 473 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 473.14, paragraph (c)(2) is revised to read as follows:

§ 473.14 Applicability.

* * * * *

(c) *Nonapplicability of rules to related determinations.* * * *

(2) Without fault determinations with respect to overpayments are made under section 1870 of the Act, and limitation on liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under sections 1870 and 1879 and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by HCFA should be read to mean initial and reconsidered determinations made by a PRO.

G. Technical Amendments.

§ 401.378 [Amended]

1. Redesignated § 401.378 is amended as follows:

a. In paragraph (b), the citations ''§ 405.372'' and ''§ 405.373'' are removed, and the citations ''§ 401.381'' and ''§ 401.384'', respectively, are added in their place.

b. In paragraph (c), the citations ''§ 405.372'' and ''§ 405.372(a)(2)'' are removed, and the citations ''§ 401.381'' and ''§ 401.381(a)(2)'', respectively, are added in their place.

§ 401.381 [Amended]

2. Redesignated § 401.381 is amended as follows:

a. In paragraph (a)(1), the citation ''§ 405.371(a)(1)'' is removed and the citation ''§ 401.378(a)(1)'' is added in its place.

b. In paragraph (a)(2), the citation ''§ 405.371(c)'' is removed and the citation ''§ 401.378(c)'' is added in its place.

c. In paragraph (b)(1), the citations ''§ 405.374'' and ''§ 405.375'' are removed and the citations ''§ 401.387'' and ''§ 401.390'', respectively, are added in their place.

d. In paragraph (e), the citations ''§ 405.371(b)'' and ''§ 405.378'' are removed and the citations ''§ 401.378(b)'' and ''§ 401.395'', respectively, are added in their place.

3. Redesignated § 401.384 is amended as follows:

a. In paragraph (a) introductory text, the citation ''§ 405.371(a)(2)'' is removed and the citation ''§ 401.378(a)(2)'' is added in its place.

b. In paragraph (a)(2), the citation ''§ 405.374'' is removed and the citation ''§ 401.387'' is added in its place.

c. In paragraph (c), the citations ''§ 405.374'' and ''§ 405.375'' are removed and the citations ''§ 401.387'' and ''§ 401.390'', respectively, are added in their place.

§ 401.387 [Amended]

4. In redesignated § 401.387, paragraph (a), the citations ''§ 405.372'' and ''§ 405.373'' are removed and the citations ''§ 401.381'' and ''§ 401.384'', respectively, are added in their place.

§ 401.390 [Amended]

5. In redesignated § 401.390, paragraph (a), the citations ''§ 405.374'' and ''§ 405.372(b)(2)'' are removed and the citations ''§ 401.387'' and ''§ 401.381(b)(2)'', respectively, are added in their place.

§ 401.394 [Amended]

6. In redesignated § 401.394, paragraph (e) introductory text, the citation ''§ 405.374'' is removed and the citation ''§ 401.387'' is added in its place.

§ 401.601 [Amended]

7. In § 401.601, the following changes are made:

a. In paragraph (d)(2)(ii), the phrase ''§§ 405.350–405.356 of this chapter'' is removed, and the citation ''§ 401.305'' is added in its place.

b. In paragraph (d)(2)(iii), the phrase ''§§ 405.374 and 405.376 of this chapter'' is removed, and the phrase ''§§ 401.387 and 401.393'' is added in its place.

§ 401.607 [Amended]

8. In § 401.607, in paragraph (d)(2), the phrase ''§§ 405.350–405.358 of this chapter'' is removed, and the phrase ''§§ 401.346 and 401.349'' is added in its place.

PART 403—RECOGNITION OF STATE REIMBURSEMENT CONTROL SYSTEMS

9. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 403.310 [Amended]

10. In § 403.310, in paragraph (a), the citation ''§ 405.378'' is removed, and the citation ''§ 401.395'' is added in its place.

§ 405.705 [Amended]

11. In § 405.705, in paragraph (d), the citation ''§ 405.376'' is removed, and the citation ''§ 401.393 of this chapter'' is added in its place.

§ 405.1801 [Amended]

12. In § 405.1801, in paragraph (a), under the definition ''Intermediary determination,'' in paragraph (4), the citation ''§ 405.376'' is removed, and the citation ''§ 401.393 of this chapter'' is added in its place.

§ 405.1803 [Amended]

13. In § 405.1803, in paragraph (c), the citation ''405.373'' is removed, and the citation ''§ 401.384(a) of this chapter'' is added in its place.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

14. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 410.1 [Amended]

15. In § 410.1, in paragraph (b), the phrase ''subpart C of part 405 of this chapter'' is removed, and the phrase ''Subpart D of Part 401 of this chapter'' is added in its place.

§ 411.28 [Amended]

16. In § 411.28, the following changes are made:

a. In paragraph (b), the citation ''405.376'' is removed, and the citation ''401.393'' is added in its place.

b. In paragraph (c), the phrase ''in subpart C of part 405 of this chapter'' is removed, and the phrase ''in subpart D of part 401 of this chapter'' is added in its place.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

17. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

§ 413.20 [Amended]

18. In § 413.20, in paragraph (e), the citation ''§ 405.372(a)'' is removed wherever it appears (twice), and the citation ''§ 401.381'' is added in its place.

§ 413.153 [Amended]

19. In § 413.153, the following changes are made:

a. In paragraph (a)(1)(ii), the citation ''§ 405.377'' is removed, and the citation ''§ 401.394'' is added in its place.

b. In paragraph (a)(1)(iii), the citation ''§ 405.378'' is removed, and the citation ''§ 401.395'' is added in its place.

PART 447—PAYMENTS FOR SERVICES

20. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 447.31 [Amended]

21. In § 447.31, in paragraph (a), the citation ''Section 405.377'' is removed, and the citation ''§ 401.394'' is added in its place.

PART 493—LABORATORY REQUIREMENTS

22. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16).

§ 493.1834 [Amended]

23. In § 493.1834, in paragraph (i)(1)(ii), the citation ''§ 405.378(d)'' is removed, and the citation ''§ 401.395(d)'' is added in its place.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93,774, Medicare—Supplementary Medical Insurance Program)

Dated: January 8, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: January 20, 1998.

Donna E. Shalala,

Secretary.

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