

Analysis, Design, Programming, & Implementation Services for Data Interfaces

Overview

The State maintains several systems and databases that must either supply or receive data from the PBM.

- Client (beneficiary) eligibility and TPL data for program beneficiaries: The State's recipient eligibility file contains all the basic data required to create the eligibility data, including TPL data, for the PBM system. This file will be used for each complete refresh (including the initial setup) of the eligibility data, and for daily adds, changes and deletes.
- Drug Monitoring Service: This system currently contains data about eligibility for extended acute dose ulcer therapy. The State has specified that the implementation of a PBM system will allow the State to retire this system. Information from this system should only be transferred for the initial implementation.
- Claims processing system: Michigan pharmacy claims are currently processed through the Medicaid Management Information System (MMIS). This system currently contains historical data that must be initially transferred to the PBM system. In addition, the claims processing system must receive a weekly paid claims file from the PBM for further processing in MMIS and other down-line systems.
- Provider eligibility database: This database contains the current Medicaid providers. Information from this system should be transferred for the initial implementation. It should be noted that the State currently expects the PBM will use the State's on-line system to obtain a provider ID for new providers that must be added to its own provider database once the initial implementation is completed. (The PBM contractor will perform Medicaid provider enrollment activities for pharmacy providers using the State's current on-line system.)
- National Drug Code database: This database contains data obtained from First DataBank; the State's covered drug parameters; HCFA drug rebate amounts; and HCFA approved manufacturers. Information from this system should be transferred for both the initial implementation and an on-going basis.
- Providers under sanction database: This database contains data about providers who are currently under State sanction. Information from this system should be transferred for both the initial implementation and an on-going basis. It should be noted that this information is also available on the Web.
- Formulary database: This database contains the formulary information for Michigan. Information from this system should be transferred for both the initial implementation and an on-going basis.
- Prior authorization database: This database contains information directing prior authorization activities. Information from this system should be

transferred for the initial implementation and updated on an on-going basis, at least until the CSHCS is fully implemented within the PBM's operations.

- Recipient monitoring database: This database identifies the recipients who are currently being monitored. Information from this system should be transferred for the initial implementation and updated on an on-going basis.

The State would like to consider two options for preparing data for starting the PBM service and for on-going data exchanges between the State and PBM:

Option One: The State will take the primary lead in this effort, conducting the necessary system analysis, design, programming, and implementation steps, with the PBM providing advice and information to the State. With this option, the PBM can expect to receive data files fully prepared for processing in its system, and the PBM will provide the standard NCPDP paid claims data (in Medicaid specific format) to the State, with the State taking responsibility for preparing this data for processing within its own systems.

Option Two: The PBM will take the primary lead in this effort, conducting the necessary system analysis, design, programming, and implementation steps, with the State providing advice and information to the PBM. With this option, the PBM must prepare to receive data files containing the data elements it requests and will itself process these data elements for entry into its own systems, both at start-up and an on-going basis. And, on an on-going basis, the PBM will provide the State both standard NCPDP paid claims data (in Medicaid specific format) and paid claims data fully formatted for immediate processing within State systems (in State specific format).

Option One

Requirements

1. The contractor shall provide all appropriate information to the State in mutually agreed formats, according to a mutually agreed project schedule.
2. The contractor shall provide technically qualified personnel who can assist the State with understanding, interpreting, and using the information the contractor provides for this effort.
3. The contractor shall maintain the ability to conduct the necessary system analysis, design programming, and implementation steps at all times, in case the State decides to opt for Option Two during the course of the contract.

Performance Standards

The contractor is encouraged to suggest improved or additional performance standards, including adding specificity where appropriate.

1. Provision of information, advice, and consultation: The contractor shall provide the information requested in a clear and timely manner, and in the technical specifications agreed upon, without fail.

2. The contractor's level of knowledge of the systems at the State that interface with the contractor's system will be measured in informal performance reviews, and is expected to improve continuously over time.
 3. If failure to meet these standards is found, the contractor will correct such failure within 24 hours. If the contractor fails to correct errors for erroneously processed claims or fails to correct a compliance failure, the State will recoup any funds paid inappropriately. In addition, the State may sanction the contractor by withholding payments until the contractor is in compliance or charge the contractor liquidated damages.
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Option Two

Requirements

1. The contractor shall submit a separate, detailed work plan for performing this service within five (5) days of award of contract. This work plan must be fully synchronized with the overall work plan provided for the project.
 2. The contractor shall provide technically qualified personnel who have demonstrated experience in designing, developing, and implementing data transfer routines for programs that require start-up electronic data transfers and on-going data transfers for databases that must be kept synchronized over time.
 3. The contractor shall recommend and use a mutually accepted, well-recognized systems development methodology for completing this effort.
 4. The contractor shall provide the State with full documentation for the interface systems that are developed and implemented in a mutually agreed electronic format.
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Performance Standards

The contractor is encouraged to suggest improved or additional performance standards, including adding specificity where appropriate.

1. Interface System Development Effort: The contractor shall complete this effort according to the approved work plan without fail.
2. Interface System: The interface system must perform exactly according to the mutually agreed specifications.
3. The contractor's level of knowledge of the systems at the State that interface with the contractor's system will be measured in informal performance reviews, and is expected to improve continuously over time.
4. If failure to meet these standards is found, the contractor will correct such failure within 24 hours. If the contractor fails to correct errors for erroneously processed claims or fails to correct a compliance failure, the State will recoup any funds paid inappropriately. In addition, the State may sanction the contractor by withholding payments until the contractor is in compliance or charge the contractor liquidated damages.

Technical Network and Operations Management

Overview

The contractor shall be responsible for supporting an in-state, out-of-state, and Canadian, pharmacy network in accordance with State of Michigan requirements. The contractor shall also perform all appropriate operations for adjudication of claims, clinical consultation, disease management, and any other appropriate steps to meet needs described in this RFP. Included with network and operations management are audit requirements to ensure cost effectiveness and quality of care.

Requirements

The requirements for the contractor's network and operations management include the following:

1. The contractor shall be responsible for providing an in-state, out-of-state, and Canadian pharmacy network that ensures adequate access to pharmacies, including pharmacies in border counties in surrounding states. This network must include an initialization of all current Medicaid-enrolled pharmacy providers. The contractor shall assure availability of compatible hardware, software, and all necessary participant instructions to fully activate this network for beneficiaries of applicable pharmacy programs. Please identify if the contractor's system interfaces with existing pharmacy "switch" networks that connect pharmacy providers.
2. If requested, the contractor shall provide MDCH with Michigan statistics of transactions between the "switches" and the contractor, with such reports including volume, longest collection period, etc. Any such requests will be made in advance of the data collection period and the resultant statistics shall be provided to MDCH within three (3) business days following the end of the data collection period.
3. The data transmissions between providers and the contractor shall be in conformance with all NCPDP Version 3.2 transaction standards (including Medicaid specific format where appropriate). As updates to NCPDP become available, the contractor will maintain compatibility with providers using Version 3.2 and those using updated version(s).
4. Federal regulations require MDCH to maintain appropriate controls over POS contractors who perform both switching services and billing services; therefore, if provided by the same company, they must be maintained as separate and distinct operations. For those situations where the contractor also serves as the providers' agent, an organizational "firewall" must be in place to separate these functions.
5. The contractor shall provide software to allow MDCH to test the contractor's system using the State's network, including submission and receipt of NCPDP POS transactions, as well as audit performance of the network, throughout the

project's life. The contractor's system shall include a criteria test capability permitting Michigan staff to simulate the effect of adding or changing criteria on a trial basis.

6. The contractor shall provide remote access that allows State staff the discretion and ability to update actual production files (eligibility, prior authorization, definition, formulary, drug utilization review, claims history, etc.) in real time basis, with an average system response time (from receipt of POS claim to transmission of response) of no greater than five (5) seconds for all transactions a minimum of ninety-eight percent (98%) of the time seven (7) days per week twenty-four (24) hours per day (except for pre-arranged downtime).
7. The contractor shall provide a dedicated team of professionals to serve the State of Michigan that will interface with and be responsive to State staff regarding inquiries, requests, and issues raised by the State. Included among the team should be persons with account management, pharmacy, and technology expertise relative to the contractor's system. The contractor shall identify in its bid response specific individuals who comprise the team.
8. The contractor shall provide a professional medical and pharmacological consulting staff who will research and maintain current (real-time), drug formulary information, and timely invoice adjudication standards to assure responsible and timely drug guidance, and federal and State of Michigan drug payment compliance (coverage integrity).
9. The contractor shall provide a professional (licensed) medical and pharmacological advisory staff and other resources necessary to provide pharmacists at the point of sale with advice pertaining to the proper use of prescription drugs, consistent with medical standards, as they apply to each beneficiary's unique needs and medical conditions.
10. The contractor will be entrusted with confidential information. Data collected on behalf of the State program is not to be distributed to any party without the written consent of the State and is not to be used by the contractor for any purposes unless specifically approved by the State. The contractor shall assure a totally confidential handling of beneficiary, provider, and other data at all times. Each member of the contractor's staff assigned to this project shall be required to sign a security form.
11. The contractor shall provide secure telecommunications links to claims processing center(s), have sufficient processing capacity, to handle Michigan's peak loads, have adequate availability and reliability for processing of Michigan's pharmacy claims, and provide for business recovery and disaster recovery (including backup and recovery activities). The bidders are to specifically identify in the bid response how it anticipates for meeting these needs.
12. As determined by MDCH, the following specific security measures may be included in operating procedures: (a) computer hardware controls that ensure acceptance of data from authorized networks only, (b) software controls that establish separate files for lists of authorized user access and identification codes, (c) manual procedures that provide secure access to the system with minimal risk, (d) passwords, identification codes, or other security procedures that shall be used by the contractor or State of Michigan staff, (e) software changes subject to MDCH approval prior to implementation, and (f) segregation of systems operations functions from system development.

The bidders shall specify in the bid response which of these measures, plus any others, that it takes or intends to take.

13. The contractor's bid response shall include evidence that it has a business continuity/disaster recovery plan for its central processing site, including the ability to continue processing in the event that the central site is rendered inoperable. If requested, test results of that plan, shall be made available to MDCH. The plan shall be able to meet the requirements of MDCH and DMB, as appropriate.
14. The contractor's bid response shall include standards to address system vulnerability from theft, viruses, mischief, efforts at tampering, etc. The contractor shall apply recognized industry standards governing security of state and federal automated data processing systems and information processing. Minimally, the State of Michigan requires the contractor to conduct a security risk analysis, with the results to be provided to state and federal agencies, as appropriate.
15. The bid response shall include sufficient information to show that the contractor meets the following requirements: (a) documentation of emergency procedures to take in the event of a natural disaster by fire, water damage, sabotage, mob action, bomb threats, etc., (b) employees at the site shall be familiar with emergency procedures, (c) smoking shall be prohibited at the site, (d) heat and smoke detectors shall be installed at the site both in the ceiling and under raised floors (if applicable), which alert the local fire department as well as internal personnel (e) portable fire extinguishers shall be located in strategic and accessible areas of the site, and be vividly marked and periodically tested, (f) protection by an automatic fire suppressing system, and (g) back up by an uninterruptible power system.
16. The contractor shall adhere to other network and operations management standards identified in other sections of this RFP.

Performance Standards

The contractor is encouraged to suggest improved or additional performance standards, including adding specificity where appropriate.

1. The contractor will monitor and report system accessibility ensuring that the average response time (from receipt of POS claim to transmission of response) is no greater than five (5) seconds (except during scheduled maintenance) for provider inquiry or billing purposes for all normal modes of entry. The contractor may have scheduled maintenance downtime as approved by MDCH. The contractor shall ensure that unscheduled system downtime does not exceed two (2) hours during any continuous seven (7) day period.
2. When requested, the contractor shall provide MDCH with Michigan statistics of transactions between the "switches" and the contractor, with such reports including volume, longest collection period, etc. Any such requests will be made in advance of the data collection period and the resultant statistics shall be provided to MDCH within three (3) business days following the end of the data collection period.
3. The documentation the contractor provides for all the network-related requirements (participants, components, standards, capacity, disaster recovery plan, and vulnerability protection plan) must meet reasonable expectations for

completeness, accuracy and clarity, as judged by appropriately assigned MDCH staff.

4. On-line access to the contractor's network, as provided to appropriately assigned MDCH personnel, must be without fail, except during scheduled downtimes.
5. The performance of the contractor's personnel assigned to interface with the State will be measured in informal performance reviews.
6. The contractor shall suggest appropriate performance thresholds in the following operational areas:
 - Percentage of claims paid with no errors.
 - Maximum percentage error in total amount paid.
 - Percentage of POS claims transactions within defined times (in seconds)
 - Percentage of batch and paper claims within defined times (in hours or days)
 - Percentage change (increase or decrease) for ingredient costs per script for the first and second years of contract.
7. If failure to meet these standards is found, the contractor will correct such failure within 24 hours. If the contractor fails to correct errors for erroneously processed claims or fails to correct a compliance failure, the State will recoup any funds paid inappropriately. In addition, the State may sanction the contractor by withholding payments until the contractor is in compliance or charge the contractor liquidated damages.

Dedicated Beneficiary & Provider Hotlines

Overview

General System Operations

The contractor shall maintain toll-free telephone access to support system operations of its systems. A systems hotline shall be available 24 hours a day, seven days a week, 365 days a year to respond to claims inquiries and questions and problems about operations. The contractor shall supply all required information systems, telecommunications, and personnel to perform these operations.

Prior Authorization

The contractor shall also provide a toll-free prior authorization hotline for physicians and pharmacists. A prior authorization hotline shall be available at least Monday through Friday from 7:00 a.m. to 7:00 p.m. eastern standard time to respond to prior authorization requests. The contractor shall staff its hotline with pharmacist(s) who can respond to pharmacy providers within 24 hours to any request and who can also support the Michigan DUR Board. The contractor will be given the State's hotline numbers (for providers and clients) so that its personnel may provide, as appropriate, when responding to prior authorization requests. The contractor shall supply all required information systems, telecommunications, and personnel to perform these operations.

Requirements

The requirements for the contractor's hotline process include the following:

1. The contractor shall maintain toll-free telephone access to support system (technical) operations. A systems hotline shall be available 24 hours a day, seven days a week, 365 days a year to respond to claims, inquiries, questions and problems regarding operations. The hotline shall be available to providers, State representatives, and beneficiaries. The contractor shall supply all required information systems, telecommunications, and personnel to perform these operations. The contractor shall appropriately staff its systems hotline, with positions such as a manager, hotline team leaders, and hotline representatives, all of who shall be extensively trained.
2. The contractor shall provide the following customer service activities, at a minimum:

- Single front-end toll-free telephone number with touch-tone routing (if necessary) to respond to requests for pharmacy locations, inquiries or claims, and complaints about pharmacist practices and services
 - Separate toll-free numbers for participants, physicians, and pharmacists
 - Voice response unit (if necessary) with a user-friendly menu that callers find easy to understand
 - Access to a pharmacist consultant 24 hours a day
 - Development of the same services through the Internet
3. The contractor's hotline staff shall have complete on-line access to all computer files and databases that support the system for applicable pharmacy programs.
 4. The contractor's hotline shall provide sufficient telecommunications capacity to meet the State of Michigan's existing needs with acceptable call completion and abandonment rates. It shall also be scalable to demand in the future. It shall also possess an advanced telephone system that provides the State of Michigan with extensive management tracking and reporting capabilities. A QA program shall be in place that samples calls and follows up to confirm efficient handling and caller satisfaction.
 5. The contractor shall maintain toll-free telephone access (available for in-state and out-of-state providers) to support prior authorization. A prior authorization hotline shall be available at least Monday through Friday from 7:00 a.m. to 7:00 p.m. eastern standard time to respond to prior authorization requests. (In the bid response, the contractor should state whether its existing prior authorization hotline is available for more than the required five days a week and whether the contractor would provide these same hours for this contract. The contractor should also indicate how they would handle emergency situations during other hours.) This hotline shall be available to providers, State representatives, and beneficiaries. The contractor shall supply all required information systems, telecommunications, and personnel to perform these operations. It shall be staffed with clinical pharmacists to field on-line drug utilization review and other clinical questions. For prior authorization services the contractor shall provide pharmacist(s) who can respond within twenty-four (24) hours to any request.
 6. The prior authorization staff shall be supervised by a R.Ph. or PharmD., who will be available to make clinical decisions. Each assigned pharmacist shall currently be licensed as a registered pharmacist in the state in which they are practicing and familiar with the State of Michigan pharmacy practice and related Board of Pharmacy rules.
 7. The contractor shall provide a professional (licensed) medical and pharmacological advisory staff and other resources necessary to provide pharmacists at the point of sale with advice pertaining to the proper use of prescription drugs, consistent with prospective drug utilization and other medical standards, as they apply to each beneficiary's unique needs and medical conditions.
 8. The contractor shall produce reports on usage of the hotline(s), including number of inquiries, types of inquiries, and timeliness of responses.

9. The contractor's process shall allow beneficiaries to locate nearby pharmacies for special situations, such as 24-hour pharmacies or those dispensing compound drugs, etc. This could be accomplished by interfaces with pharmacy network database to identify the participating pharmacies near beneficiary's address.
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Performance Standards

The contractor is encouraged to suggest improved or additional performance standards, including adding specificity where appropriate.

1. The State will conduct ad-hoc tests at any time to ensure the contractor is performing prior authorization services via telephone and telecommunications device in accordance with federal and MDCH policies and guidelines, and that the contractor is adhering to each of the following:
 - Routine prior authorization requests shall be approved while the dispensing provider is still on the telephone.
 - Requests that cannot be answered routinely shall be escalated and completed within one (1) hour.
 - Federal law requires response to prior authorization requests within twenty-four (24) hours for drugs not included on the formulary.
 - Under certain emergency situations, as defined by the federal Secretary of Human Services, a seventy-two (72) hour supply of a covered outpatient drug may be dispensed until authorization can be determined (e.g. if contractor-provided hotline services is not available on weekends and/or holidays).
2. The contractor shall provide reports demonstrating that it has performed as follows:
 - 100% of telephone inquiries shall be answered within 24 hours.
 - The bidder shall specify the percentage of calls returned by account service representatives within 12 to 24 hours of receipt.
 - The bidder shall specify the percentage of calls resolved within 24 hours of receipt.
 - Calls to hotlines shall be answered within three (3) rings or fifteen (15) seconds. If an automated voice response system is used, an option must exist that allows the caller to speak directly with an operator. Total wait time to speak with an operator shall not exceed two (2) minutes.
 - The inquiry telephone system shall maintain sufficient staffing to respond to telephone calls by not allowing an average in excess of 30 seconds on hold.
 - The bidder shall specify the average time in seconds to answer customer service calls.
 - The bidder shall specify the percentage of calls it will answer within 15 seconds, 20 seconds, and 30 seconds.

- The inquiry telephone line for beneficiaries shall have no more than 5% lost calls.
 - The bidder shall specify the percentage of calls abandoned.
 - The bidder shall specify the percentage of calls blocked.
 - 95% of written inquiries that the contractor receives either from State staff or from beneficiaries shall be answered within five calendar days. The contractor shall calculate response time from the date of receipt to final resolution.
 - The bidder shall specify the percentage of written inquiries responded to within five days.
 - The bidder shall specify the percentage of written inquiries responded to within ten business days.
3. If failure to meet these standards is found, the contractor will correct such failure within 24 hours. If the contractor fails to correct errors for erroneously processed claims or fails to correct a compliance failure, the State will recoup any funds paid inappropriately. In addition, the State may sanction the contractor by withholding payments until the contractor is in compliance or charge the contractor liquidated damages.

Communications

Overview

The State of Michigan has dedicated resources for providing all types and levels of communication with beneficiaries, providers, and the general public. The contractor shall become familiar with these services so as not to duplicate communications. The contractor will be encouraged to develop and distribute communications unique to pharmacy services, including but not limited to: seasonal warnings or alerts, new drug benefits, and prevention oriented materials. The contractor shall NOT be expected to provide individual pharmacy benefit cards to each eligible person. The State will continue to issue Medicaid identification (ID) cards, which are the official documents to verify beneficiaries' eligibility for Medicaid services, including pharmacy.

Requirements

1. The contractor shall develop and distribute communications unique to pharmacy services, including but not limited to: seasonal warnings or alerts, new drug benefits, and prevention oriented materials.
 2. The State shall approve all communications involving the Medicaid program prior to use.
 3. The contractor shall work with MDCH to develop and distribute fraud and abuse education information to pharmacists billing for pharmaceutical services and shall receive approval from MDCH before distribution of such information.
 4. The bidder must submit examples of proposed communications with beneficiaries and providers that they would recommend if they were awarded the contract.
 5. The contractor shall provide appropriate communications to pharmacy providers to address the counseling requirements as described in OBRA '90 legislation (see Appendix F).
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Performance Standards

The contractor is encouraged to suggest improved or additional performance standards, including adding specificity where appropriate.

1. Timeliness, appropriateness, and quality of information: The contractor's response to the toll-free number service will be tested by State personnel for timeliness, appropriateness, and quality of information through ad-hoc testing at any time.
2. Hotline statistics: The contractor will provide written statistics regarding the toll-free number service that includes level of activity and number,

nature and disposition of calls involving any issues that could not be resolved during the calling session.

3. All submissions by the contractor, such as educational information: Whenever appropriate the contractor and the State will develop specific requirements of each of these submissions and the contractor will meet these specific requirements and otherwise demonstrate a very high level of performance, measured in informal performance reviews of the timeliness, appropriateness, and clarity of such material and consultation and advice.
4. If failure to meet these standards is found, the contractor will correct such failure within 24 hours. If the contractor fails to correct errors for erroneously processed claims or fails to correct a compliance failure, the State will recoup any funds paid inappropriately. In addition, the State may sanction the contractor by withholding payments until the contractor is in compliance or charge the contractor liquidated damages.

Appendix C
Phase II - Clinical Consultation

- Drug utilization review
- Utilization management

The retrospective DUR shall assess data on drug use against explicit predetermined standards and introduce appropriate remedial strategies to improve the quality of care and reduce medical care costs.

Finally, the contractor shall develop active and ongoing educational outreach programs to educate practitioners on common drug therapy problems, in order to improve prescribing or dispensing practices.

The State of Michigan Drug Utilization Review Board (DUR Board) shall be responsible for approving all prospective and retrospective DUR programs prior to their distribution or implementation.

Requirements

The requirements for the contractor's DUR and education programs include the following:

General

1. The contractor shall provide a dedicated clinical manager (RPh or PharmD) who will be responsible for daily oversight of the DUR programs and provide clinical analysis and guidance to the DUR Board and Pharmaceuticals & Therapeutics (P&T) Committee (sometimes referred to as the Formulary Committee).
2. The contractor/clinical manager shall coordinate with the State of Michigan DUR Board, which includes health care professionals who will be responsible for approving all DUR programs.
3. Within 120 days of contract implementation and annually thereafter, the contractor's clinical manager shall present an annual DUR plan to the DUR Board for consideration, including a profile of all proposed DUR programs and dates for execution, as well as expert advice regarding standards for pharmacist counseling of beneficiaries.
4. On an annual basis, the contractor shall participate in the preparation of a report to the State that includes a description of the DUR activities (part of annual clinical plan), scope and nature of the prospective and retrospective drug use review programs, a summary of the interventions used, and an assessment of the impact of these educational interventions on the quality of care and an estimate of the cost savings generated as a result. This report shall be used to evaluate the effectiveness of the DUR program.
5. A clinical manager shall attend each DUR Board meeting and present the committee with a written report containing the following information:
 - Based on previous quarter's pharmacy claims, present 10 top therapeutic classes and top 5 high growth therapeutic classes, their current DUR protocol and recommendations for additions or changes in the DUR program
 - Provide educational materials including supportive clinical research, protocols and financial analysis for newly approved therapies and

Drug Utilization Review

Overview

Drug utilization review (DUR) will include the three major elements defined by OBRA '90, including:

- Prospective drug utilization review (requirements for prospective DUR during POS edits are detailed in Appendix B, which defines the requested Phase I tasks)
- Retrospective drug utilization review
- Education programs

The purpose of the DUR program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and that they are not likely to result in adverse medical results, in accordance with OBRA '90. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. The program shall evaluate drug use patterns among physicians, pharmacists and beneficiaries, and those associated with specific drugs or groups of drugs. DUR shall assess data on drug use against predetermined standards, consistent with peer-reviewed literature and the recommendations of the State's DUR Board. The assessment must include, but shall not be limited to:

- Monitoring for therapeutic appropriateness
- Over-utilization and under-utilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage or duration of drug treatment
- Clinical abuse/misuse

The prospective DUR shall provide for a review of drug therapy before each prescription is filled or delivered to a beneficiary. The review must include screening for the items listed above, as well as drug-allergy interactions. The contractor shall develop a program that encourages pharmacists to comply with State law, which requires pharmacists to offer to discuss anything about the prescription that the pharmacist feels is important, based on the prospective DUR. The contractor shall also encourage pharmacists to make a reasonable effort to obtain, record and maintain specific beneficiary profile information.

In compliance with OBRA '90, State law requires pharmacists to counsel beneficiaries on the significant findings of the prospective DUR. The contractor shall encourage pharmacists to comply with this law. The State is responsible for establishing the standards for this counseling, and the contractor should provide expert advice to the DUR Board in this regard.

indications to the DUR Board for consideration. Upon approval, this information will be included as part of the prospective and retrospective DUR program to targeted physicians.

6. On a quarterly basis, the contractor will provide face-to-face clinical detailing to top 25% of all prescribers, with detailed criteria to be provided by the State.
7. The contractor's DUR programs shall comply with all OBRA '90 requirements.

Prospective DUR

1. The contractor shall provide a prospective drug utilization review process that is linked to the electronic claims management network, so as to furnish medical and drug history information for each beneficiary. This process is subject to the review and recommendation of the State's DUR Board. This process shall have the flexibility to adjust to changes in criteria or procedures as recommended by the DUR Board.
2. The contractor shall provide educational materials targeted to pharmacists informing pharmacists about their legal obligation to provide counseling to beneficiaries regarding meaningful prospective DUR findings.

Retrospective DUR

1. The contractor shall analyze pharmacy and non-pharmacy (primarily hospitalization and laboratory) claims on an ongoing basis and present recommendations quarterly for additions or changes to the retrospective DUR programs and interventions. (The State will be responsible for providing non-pharmacy claims data from its MMIS application, and encounter data of health plan services are included.) The proposed DUR programs shall address both high risk and high cost/utilization drug therapies and shall tie to the top drugs/disease states that are being used by beneficiaries of applicable pharmacy programs.
2. The program shall, on a monthly to quarterly basis, assess data on drug use against explicit predetermined standards including but not limited to monitoring for therapeutic appropriateness, over-utilization and under-utilization, incorrect drug dosage, or duration of drug treatment and clinical abuse/misuse and, as necessary, introduce remedial strategies to improve the quality of care and to conserve program funds or personal expenditures.
3. The retrospective DUR program shall provide ongoing interventions for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective DUR activities.
4. The retrospective DUR program shall include written, oral, or electronic reminders containing beneficiary-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of beneficiary-related information.

5. The contractor's process shall include intensified review or monitoring of selected prescribers or dispensers, proposing detailed program interventions to the DUR Board for consideration.
 6. The contractor's process shall include periodic evaluation of interventions to determine if the interventions improved the quality of drug therapy. The contractor is to evaluate the success of interventions and make modifications as necessary.
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Educational Programs

1. On a quarterly basis, the contractor shall provide educational materials including supportive clinical research, protocols, and financial analyses for newly approved therapies and indications to the DUR Board for consideration. Upon approval, this information will be included as part of the prospective DUR program to targeted physicians.
 2. The DUR program shall integrate with edits (whether POS, batch, or paper claims processing), and provide communications and education to pharmacies that are not appropriately complying with these edits, including encouraging pharmacists to counsel beneficiaries on DUR findings. The pharmacy-focus DUR program shall also be incorporated into the network management program.
 3. The contractor shall demonstrate experience in effective physician and pharmacy targeting, that is focusing on the high value prescribers that contribute the largest impact on improved quality of care and drug cost reduction, then implementing interventions to optimize prescriber behavior.
 4. The contractor shall have demonstrated success in attaining prescriber agreement to use a clinically appropriate alternative product or generic, if relevant, in the same therapeutic class.
 5. The contractor shall have demonstrated use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing or pharmacy care practices and follow-up face-to-face discussions.
 6. The contractor shall have a team of clinical pharmacists (RPh or PharmD) to meet with targeted physicians. The face-to-face meetings shall include prospective and retrospective, beneficiary specific, DUR. The clinical pharmacists may also meet with physician groups, providing prospective and retrospective DUR education that is not beneficiary specific.
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Performance Standards

1. The specific standards are to be established during contract negotiation based on input from State and contractor representatives.
2. The consultation and advice provided the State, Michigan DUR Board, and health care professionals by the dedicated clinical manager, clinical pharmacists and any other contractor personnel assigned such activities: A very high level of performance measured in regular performance reviews of the timeliness, appropriateness, and clarity of such consultation and advice, completed by the

appropriate State management personnel and the Michigan DUR Board members, or any other appropriate participating parties.

3. All submissions by the contractor, such as recommendations for a DUR process, the development of an Annual DUR Plan, the educational materials, the data assessments, the evaluations and recommendations for interventions, the reminders, and any other material submitted to the State to the participating providers, the targeted physicians, the DUR Board or the Michigan P&T Committee: Whenever appropriate the contractor and the State will develop specific requirements of each of these submissions and the contractor will meet these specific requirements and otherwise demonstrate a very high level of performance, measured in informal performance reviews of the timeliness, appropriateness, and clarity of such material and consultation and advice.

Utilization Management

Overview

Utilization management must focus beneficiary, physician, and pharmacist utilization patterns and will be integrated with both the retrospective DUR and network management programs. The utilization management protocols will be proposed by the State of Michigan Drug Utilization Review Board (DUR Board) and presented to the State for approval. While the primary focus of utilization management is controlling/reducing pharmacy utilization, utilization management programs may also integrate with disease management and retrospective DUR, identifying beneficiaries who are non-compliant or inconsistently using their therapies.

Utilization management consists of reviewing, on a monthly basis, the utilization patterns of beneficiaries - focusing on beneficiaries receiving a large number of prescriptions each month, high cost prescriptions, controlled substances and beneficiaries seeing multiple physicians and/or receiving prescriptions from multiple pharmacists (referred to as poly-physician, poly-pharm). Once beneficiaries are systematically identified, they will be assessed by the clinical manager to determine the appropriate intervention, which may include referring the beneficiary to a case management program, physician notification, beneficiary lock-in (restricting the potentially abusive beneficiary to a single physician and pharmacy, within applicable legislation, unless prior authorization is received), or others.

Pharmacy utilization management consists of systematic reviews of pharmacy prescribing patterns, focusing on unusual activity such as disproportionate drug dispensing patterns and generic substitution opportunities. Pharmacy utilization management will integrate with pharmacy network management, identifying potential candidates for further investigation or on-site audits. Physician utilization management is integrated with retrospective DUR and assists in targeting the appropriate method of communication and intervention with the physician.

The DUR Board will be responsible for approving all utilization management targeting protocols and beneficiary lock-in candidates.

Requirements

The requirements to the contractor's utilization management program includes the following:

1. The contractor shall provide a dedicated clinical manager (RPh or PharmD) who will be responsible for daily oversight and clinical review of beneficiaries, physicians, and pharmacies that that have been identified through the utilization management program.

2. The contractor/clinical manager shall coordinate with the State of Michigan DUR Board, which includes health care professionals who will be responsible for approving all utilization management programs.
3. Within 120 days of contract implementation and annually thereafter, the contractor's clinical manager shall present an annual utilization management plan to the DUR Board for consideration.
4. The contractor shall analyze pharmacy claims on a monthly basis and present recommendations for additions or changes to the utilization management program and interventions. The proposed utilization management program shall include review of both high risk and high cost/utilization therapies for integration with prior authorization, POS edits, and DUR programs.
5. On a quarterly basis, contractor will provide a written report profiling the top 100 utilizing beneficiaries, pharmacies and physicians. The report will highlight the percentage of cost (to total) attributed to the top utilizers, the actions taken (including DUR and detailing programs) and future action to be taken.
6. The contractor shall demonstrate experience in effective and efficient utilization management programs that integrate with formulary protocols, DUR, and pharmacy network management.
7. The contractor shall have developed information system programs for utilization management screening, which includes flexible evaluation criteria and timely data integration.
8. Where appropriate, the contractor shall have the ability to use face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for utilization management.
9. Utilization management shall include written, oral, or electronic reminders containing specific information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of beneficiary-related information.

Performance Standards

1. The consultation and advice provided the State, Michigan DUR Board, and health care professionals by the dedicated clinical manager, clinical pharmacists and any other contractor personnel assigned such activities: A very high level of performance measured in regular performance reviews of the timeliness, appropriateness, and clarity of such consultation and advice, completed by the appropriate State management personnel and the Michigan DUR Board members, or any other appropriate participating parties.
2. All submissions by the contractor, such as clinical reviews, analyses, proposed utilization plans, and any other material submitted to the State to the participating providers, the targeted physicians, the DUR Board or the Michigan P&T Committee: Whenever appropriate the contractor and the State will develop specific requirements of each of these submissions and the contractor will meet these specific requirements and otherwise demonstrate a very high level of performance, measured in informal performance reviews of

the timeliness, appropriateness, and clarity of such material and consultation and advice.

Appendix D

Phase III - Disease Management

Overview

Public Act 114 of 1999, Section 1612 (2) is the statutory basis for development of a disease management system for care rendered beneficiaries.

" The MSA may implement prospective drug utilization review and disease management systems. The prospective drug utilization review and disease management systems authorized by this subsection shall have physician oversight, shall focus on patient, physician, and pharmacist education, and shall be developed in consultation with the National Pharmaceutical Council, Michigan State Medical Society, Michigan Association of Osteopathic Physicians, Michigan Pharmacists' Association, Michigan Partner for Patient Advocacy, and Michigan Nurses' Association."

Disease management is a name applied to use of pre-established protocols or best practices, as identified by qualified medical personnel, to review care and services received by beneficiaries with a specified condition(s) to validate that care offered is optimal and conforms to the best practices for treatment guidelines. This review may apply to either acute illness, e.g., pneumonia in adults, or to chronic medical conditions such as asthma, hypertension, and schizophrenia.

As specified in statute, a disease management system/process must be developed in consultation with the organizations listed, must have physician oversight, and shall focus on beneficiary, physician, and pharmacist education. Therefore, the contractor shall coordinate meetings with these organizations and MDCH staff, especially the Office of Medical Affairs (OMA), shall facilitate literature review of existing disease management protocols for MDCH's benefit, shall select a topic or topics for implementation, shall analyze the capacity of data to support such a topic, and shall prepare strategies for translating disease management protocols and observed findings to educational opportunities for eligible beneficiaries of applicable pharmacy programs with the selected condition, and the pharmacy and physician providers caring for them. Of necessity, this function will rely on identification of physician services and other data containing diagnoses, if available, in addition to pharmacy and other paid claims information detailing treatments.

Following consensus with MDCH and the other organizations to be consulted, the contractor shall identify the selected disease(s), the beneficiaries to be reviewed, the findings of the review, the analysis of strategies to improve the findings, and re-measurement of the findings after interventions with the beneficiary, physician, and pharmacist communities. The statute does not specify frequency, and due to the labor-intensive nature of such an activity, it may be best to proceed incrementally, perhaps choosing one disease only until experience is gained with data requirements and interventions.

The bidder, in its response, is to provide recommendations as to what the State of Michigan should do with regards to direction and operations of its disease management program, including the type and frequency of activities to be performed, including extent of education and intervention efforts. The bidder should list the types of diseases that will be covered in its program.

The State of Michigan will provide each bidder, upon request, with a sample of electronic FFS data of previously paid claims. For reasons of confidentiality, there will be no names or other identifying information associated with the data records. The bidder, in its bid response, should use this data to make more specific recommendations on how the State should plan its disease management program, such as case management services, etc. The bidder should give examples of existing disease management services it offers. In the price proposal of its bid response, the bidder is to identify in quantifiable terms the amount of savings that the State can expect given the proposed approach and costs for disease management. The bidder should be aware that any actual cost savings realized through implementation of this program will be used to fund Phases II and III of this program.

Requirements

The requirements to the contractor's disease management process include the following:

1. The contractor shall provide disease management activities to identify and manage troublesome therapies.
2. The bidder shall give ongoing examples of disease management activities including any materials and documentation that are part of its program.
3. The contractor shall describe the philosophy and strategy behind its clinical management services and initiatives, including:
 - How program emphasizes beneficiary-centered care
 - Summary of top five features that distinguish its clinical management capabilities
4. The contractor shall provide clinical management activities, including but not limited to: outreach and education, physician profiling, retrospective and prospective drug utilization review, prior authorization, formulary management, predictive modeling. As part of the bid response, the contractor shall identify how these activities fit within its recommended disease management program.
5. The contractor shall provide new, innovative and effective programs for clinical and disease management activities.
6. The contractor shall introduce innovative services that improve physician prescribing and treatment.
7. The contractor shall provide comprehensive beneficiary and provider (pharmacy and physician) education services.
8. The contractor shall maintain an ongoing physician educational program on proper drug and dosage prescribing protocols.

9. The contractor shall educate physicians to choose particular medications for certain diagnoses, prescribe proper dosages, select generics when available, and utilize preferred single source products as needed.
 10. The contractor shall offer utilization and health management programs that decrease inappropriate Rx and medical utilization while ensuring better compliance with best practices for treatment guidelines and improved health care outcomes.
 11. The contractor's system shall have the capability to screen for drug therapy concerns, by specific drugs relative to high risk disease to include (but not be limited to): cardiovascular disease, cerebrovascular disease, central nervous system disease, renal disease, endocrine disease, gastrointestinal disease, psychiatric disease, and respiratory disease. The contractor shall also be asked to provide pricing to the State by disease grouping.
 12. The contractor shall provide physician profiling/other clinical effectiveness reports.
 13. The contractor shall consult not only with the State's DUR Board on its disease management activities, but also coordinate with other State agencies impacting beneficiary care.
-

Performance Standards

1. The specific standards are to be established during contract negotiation based on input from State and contractor representatives.
2. Refer to other tasks for anticipated standards identified with activities such as outreach and education, physician profiling, retrospective and prospective drug utilization review, prior authorization, formulary management, and predictive modeling.

Appendix E

Michigan Medicaid Information System (MMIS) Edits

The following pages are the edits now being used for processing rules within the State's MMIS application.

- 006 **The provider was not enrolled as an eligible provider on the date(s) of service.** The provider should verify the date of service and the date the provider became an enrolled provider (using the Provider Turn-Around form). The claim should be rebilled if the date of provider enrollment is prior to, or on, the date of service.
- 007 **The provider has not submitted a complete cost report or has failed to provide other documentation requested by the Medical Services Administration.**
- 013 **The claim was submitted on magnetic tape and there is no authorization for this billing agent from the provider on file with Provider Enrollment.** The provider must submit a completed MSA-1343 to Provider Enrollment, wait for verification of receipt of the MSA-1343 (on the Provider Turn-Around form), and then rebill the claim.
- 014, 015 **The date of service is more than 180 days from the Julian Date of the Prior Authorization Number.**
- 019 **The beneficiary ID Number is missing.** The claim should be corrected and rebilled.
- 020 **The beneficiary ID Number is not numeric.** The provider should verify the beneficiary ID Number. The claim should be corrected and rebilled.
- 021 **The beneficiary ID Number is invalid.** The provider should verify the beneficiary ID Number. The claim should be corrected and rebilled.
- 022 **The beneficiary ID Number does not match any beneficiary ID Number on ACCESS.**
- 023 **The beneficiary was not eligible for Medicaid or State Medical Program coverage on the date(s) of service.**
- 024 **The beneficiary was not eligible for Children's Special Health Care Services Program coverage on the date(s) of service.** The provider should verify the beneficiary ID Number with the Eligibility Notice. If the date of service is within the period of beneficiary eligibility, the claim should be rebilled.
- 025 **The beneficiary is enrolled in a Qualified Health Plan/Health Maintenance Organization/Clinic Plan.** The provider should contact the Qualified Health Plan/Health Maintenance Organization/Clinic Plan for reimbursement.
- 026 **The beneficiary is eligible for only Children's Special Health Care Services Program coverage on the date of service.** The explanation code is for informational purposes only.

- 027 **The beneficiary is eligible for both Children's Special Health Care Services and Medicaid coverage on the date(s) of service. The explanation code is for informational purposes only.**
- 029 **The beneficiary is eligible for State Medical Program coverage on the date(s) of service. The explanation code is for informational purposes only.**
- 036 **The beneficiary is eligible for Resident County Hospitalization coverage on the date(s) of service. The explanation code is for informational purposes only.**
- 037 **Reimbursement for a Resident County Hospitalization claim(s) must be obtained from the beneficiary's local Family Independence Agency office, not Medicaid. The provider should contact the local Family Independence Agency office.**
- 038 **The local Family Independence Agency office has not entered the proper authorization on ACCESS.**
- 040 **The primary diagnosis code is missing. The claim should be corrected and rebilled.**
- 041 **The primary diagnosis code does not match the diagnosis file.**
- 042 **The primary diagnosis code is being manually reviewed for Program criteria.**
- 044 **The secondary diagnosis is being manually reviewed for Program criteria.**
- 045 **The primary diagnosis code is being manually reviewed as the beneficiary's age does not fall within the normally accepted age range for this diagnosis.**
- 046 **The primary diagnosis code is being manually reviewed as the diagnosis is not normally acceptable for the beneficiary's sex.**
- 049 **The primary diagnosis is being manually reviewed.**
- 050 **The primary diagnosis is being manually reviewed as this type of provider does not normally render treatment for this diagnosis.**
- 051 **The procedure code billed does not reflect the appropriate treatment for the primary diagnosis.**
- 058 **The procedure code billed does not reflect the appropriate treatment for the secondary diagnosis.**

- 059 **The secondary diagnosis is being manually reviewed as this type of provider does not normally render treatment for this diagnosis.**
- 061 **The secondary diagnosis code does not match the diagnosis file.**
- 062 **The secondary diagnosis is being manually reviewed as this type of provider does not normally render treatment for this diagnosis.**
- 063 **The secondary diagnosis is being manually reviewed as the diagnosis is not normally acceptable for the beneficiary's sex.**
- 064 **The secondary diagnosis is being manually reviewed as the beneficiary's age does not fall within the normally accepted age range for this diagnosis.**
- 065,066,
067 **The claim has a prior authorization number which is not yet on file with the Medical Services Administration for this beneficiary, OR services on the prior authorization form have been deleted or already paid.**
- 068 **The claim is being reviewed for a prior authorization condition.**
- 072 **The dental copayment has been deducted. The explanation code is for informational purposes only.**
- 073 **The tooth number/letter is invalid. The claim should be corrected and rebilled.**
- 074 **The tooth surface is invalid. The claim should be corrected and rebilled.**
- 075 **The tooth number/letter is missing. The claim should be corrected and rebilled.**
- 076 **The tooth surface is missing. The claim should be corrected and rebilled.**
- 078 **The quantity on the claim exceeds the allowable quantity for this procedure code. The explanation code is for informational purposes only.**
- 079 **The injury code is missing. The claim should be corrected and rebilled.**
- 080 **The injury code is invalid.**

- 087 **This procedure is being manually reviewed to determine the medical necessity and/or appropriateness of the service.** The provider is required to forward the medical record for this date of service and any other documentation which supports this service to: Selective Edit Unit, Medical Services Administration, P.O. Box 30479, Lansing, MI 48909. If records are not received within 30 days of the payment date of this Remittance Advice on which this explanation code first appears for this claim, the claim will be rejected.
- 088 **The copayment has been deducted for chiropractic, podiatric, or hearing aid services.** The explanation code is for informational purposes only.
- 089 **The procedure code is missing.** The claim should be corrected and rebilled.
- 090 **The type of service code is missing or invalid.** The claim should be corrected and rebilled.
- 091 **The procedure code is invalid.** The claim should be corrected and rebilled.
- 092 **The procedure code is invalid, OR the combination of the type of service code and procedure code is invalid, OR the procedure code is incorrect for the provider.** The provider should verify the procedure code, type of service code, and provider type code. The claim should be corrected and rebilled.
- 093 **The procedure code or the combination of the type of service code and procedure code is not covered on the date of service.** The provider should verify the procedure code, type of service code, and date of service. Providers should also verify the billing procedure with current manual material for possible changes. The claim should be corrected and rebilled.
- 095 **The place of service is not acceptable for this procedure code or type of service.**
- 096 **The procedure code is being manually reviewed as the beneficiary's age does not fall within the normally accepted age range for the procedure.**
- 097 **The procedure code is being manually reviewed as the procedure is not normally acceptable for the beneficiary's sex.**
- 099 **The procedure is being manually reviewed as this type of provider does not normally render the indicated procedure.**

- 100 **The amount to be paid for this procedure is being determined manually.**
- 101 **Reimbursement for the procedure billed has been made based on Medicaid's allowable quantity.** The quantity has been reduced to Medicaid's allowable quantity. The Remittance Advice indicates the quantity on which reimbursement is based. The explanation code is for informational purposes only.
- 102 **The amount billed is being manually reviewed.**
- 103 **The amount to be paid on this claim is different than the total Medicare coinsurance and/or deductible amounts.**
- 104 **This procedure code or drug code is being manually reviewed for Program criteria.**
- 105 **The combination of services billed is being manually reviewed.**
- 107 **The sum of Medicare and other insurance payments equals or exceeds Medicaid's rate.** The service should not be rebilled.
- 110 **The level of care shown on the claim does not match the level of care on ACCESS for this beneficiary.**
- 114 **The necessity for the private room is being manually reviewed.** The explanation code is for informational purposes only.
- 116 **Medicare coverage may be available when a diagnosis or procedure is for chronic renal disease.**
- 119 **The provider does not have the appropriate specialty on file with Provider Enrollment to be reimbursed for this service.** This service must not be rebilled
- 120 **The primary surgical procedure code is invalid.** The claim should be corrected and rebilled.
- 121 **The primary surgical procedure code does not match the procedure file.** The claim should be corrected and rebilled.
- 122 **Operating room charges were billed without a primary surgical procedure code.** The claim should be corrected and rebilled.
- 125 **The secondary surgical procedure code is invalid.**
- 126 **The secondary surgical procedure code does not match the procedure file.** The provider should correct the secondary surgical procedure code and rebill the claim.

- 127 **The surgical procedure is being reviewed because of an emergent or urgent condition.**
- 130 **The individual consideration code is invalid.** The explanation code is for informational purposes only.
- 132 **The provider has requested individual consideration.**
- 136 **The attending physician provider ID Number is missing.**
- 137 **The attending physician provider ID Number is invalid.** The claim should be corrected and rebilled.
- 140 **The beneficiary was eligible for State Medical Program coverage on the date of service but no authorization from the local Family Independence Agency office is on file for the service.** If the provider did receive authorization from the local Family Independence Agency office, the claim may be rebilled with a copy of the authorization attached.
- 141 **This type of provider is not authorized to provide treatment under the State Medical Program.**
- 142 **The place of service is not acceptable for the State Medical Program.** The service must not be rebilled.
- 143 **The procedure or drug code is not covered for the State Medical Program.**
- 147 **The provider type is not authorized to provide treatment under Resident County Hospitalization.** (Only types 10, 11, 13, 14, 30, and 74 are allowed provider types.)
- 148 **The place of service is not acceptable by the Resident County Hospitalization Program.** (Only the inpatient place of service is acceptable.)
- 150 **The prescribing/referring physician ID Number is missing.** The claim should be corrected and rebilled.
- 151 **The prescribing/referring physician ID Number is invalid.** The claim should be corrected and rebilled.
- 152 **The prescribing/referring physician ID Number on the claim is being manually reviewed.**
- 153 **The pharmacy copayment has been deducted.** The explanation code is for informational purposes only.

- 154 **The date of service is missing.** The claim should be corrected and rebilled.
- 155 **The date of service is invalid.** The claim should be corrected and rebilled.
- 156 **The date of service is after the date the claim was received by the Medical Services Administration.** The date should be verified. If appropriate, the claim should be corrected and rebilled. If the date is correct, the service must **not** be rebilled.
- 157 **The claim line date of service is not included in the range of dates indicated by the begin to end dates of service.** If appropriate, the claim should be corrected and rebilled.
- 158 **The claim was received by the Medical Services Administration more than one year after the date of service.**
- 161 **The provider is a hospital-based physician.** The explanation code is for informational purposes only.
- 162 **The provider does not have the appropriate specialty on file with Provider Enrollment to be reimbursed for this procedure.** The provider must submit a copy of his/her board certification or proof of completing a residency in the specialty area, along with his/her provider ID Number, to the Provider Enrollment Unit.
- 163 **This is a Friday/Saturday elective admission.** The service must **not** be rebilled.
- 164 **The admission date is missing.** The claim should be corrected and rebilled.
- 165 **The admission date is invalid.**
- 166 **The admission date is after the begin date of service.** The date(s) should be verified. If appropriate, the claim should be corrected and rebilled.
- 167 **The Resident County Hospitalization Program does not cover this dental procedure.**
- 168 **The provider's total charge exceeds Medicaid's rate.** This results in a Medicaid payment, but the amount is less than requested. The explanation code is for informational purposes only.

- 169 **The provider type on the prior authorization form on file with the Medical Services Administration does not match the provider type on the claim.**
- 170 **The provider ID Number on the claim does not match the provider ID Number on the prior authorization form on file with the Medical Services Administration.** The explanation code is for informational purposes only.
- 171 **The procedure code on the claim does not match the procedure code on the prior authorization form on file with the Medical Services Administration.** The provider should verify the code used with the procedure codes on the approved prior authorization form. If the procedure code is incorrect, only those services that have been prior authorized should be rendered and billed. If the procedure code is correct, the service should not be rebilled.
- 173 **The Dental Invoice tooth number/letter does not match the tooth number/letter on the prior authorization form on file with the Medical Services Administration.** The provider should verify the tooth number/letter billed with the number/letter that was prior authorized. If they match, the provider should contact the dental consultant.
- 174 **The begin date of service is missing.** The claim should be corrected and rebilled.
- 175 **The begin date of service is invalid.**
- 176 **The begin date of service is after the end date of service.** The date(s) should be verified. If appropriate, the claim should be corrected and rebilled. If the data is correct, the service must not be rebilled.
- 177 **The tooth surface on the Dental Invoice does not match the tooth surface on the prior authorization form on file with the Medical Services Administration.** The provider should verify the tooth surface billed with the surface that was prior authorized. If they match, the provider should contact the dental consultant.
- 178 **The quantity indicated on the claim is greater than the quantity indicated on the prior authorization form on file with the Medical Services Administration.**
- 180 **The procedure code billed has been deleted from the prior authorization form on file with the Medical Services Administration.**
- 181 **The prior authorization on file with the Medical Services Administration indicates the procedure code has previously been paid.** The service must not be rebilled.

- 182 **The service should have been included in the treatment plan on the prior authorization form, OR the prior authorization number has not been entered on the claim.**
- 183 **The date of service is prior to the date of the prior authorization.**
- 184 **The end date of service is missing.** The claim should be corrected and rebilled.
- 185 **The end date of service is invalid.**
- 186 **The end date of service is after the date the claim was received by the Medical Services Administration.** The date(s) should be verified. If appropriate, the claim should be corrected and rebilled.
- 187 **The range from begin to end date of service covers more than one month.** The provider should rebill each month on a separate claim.
- 188 **There is no authorization for long-term care on ACCESS for at least one of the dates covered by this claim.**
- 190 **The prior authorization number is not numeric.** The claim should be corrected and rebilled.
- 191 **The prior authorization number is invalid.**
- 192 **The provider does not have the appropriate specialty on file to be reimbursed for this procedure.** If the provider has the appropriate specialty, then the Provider Enrollment Unit should be notified and the claim rebilled. If the provider does not have the appropriate specialty, then the service must not be rebilled.
- 193 **The Children's Special Health Care Services Program has not authorized this date of service.**
- 194 **The Children's Special Health Care Services Program has not authorized this provider type to render treatment to this child.**
- 195 **The Children's Special Health Care Services Program has not authorized this provider ID Number to render treatment to this child.**
- 197 **The service requires prior authorization and the prior authorization number is not on the claim.**
- 199 **The procedure was reimbursed at the lesser of charge or screen.** The explanation code is for informational purposes only.
- 201 **The provider ID Number on the claim does not match the provider ID Number that was authorized to treat this beneficiary.**

- 202 **Medicaid has been billed before six months had elapsed since billing the other insurance carrier.** The provider should wait until six months after billing the other insurance carrier before rebilling the claim.
- 203 **The provider must bill the other insurance carrier first for ancillary services.** (ACCESS indicates that the beneficiary has other insurance but the claim indicates no action was taken by the other insurance carrier.) The provider should bill the other insurance carrier, await a response, then rebill the claim.
- 209 **The vision copayment has been deducted.** The explanation code is for informational purposes only.
- 210 **The original Claim Reference Number on the claim adjustment is invalid.**
- 211 **The original Claim Reference Number on the claim adjustment is missing.** The claim should be corrected and rebilled.
- 213 **The original claim line number on the claim adjustment is invalid**
- 214 **The original claim line number on the claim adjustment is missing.**
- 216 **The Health Maintenance Organization or Clinic Plan has billed too far in advance.** The date(s) should be verified. If incorrect, the claim should be corrected and rebilled.
- 217 **The end date of service does not equal the last day of the month.**
- 218 **The begin date of service does not equal the first day of the month.**
- 219 **The primary surgical procedure date is invalid.**
- 220 **The primary surgical procedure date is missing.** The claim should be corrected and rebilled
- 222 **The prescription number is missing.** The claim should be corrected and rebilled.
- 223 **The prescription number is invalid.**
- 224 **The beneficiary is restricted to primary providers as indicated on the beneficiary's ID Card.**
- 225 **The beneficiary requires prior authorization as indicated on the beneficiary's ID Card.**

- 228 **The pharmacy's prescribing/referring physician is not the restricted beneficiary's primary provider as indicated on the beneficiary's ID Card.**
- 229 **The emergent condition code is missing.** The claim should be corrected and rebilled.
- 230 **The emergent condition code is invalid.**
- 232 **The beneficiary is eligible for Children's Special Health Care Services Program coverage on the date(s) of service.**
- 233 **The referral code is missing.** The claim should be corrected and rebilled.
- 234 **The referral code is invalid.**
- 235 **The provider ID and the procedure code billed are not compatible.**
- 236 **The beneficiary was not enrolled in a Qualified Health Plan/Health Maintenance Organization/Clinic Plan on the date(s) of service.**
- 238 **The locator code is invalid.**
- 239 **The Medicare status code is missing.** The claim should be corrected and rebilled.
- 240 **The Medicare status code is invalid.**
- 242 **The Medicare status code and Medicare coinsurance and deductible relationship is invalid, as:**
- the status code indicates the entire charge was applied to the deductible and no deductible was billed, or
 - the status code indicates Medicare payment was made and no coinsurance/deductible was billed, or
 - the status code indicates Medicare did not cover the service and the coinsurance/deductible was billed.
- 243 **The Medicare status code and Medicare payment relationship is invalid, as:**
- the status code indicates payment and no claim line payment(s) is shown, or
 - the status code indicates no payment and claim line payment(s) is shown.

- The claim should be corrected and rebilled.
- 244,245 **The claim is being reviewed for possible Medicare coverage.**
- 246 **The beneficiary is eligible for Medicare, however, the claim shows the beneficiary is under age 65.**
- 247 **The beneficiary is age 65 or older and there is no indication that Medicare has made payment or applied the charge to the beneficiary's deductible.**
- 251 **The facility is billing for ancillary services that have not been approved by Medicare.** Only those ancillary services with a coinsurance or deductible amount may be billed by the facility. The service must not be rebilled.
- 252 **The type of service code on the claim does not match the type of service code on the prior authorization form on file with the Medical Services Administration.** The provider should verify the type of service code on the claim with his/her copy of the prior authorization form. If the claim is incorrect, the provider should correct and rebill the claim. If the prior authorization form is incorrect, the provider should submit a copy of the prior authorization form, indicating the correction, to the Provider Professional Review Section. The claim should be rebilled when the provider receives his/her corrected prior authorization from Medicaid.
- 253 **The wrong procedure code system is being billed.**
- 254 **The other insurance code is missing.** The claim should be corrected and rebilled.
- 255 **The other insurance code is invalid.**
- 259 **Medicaid was billed before six months had elapsed since billing the other insurance carrier.** The provider must allow six months for the other insurance carrier to respond. If no response is received within six months, the service should be billed.
- 262 **The beneficiary data on ACCESS indicates other insurance.** The provider should investigate to determine if benefits are available. The claim should be rebilled using the correct other insurance code and documentation.
- 264 **The discharge status code is missing.** The claim should be corrected and rebilled.
- 265 **The discharge status code is invalid.**

- 269 **The claim is being manually reviewed for possible change in other insurance status.**
- 271 **The Qualified Health Plan/Health Maintenance Organization/Clinic Plan beneficiary has other insurance.** The explanation code is for informational purposes only.
- 272,273 **The beneficiary has another insurance coverage for pharmacy;** The pharmacy must bill the Other Insurance carrier first before billing Medicaid, Children's Special Health Care Services, or the State Medical Program. See your Pharmacy Manual Appendix C for requirements regarding Other Insurance billings and Chapter IV for billing instructions for prescriptions with Other Insurance payments.
- Beneficiary ID cards will indicate an Other Insurance Code of 87 when a beneficiary has another pharmacy insurer. Also, pharmacies may identify this Other insurance Code and obtain Carrier Codes from ACCESS by calling 1-800-723-8247 (telephone voice response) or 1-800-759-3425 (computer-modem).**
- 276 **The sum of the amounts paid by the other insurance carrier does not equal the total other insurance amount paid.** The provider should recalculate the dollar amount on each claim line. The total of the other insurance payment on each claim line must equal the total other insurance payment item. The claim should be corrected and rebilled. (The provider may rebill indicating a lump sum other insurance payment in the Remarks section or Total Other Insurance Paid item. A copy of the other insurance's payment voucher must accompany the claim.)
- 277 **The sum of the amounts billed does not equal the total amount billed.** The provider should correct the dollar amounts on each claim line and rebill the claim.
- 278 **The noncovered charge is greater than the beneficiary-pay amount.** The explanation code is for informational purposes only.
- 279 **The claim line date of service is not included in the range of dates indicated by the from and thru dates on the claim.** The claim should be corrected and rebilled.
- 280 **The surgeon's provider ID Number is invalid.**
- 282 **The beneficiary-pay amount does not agree with the data on ACCESS for this date of service.** The beneficiary-pay amount for this beneficiary should be verified by the provider before billing another claim for this beneficiary. The explanation code is for informational purposes only.

- 284 **State-owned and operated facilities are not allowed to offset beneficiary-pay amounts.** The service must not be rebilled.
- 287 **State-owned and operated facilities may not bill for services that have been applied to the Medicare Part B deductible.** The claim should not be rebilled.
- 288 **The relationship between the claim status code and discharge status code is invalid.** The claim should be corrected and rebilled.
- 292 **This beneficiary is not authorized for long-term care for these dates of service.** The claim should not be rebilled.
- 294 **There is an invalid relationship between the claim line date of service and the number of days/quantity.** The claim should be corrected and rebilled.
- 295 **The claim status code is invalid or missing.** The claim should be corrected and rebilled.
- 296 **The relationship between the claim status code and the admission begin date is invalid.** The claim should be corrected and rebilled.
- 298 **The relationship between the Medicare indicator and the beneficiary's age is invalid.** The claim should be corrected and rebilled.
- 299 **Ancillary services may not be billed to Medicaid by State-owned and operated facilities.** The claim should not be rebilled.
- 301 **The relationship between the Adjustment Code (Type of Bill indicator) and the Original Claim Reference Number is invalid.** The claim should be corrected and rebilled.
- 302 **Outpatient services for beneficiaries in a long-term care facility are limited to ancillary services.** The service must not be rebilled.
- 303 **The Medicare indicator is invalid.** The claim should be corrected and rebilled.
- 306 **Pharmacies cannot bill over-the-counter products that are included in the facility's per diem rate for a beneficiary in a long-term care facility.** The service must not be rebilled.
- 308 **Payment was forced for this enrollee who lost Medicaid eligibility for this month.** The explanation code is for informational purposes only.
- 309 **The first date of service may not be a therapeutic leave day.**

- 310 **The service is included in the long-term care facility's per diem rate.**
- 313 **The last date of service cannot be a therapeutic leave day.**
- 314 **The coinsurance amount plus deductible amount is greater than the amount billed on the Medicare lines.** The provider should verify the amount used with the Medicare voucher and correct and rebill the claim.
- 315 The date the claim was submitted to the other insurance carrier is invalid. The explanation code is for informational purposes only.
- 317 **The relationship between the beneficiary's level of care and the provider type is invalid.**
- 319 **This is a continuous or final billing for outpatient services.** The claim status code should be corrected and the services rebilled.
- 320 **The relationship between Medicare indicator on claim lines 6 through 10 and the information on the claim line may be invalid as:**
- **the indicator is blank, which is to be used for claims with Medicare (T18) payment, and no claim line Medicare payment is shown, or**
 - **the indicator is "2", which is to be used for claims without Medicare payment, and a claim line Medicare payment is shown.**
- The claim should be corrected and rebilled.
- 321 **The procedure is being reviewed as a separate procedure.**
- 322 **The noncovered charges are not prior authorized.** The service must not be rebilled.
- 323, 325 **Multiple procedures are being reviewed for appropriate reimbursement.**
- 324 **Multiple procedures will be reimbursed based on claim line order with the primary procedure first.**
- 326, 327 **The appropriate CLIA lab specialty code is not on the Provider Enrollment file.** The provider should notify Provider Enrollment, in writing, of its CLIA certification. The claim must not be rebilled until the Provider Enrollment file is updated.
- 328 **The beneficiary is eligible for only Children's Special Health Care Services Program coverage and the service billed is not a benefit of that program.** The service should not be rebilled.

- 329 **The number of days or visits is missing.** The claim should be corrected and rebilled.
- 330 **The number of days or visits is invalid**
- 331 **The relationship between the number of days billed, the from and thru dates, and discharge status code is invalid.** The claim should be corrected and rebilled.
- 332 **The total number of days billed does not equal the sum of the days on the claim lines.**
- 333 **This procedure code cannot be used by this provider.** The service should **not** be rebilled.
- 334 **Days supply is invalid or missing.** The claim should be corrected and rebilled.
- 335 **The originating county code is invalid.** The explanation code is for informational purposes only.
- 336 **Days supply is greater than 100 days.** The service must **not** be rebilled.
- 337 The compounded indicator was changed to 1, as the value submitted was invalid. **Valid values are 4 (home infusion therapy), 3 (compound for capsules, suppositories, and tissue papers), 2 (compound for other forms) and 1 (not a compound).** The explanation code is for informational purposes only.
- 338 **The procedure code billed with this diagnosis code requires prior authorization, but there is no prior authorization number on the claim.**
- 339 **The claim adjustment is for a procedure code requiring prior authorization.**
- 340 **The destination county code is invalid.** The explanation code is for informational purposes only.
- 341 **This laboratory service is not allowed for this provider type.** The service must **not** be rebilled.
- 342 **A unit dose fee has been approved for this provider.** The explanation code is for informational purposes only.
- 343 **This procedure is being manually reviewed for identification of the referring/attending provider.**

- 344 **This procedure cannot be reimbursed as the referring/attending provider ID Number on the claim is missing or invalid. The claim should be corrected and rebilled.**
- 348 **This service has been reimbursed as a bilateral procedure based on the reporting of Modifier Code 50. This explanation code is for informational purposes only.**
- 349 **Modifier Code 50 has been reported for this procedure, but no additional reimbursement has been made. This explanation code is for informational purposes only.**
- 350 **The place of service code is missing. The claim should be corrected and rebilled.**
- 355 **The quantity billed is invalid or missing.**
- 364 **The service has been rejected as it was rendered upon an order/prescription from a suspended provider. The claim must not be rebilled.**
- 367 **The claim reflects a quantity in excess of the quantity normally accepted for this drug. This explanation code frequently causes payment rejections, because the proper billing unit was not used (e.g. milliliters were used instead of vials). Pharmacies should rebill with corrected quantity entries.**
- When quantity limits are exceeded, a pharmacy may receive payment by rebilling and *listing the prescriber's daily dosage instruction* in the Remarks or Drug Description of the invoice. For dermatologicals, also list the size of the application area. [Note: The prescriber's daily dosage instruction times the number of Days Supply billed must equal the Quantity billed.]**
- 369 **The drug billed requires prior approval and the required prior authorization number was invalid for the beneficiary. The claim should be corrected and rebilled, if appropriate. (The prior authorization number must be entered in the Authorization No. field, not the Remarks.)**
- 370 **The National Drug Code (NDC) is not on the Program's drug file. Check the NDC entry for accuracy and rebill.**
- 371 **The National Drug Code (NDC) billed is not normally dispensed for a beneficiary of this age.**
- 372 **The National Drug Code (NDC) billed is not applicable for the beneficiary's sex. All data should be verified. If appropriate, corrections should be made and the claim rebilled. If the data is correct, the service must not be rebilled.**

- 373 **The compounded drug claim is being manually priced.**
- 374 **The amount billed is being manually reviewed.**
- 376 **Medicaid, Children's Special Health Care Services or the State Medical Program does not cover the drug billed. All data should be verified, especially the Michigan Medicaid Drug List (Appendix F). If appropriate, corrections should be made and the prescription rebilled. If the data is correct, the prescription must not be rebilled.**
- 377 **The new/refill code is missing. The claim should be corrected and rebilled.**
- 378 **The new/refill code is invalid. The claim should be corrected and rebilled.**
- 379 **The fee for this procedure is being manually reviewed.**
- 380 **The acquisition charge is missing.**
- 381 **The facility charge is invalid.**
- 382 **The quantity times the rate does not equal the hospital charge.**
- 383 **The professional charge is missing. The claim should be corrected and rebilled.**
- 384 **The professional charge is invalid. The claim should be corrected and rebilled.**
- 386 **Charges billed appear inconsistent for the National Drug Code (NDC). Possible problems are (1) the pharmacy may have billed a generic drug under a brand name NDC or (2) the pharmacy billed only a beneficiary's copayment for another insurer (e.g., \$2, \$5, \$10) instead of separately listing the pharmacy's total charges for product cost and professional fee with the Other Insurance payment on the claim. See the Pharmacy Chapter IV for billing instructions for prescriptions with Other Insurance payments.**
- 388 **The diagnosis code does not appear to support the procedure billed.**
- 389 **There is an invalid relationship between the number of days billed, the from and thru dates, and the discharge status code.**
- 390 **The other insurance payment on this claim line is invalid.**

- 391 **Proposed less than effective drugs and identical, related, and similar products are not covered. The services must not be rebilled.**
- 392 **The quantity entry and package size for the National Drug Code (NDC) billed are inconsistent. The pharmacy should check the quantity entry on the claim to make sure that decimals were billed for fractional package sizes (e.g. 18.1 gms) or that the quantity relates to the NDC package (e.g., billing 21, not 28, for an oral contraceptive sold in packages of 21).**
- 394 **Inpatient hospital services for Wayne County Resident County Hospitalization beneficiaries require prior authorization by the Wayne County PLUS CARE Program.**
- 395 **The amount billed on this claim line is missing.**
- 396 **The charges minus Medicare and other insurance payment(s) do not equal the amount billed. The explanation code is for informational purposes only.**
- 397 **The charges minus Medicare and other insurance payment(s) do not equal the amount billed.**
- 400 **The total number of lines is invalid. The explanation code is for informational purposes only.**
- 401 **The total number of lines is missing. The explanation code is for informational purposes only.**
- 402 **The number of claim lines read does not equal the total number of lines indicated. The explanation code is for informational purposes only.**
- 403, 407,
409 **The data on ACCESS indicates other insurance. The provider should investigate to determine if benefits are available. The claim should be rebilled using the correct other insurance code and documentation.**
- 404 **The claim is being manually reviewed for possible change in other insurance status.**
- 408 **The claim is being manually reviewed for possible change in other insurance status.**
- 410 **The Medicare payment is invalid.**
- 411 **The claim is being manually reviewed for possible change in other insurance status.**

- 412, 413,
414 **Medicaid was billed before six months had elapsed since billing the other insurance carrier. The provider must allow six months for the other insurance carrier to respond. If no response is received within six months, the service should be rebilled.**
- 415 **The Medicare coinsurance amount is invalid.**
- 416 **The amount billed as Medicare coinsurance is not calculated correctly based on the total Medicare payment.**
- 417 **This elective service (Emergent Condition Code 2) was performed in the emergency room. The service should be rebilled using the clinic visit Procedure Code 169525.**
- 418 **This urgent service (Emergent Condition Code 3) was performed in the emergency room. The service should be rebilled using the clinic visit Procedure Code 169525.**
- 420 **The amount applied to the Medicare deductible exceeds the yearly Medicare deductible.**
- 421 **The provider is billing a procedure code that is incompatible for the setting and the provider specialty.**
- 422 **A hospital charge is not allowed for this procedure, or the procedure performed is not indicated on the claim.**
- 423 **This procedure code and type must be billed on the Michigan Health Benefits Claim form.**
- 424 **This procedure code supports the hospital charge codes, no charge is allowed. The explanation code is for informational purposes only.**
- 425 **The total other insurance paid is invalid.**
- 426 **The beneficiary is enrolled in the Wayne County PLUS CARE Program. The provider should contact the beneficiary's health care or dental contractor.**
- 427 **Effective October 1, 1988, Wayne County does not have a Resident County Hospitalization Only program. The claim should not be rebilled.**
- 428 **State Medical Program coverage does not include inpatient hospital services. The claim should not be rebilled. The provider should contact the Wayne County Family Independence Agency office.**

- 429 **Services to beneficiaries eligible for the State Medical Program in Wayne County rendered prior to enrollment with a health care/dental contractor are not covered. The claim must not be rebilled.**
- 432 **The quantity billed is missing or invalid, or the outpatient hospital has asked for individual consideration.**
- 433 **The total charge is invalid or missing.**
- 434 **The total Medicare payment is not numeric.**
- 435 **The total facility charge is invalid.**
- 436 **The sum of the hospital charges does not equal the total hospital charge.**
- 437 **The sum of the charges does not equal the total charge.**
- 438 **The sum of the Medicare payments does not equal the total Medicare payment. The explanation code is for informational purposes only.**
- 439 **The sum of the other insurance payments does not equal the total other insurance payment.**
- 440 **The professional charges total is invalid.**
- 441 **The sum of the professional charges does not equal the total professional charge.**
- 443 **The date of service is not within the authorized period. The service must not be rebilled.**
- 444 **Services may be the responsibility of the beneficiary's health care or dental contractor in the Wayne County PLUS CARE Program.**
- 445 **The total payments from other sources is invalid.**
- 446 **The drug requires prior approval and the prior authorization number is missing.**
- 447 **The beneficiary is a Qualified Medicare Beneficiary. This code is for informational purposes only.**
- 448 **Medicaid is liable only for the coinsurance and deductible portion of a Medicare-covered service for Medicare Qualified Beneficiaries. The claim must not be rebilled to Medicaid.**

- 450 **The beneficiary-pay amount is invalid.**
- 452 **The claim is pending for manual review of the beneficiary-pay amount.**
- 454 **This service is not covered by the Program. The service must not be rebilled.**
- 456 **The beneficiary-pay amount less the noncovered charge is not equal to the net beneficiary-pay amount.**
- 457 **The claim is being reviewed as the place of service may not be acceptable for this surgery.**
- 458 **The inpatient stay has exceeded 30 days.**
- 459 **The inpatient stay has exceeded 60 days.**
- 462 **The beneficiary is only eligible for emergent/urgent services and elective services have been billed. The service must not be rebilled.**
- 463 **The physician sponsor's ID Number and type code are not the same as the provider ID Number and type code or referring/attending provider ID Number and type code on the claim. The provider should verify that the provider ID Number and type code used on the claim are the physician sponsor ID Number and type code. (There may be instances when the physician sponsor has more than one ID Number but only one is the correct number for the Physician Sponsor Plan for this beneficiary.)**
- 464 **The total amount billed is missing. The claim should be corrected and rebilled.**
- 465 **The total amount billed is invalid.**
- 467 **The total net charge minus the net beneficiary-pay amount does not equal the amount billed. The explanation code is for informational purposes only.**
- 468 **The summary of the charges does not agree with the total amount billed.**
- 469 **The sum of the amounts billed does not equal the total amount billed. The explanation code is for informational purposes only.**
- 472 **The Physician Sponsor's/Clinic Plan's Medicaid provider ID Number is not the same as the attending physician's provider ID Number on the claim. The provider should verify the attending physician's provider ID Number on the claim. If the number on the claim is incorrect, the**

provider should correct and rebill the claim. If the beneficiary was referred for medical care, the attending physician's provider ID Number must indicate the Physician Sponsor's/Clinic Plan provider ID Number on the claim when billing. Medicaid will not cover services rendered to a Physician Sponsor/Clinic Plan beneficiary without the physician sponsor's/Clinic Plan authorization unless the services were in response to an emergency situation.

- 473 **The beneficiary is enrolled in the Beneficiary Monitoring Program as requiring prior authorization for services.**
- 474 **The beneficiary is enrolled in the Beneficiary Monitoring Restricted Provider Control Program and the provider ID Number is not the same as the provider or referring/attending/prescribing provider ID Number on the claim.**
- 480 **The unit dose repackaging fee was not included in reimbursement because the prescription was not dispensed to a long-term care beneficiary OR the product is not an oral solid OR the product is a manufacturer prepackaged unit dose OR the pharmacy is not authorized for unit dose repackaging reimbursement. This code is for informational purposes only.**
- 483 **The beneficiary-pay amount has been corrected to match the amount on ACCESS. If an insufficient beneficiary-pay amount has been collected, the balance is due from the beneficiary. If an excessive amount has been collected, the balance is due to the beneficiary. This code is for informational purposes only.**
- 486 **The beneficiary no longer resides in the Qualified Health Plan/Health Maintenance Organization/Clinic Plan service area.**
- 488 **The Children's Special Health Care Services Program has not authorized this provider type to render services to this child.**
- 489 **The beneficiary is not eligible for Health Maintenance Organization or Clinic Plan enrollment.**
- 492 **The beneficiary was not eligible for Children's Special Health Care Services, Medicaid, State Medical Program, or Resident County Hospitalization coverage on the date(s) of service. The date(s) and beneficiary ID Number should be verified. If appropriate, the claim should be corrected and rebilled. If the data is correct, the service must not be rebilled.**
- 494 **The beneficiary was determined ineligible for Medical Assistance after a Medicaid ID Card was issued. Since a card was issued, the claim has been processed for payment. This also applies to the**

State Medical Program in those counties where an ID Card is issued. The explanation code is for informational purposes only.

- 495 **The beneficiary is over one year of age and is not enrolled in a health maintenance organization or clinic plan on the date of service.**
- 497 **This claim line is paid at 50% of the provider's charge or at 50% of Medicaid reimbursement, whichever is less. The explanation code is for informational purposes only.**
- 498 **This service must be billed with a modifier. The claim should be rebilled with the appropriate modifier.**
- 500 **Multiple procedures have been billed. Reimbursement on this claim line, combined with other paid procedures, represents the total payment for this service.**
- 503 **The date of service on the claim requires manual review. Adjustments will be processed manually.**
- 504 **The date of service on the claim is too old for immediate computer processing. The claim will be processed within 90 days.**
- 505 **The dates of service span two or more historical processing periods. Each date of service must be rebilled on a separate claim.**
- 506 **The services do not reflect the provision of nursing or physical therapy services.**
- 510 **The claim indicates a possible DRG overpayment.**
- 511 **The claim indicates a readmission to the hospital within 15 days of discharge from a different hospital.**
- 513 **The claim indicates a readmission to the same hospital within 15 days of discharge. The claim should be rebilled as explained in the Medicaid Hospital Manual.**
- 515 **The outpatient claim indicates emergency room services (Procedure Code 169032) and subsequent admission to the inpatient hospital setting.**
- 518 **This beneficiary was readmitted/rehospitalized within 15 days of discharge from a different hospital.**
- 519 **This beneficiary was readmitted/rehospitalized to the same hospital within 15 days of discharge.**

- 526 **The documentation submitted does not reflect the diagnosis and/or procedure as indicated on the claim. The claim has been reassigned to a new DRG.**
- 530 **The outpatient claim is for services provided during an inpatient stay. These outpatient services must be included on the inpatient claim. The outpatient hospital must contact the inpatient hospital for reimbursement for these services.**
- 534 **The total of the beneficiary-pay amount on all long-term care invoices for this beneficiary for this month of service exceeds the beneficiary-pay amount shown on ACCESS. The explanation code is for informational purposes only. The provider should refund the excess beneficiary-pay amount to the beneficiary and submit a claim adjustment.**
- 535 **The total of the beneficiary-pay amount on all long-term care invoices for this beneficiary for this month of service is less than the beneficiary-pay amount shown on ACCESS. The Medical Services Administration has corrected the beneficiary-pay amount on this claim to reflect the beneficiary-pay amount shown on ACCESS for the month.**
- 536, 538 **The amount billed for this laboratory service exceeds the dollar limitation established by the Program.**
- 548 **The claim is a duplicate of a previously paid claim. The Claim Reference Number, line number, and payment date of the paid claim are shown. (If the Claim Reference Number following Explanation Code 548 is the same as the number assigned to this claim in the left column on the Remittance Advice, duplicate services are billed on this claim.)**
- 549 **The claim is a duplicate of a claim paid to another Health Maintenance Organization.**
- 552 **The claim is a duplicate of a previously paid claim. The Claim Reference Number, line number, and payment date of the paid claim are shown. (If the Claim Reference Number following Explanation Code 552 is the same as the number assigned to this claim in the left column on the Remittance Advice, duplicate services are billed on this claim.) If the service was to be included with another service that has already been paid, then the paid claim must be claim adjusted to include the first service.**
- 553 **The frequency of this service is being manually reviewed.**
- 555 **The date(s) of service is invalid.**

- 560 **A claim is on file with a different drug entity for the same beneficiary and prescription number.** The explanation code is for informational purposes only.
- 562 **Refills of Schedule II drugs are not covered.** The prescription must not be rebilled.
- 563 **A refill for a Schedule III, IV, or V drug was billed more than 180 days from the date of service of the original prescription.** A new prescription is required.
- 564 **A new prescription with refill code "1" has already been paid for this prescription.** The service must be rebilled with refill code "2" or a new prescription is required.
- 565 **The claim is billing for the sixth refill of the prescription for a Schedule III, IV, or V drug.** Only five refills are allowed. A new prescription must be obtained before the prescription is rebilled.
- 567 **The beneficiary has received the same drug from two different pharmacies within a short period of time.** The explanation code is for informational purposes only.
- 571 **The dates of service for this inpatient claim overlap the dates of service for another paid claim and the amounts billed are equal.**
- 572 **This is a duplicate claim paid to the same Qualified Health Plan/Health Maintenance Organization/Clinic Plan for the same beneficiary and the same date(s) of service.** The Claim Reference Number and payment date of the paid claim are shown. (If the Claim Reference Number following Explanation Code 572 is the **same number** assigned to this claim in the left column on the Remittance Advice, duplicate services are billed on this claim.) The service must **not** be rebilled.
- 573 **The service was previously paid to a Health Maintenance Organization or Clinic Plan.**
- 574 **The Qualified Health Plan/Health Maintenance Organization/Clinic Plan invoice dates of service overlap the dates of the previously paid claim to another type of provider.**
- 575 **The dates of services for this claim are duplicate or overlapping the dates of service for another paid claim.**
- 576 **The payment of this Medicare deductible would result in overpayment of the Medicare deductible for the year.**

- 577 **More than 28 therapeutic leave days have been used in the last 365 days.**
- 579 **The sum of all beneficiary-pay amounts accumulated by this payment system, for this beneficiary, for this month of service, does not equal the beneficiary-pay amount on the system. This explanation code applies to claim adjustments only. If the claim is rejected, correct the beneficiary pay amount and rebill the adjustment.**
- 581 **The claim to be adjusted cannot be located as a paid claim for this beneficiary.**
- 582 **An attempt was made to adjust a Claim Reference Number or line number which has already been adjusted. Only the last paid Claim Reference Number/line number can be adjusted. The claim adjustment should be rebilled using the last paid Claim Reference Number.**
- 584 **This is the Claim Reference Number of the claim being adjusted. The explanation code is for informational purposes only.**
- 585 **Based on the last date billed, the drug was dispensed too early, or the drug was dispensed more frequently than allowed. The service must not be rebilled.**
- 586 **The drug quantity billed exceeds accepted dosing policies allowed, and an authorization number was not documented on the claim. The claim should be corrected and rebilled, if appropriate.**
- 589 **This fiscal year has been final gross adjusted.**
- 590 **The acute dosing coverage for ulcer drugs has been exceeded and no Utilization Review Number has been submitted with the request for payment. The service must not be rebilled.**
- 592, 593 **Services within a group practice may have exceeded the allowable frequency.**
- 596 **More than one provider type has billed for case management for the same month. The explanation code is for informational purposes only.**
- 600 **Determination of reimbursement for the DRG is being made. The explanation code is for informational purposes only.**
- 601, 603 **The combination of services billed for the same date of service is being manually reviewed.**
- 602 **This service was included in another procedure code billed on the same date of service. The service must not be rebilled. To be considered for additional payment, the first service, which was paid, must**

be claim adjusted, individual consideration requested, and documentation of all services rendered must be attached to the claim adjustment.

- 604 **A component part of this procedure was billed for the same date of service on a previously paid claim.** To be paid for this service, it is necessary to claim adjust the previously paid claim line.
- 606 **Multiple procedures or services have been billed on separate claims.** To be paid for this service, it is necessary to claim adjust the previously paid claim line.
- 607 **The frequency of the combination of services billed exceeds Program policy limits.** The services must **not** be rebilled.
- 608, 609 **The frequency of the combination of services billed exceeds Program Policy Limits. Medical necessity must be documented.**
- 681 **This claim adjustment has been created by the Medical Services Administration to recover payment for a retroactive health maintenance organization disenrollment.** This explanation code is for informational purposes only.
- 690, 691 **This claim has been re-entered/created by the Medical Services Administration.** The explanation code is for informational purposes only.
- 693-699 **The beneficiary's eligibility has been manually reviewed.** The explanation code is for informational purposes only.
- 700 **The reimbursement amount was manually determined.** The explanation code is for informational purposes only.
- 701 **A portion or all of the outlier days have been denied.** The claim has been adjusted accordingly.
- 702 **The quantity has been corrected to correspond with the procedure code description and submitted documentation.** In the future, the quantity field must be completed with the correct quantity. The explanation code is for informational purposes only.

OR

The quantity of visits has been changed to reflect those on the submitted beneficiary care plan of treatment. For payment to be considered for additional visits, a claim adjustment is required with documentation supporting the necessity for the additional visits.

- 703 **Medicaid is only responsible for the Medicare 20% coinsurance amount for those beneficiaries eligible for Medicare Part B for a total amount not to exceed Medicaid's reimbursement limitation.** The claim has been processed for this amount up to Medicaid's maximum limitation. The explanation code is for informational purposes only.
- 704 **The maximum allowance for this service has been paid. For inpatient hospitals, any change in the charges will be manually reflected in the final settlement data.** The explanation code is for informational purposes only.
- 705 **A computational error has been corrected and the total amount billed has been processed accordingly.** The explanation code is for informational purposes only.
- 706 **For Inpatient Hospital: The beneficiary's beneficiary-pay amount according to ACCESS is less than the amount reflected on the claim.** If you have collected an inappropriate beneficiary-pay amount, the difference should be refunded to the beneficiary. The explanation code is for informational purposes only.
- For Long-Term Care: The total of the beneficiary-pay amount on all long-term care invoices for this beneficiary for this month of service is less than the beneficiary-pay amount on ACCESS.** The Medical Services Administration has corrected the beneficiary-pay amount on this claim to reflect the beneficiary-pay amount shown on ACCESS for the month.
- 707 **The service on this claim line has been recoded to the correct procedure/type/drug code.** The provider must use the corrected code for future billings. The explanation code is for informational purposes only.
- 708 **The utilization review sheet, discharge summary, anesthesia report, or admission history and physical was either not received or incomplete.** **The claim should be rebilled with the appropriate documentation**
- 709 **A PACER number must be obtained before this claim can be paid**
- 710 **The documentation submitted for review of this admission does not warrant a second DRG payment.** The provider should include the services for this admission on the claim for the first admission. If the first admission has been paid, then these services must be included on a claim adjustment for the first admission.
- 711 **The Optical Character Reader could not read the typed print properly.** This may be corrected by cleaning the type font, changing the

ribbon, or properly aligning the claim. The explanation code is for informational purposes only.

- 712 **A review of this readmission appears to warrant two separate DRGs.** A claim for each admission must be submitted along with the required documentation attached to each claim.
- 713 **The claim has been manually rejected.** A separate cover letter has been sent to the provider explaining the reason for this rejection.
- 714 **The documentation is not adequate to warrant additional payment for this service.** If appropriate, a claim adjustment should be submitted with complete documentation of the service provided. The explanation code is for informational purposes only.
- 715 **Claims should be rebilled with the actual product cost of the item documented.** The explanation code is for informational purposes only.
- 716 **This claim was rejected in error and has been resubmitted by the Medical Services Administration.** The explanation code is for informational purposes only.
- 717 **The provider type code and/or provider ID Number were corrected. In the future, this information must be completed properly.** The explanation code is for informational purposes only.
- 718 **This claim has been corrected to correspond with information on the prior authorization form.** The explanation code is for informational purposes only.
- 719 **Reimbursement for this Medicare Part A only claim includes a full DRG payment minus the coinsurance and/or deductible payments previously paid on the Part B only claim.** The explanation code is for informational purposes only.
- 720 **The diagnosis code has been corrected to correspond with the diagnosis description.** The explanation code is for informational purposes only.
- 721 **The Medicare status code has been corrected.** The explanation code is for informational purposes only.
- 722 **Your request for individual consideration has unnecessarily delayed the processing of your claim.** Please refer to Chapter IV of your billing manual for information on the appropriate use of individual consideration.

- 723 **The frequency of this service exceeds Program parameters. Medical necessity must be documented.** The explanation code is for informational purposes only.
- 724 **The information on this claim does not adequately support the use of Emergent Condition Code 1 (emergency).** If appropriate, the claim should be rebilled with complete documentation supporting the Emergent Condition Code 1.
- 725 **This procedure, reviewed under Explanation Code 087, has been rejected.** Having been previously advised of a provider's right to contest this decision, the provider may wish to address a request for an Administrative Hearing to the Manager, Plan Administration and Customer Services Bureau, Appeals Review Section, PO Box 30479, Lansing, MI 48909-7979.
- 727 **This claim has been manually rejected for reasons specified by the accompanying explanation codes with "P" (pend) indicators.**
- 728 **This rejected claim will be paid with a gross adjustment in accordance with the provisions of a letter forwarded under separate cover to the address indicated on page 1 of the Remittance Advice.** The claim should not be rebilled.
- 729 **This service has been billed on the wrong claim form.** The provider should refer to his/her provider manual for the correct claim form to use and rebill the claim.
- 730 **Multiple procedures have been billed on separate claim lines.** These procedures must be combined and rebilled on one claim line, using the appropriate procedure code.
- 731 **This service is included in another procedure performed on the same date.** The service must not be rebilled.
- 732 **This service is included in the reimbursement for the medical visit provided on the same date of service.** The service must not be rebilled.
- 733 **There is not sufficient information to process this claim line.** The claim line should be rebilled with complete documentation to support the service provided. If claim adjusting, a copy of the Remittance Advice page showing the last payment must also be attached.
- 734 **The quantity billed on this line is not consistent with the billing unit specified in Appendix F.** The claim should be billed with the correct quantity as specified in Appendix F.

- 735 **Multiple services are combined on one claim line.** Each service should be rebilled on a separate claim line.
- 736 **This service is included in the surgical fee/delivery fee/antepartum fee.** The service must not be rebilled.
- 737 **The service rendered is not covered by the Program.** The service must not be rebilled.
- 738 **This service is included as a component part of another service and cannot be reimbursed separately.** The service must not be rebilled.
- 739 **The procedure code/procedure type code/drug code on this claim line should be rebilled with the correct code.** (The provider should also review the combination of procedure type code and place of service code.) The claim should be corrected and rebilled.
- 740 **This service must be rebilled with a copy of the operative report, pathology report, or office or progress notes.** The claim should be rebilled with the appropriate documentation.
- 741 **This payment reflects the maximum Medicaid allowance minus the other insurance payment indicated on the claim.** The explanation code is for informational purposes only.
- 742 **The surgical procedures should be rebilled according to Program guidelines, in the proper sequence (indicating the primary procedure on the first claim line), with appropriate modifiers.** The claim should be corrected and rebilled.
- 743 **This claim has been manually rejected due to technical reasons.** The provider should not submit a new claim. The Medical Services Administration will re-enter the claim. It will be processed under a new Claim Reference Number and will appear on a future Remittance Advice.
- 744 **This claim has been rejected because the provider signature item was blank.** A signed claim should be rebilled.
- 745 **The drug listed on the claim cannot be paid without additional information including the manufacturer, National Drug Code, and dose (quantity given).** The invoice from the manufacturer, wholesaler, or pharmacy must be attached to the rebilled claim.
- 746 **This service cannot be series billed.** Each date of service must be rebilled on separate claim lines.
- 747 **Only one comprehensive examination or initial consultation is covered within six months.** The service should not be rebilled unless

there is appropriate documentation to support additional consultations and/or comprehensive visits.

- 748 **Services performed for the reported diagnosis code are not reimbursable due to the age or sex of the beneficiary.** The service must not be rebilled.
- 749 The pharmacy should recheck that the correct metric-billing unit as listed in the Michigan Medicaid Drug List (Appendix F) was used for the Quantity entry. Drug quantity exceeding the Medical Services Administration's established allowable amounts must be fully documented by "daily dosage instructions." **The claim should be rebilled with the appropriate documentation or corrected metric billing units.**
- 750 **Reimbursement cannot be determined for this product without additional information such as product name, manufacturer, National Drug Code or product number, dosage, form, strength, and quantity dispensed.** The claim should be rebilled with complete documentation.
- 751 **Medicaid records do not verify that the beneficiary-pay amount has been collected for this month of service.** The service must first be applied to the beneficiary's beneficiary-pay amount. Any services that are not covered by this amount may be rebilled.
- 752 **Medicaid records show this beneficiary was deceased during this period.** The claim should be rebilled for services rendered prior to date the beneficiary expired.
- 754 **The only noncovered services rejected by Medicare that can be billed to Medicaid are those specifically identified as Medicare exclusions.** The provider should contact Medicare to determine the reason for the Medicare rejection. If the claim was rejected by Medicare because:
- The service was billed incorrectly to Medicare, the provider should rebill Medicare.
 - The service was not medically necessary, Medicaid will not reimburse for the service.
 - The service is not a Medicare covered service, the provider may rebill Medicaid. The service must be rebilled on a separate claim. Only Medicare excluded services should be included on the claim.
- 755 **Those services covered by Medicare cannot be combined on one claim with services not covered by Medicare.** The provider must bill covered Medicare services on one claim and Medicare noncovered

services on a second claim with the appropriate Medicare status code on each claim.

- 756 **The Medicare payment voucher should be reviewed for approved amounts, payments, total coinsurance, and deductible.** The claim should be corrected and rebilled.
- 757 **An invoice cannot be submitted to adjust a previous payment.** Proper claim adjustment procedures must be followed as specified in Chapter IV of the manual.
- 758 **This claim adjustment cannot be processed.** A claim adjustment must match the last **paid** claim for the following items: provider ID number, beneficiary ID number, Claim Reference Number, and claim line number. The claim adjustment should be corrected and rebilled.
- NOTE:** A rejected claim cannot be claim adjusted, but requires submission of a **new** claim. Also, for purposes of claim adjusting, a claim that indicated a \$0.00 payment is considered a **paid** claim.
- 759 **Series billing on any one claim line cannot encompass services rendered in more than one calendar month.** The last date in the month that the service was rendered must be used. The claim should be rebilled indicating one calendar month per claim line **Note:** For long-term care-facilities: When billing for more than one month of service, each month must be submitted on separate claims
- 760 **This service requires prior authorization.** Since prior authorization was not obtained, the service is not covered by Medicaid. The beneficiary, his/her family, or representative, must not be billed for this service.
- 761 **The necessary documentation was not received.** The claim should be rebilled with appropriate, complete, legible documentation.
- 762 **The submitted documentation was not adequate or not legible.** The claim should be rebilled with complete, legible documentation.
- 763 **The date of service is more than 12 months old and the Medical Services Administration is unable to verify previous activity.** If the required documentation is available, the claim should be rebilled indicating the appropriate Pay Cycle numbers and Claim Reference Numbers of previous claim submissions for this service. Chapter I contains information on the billing limitation.
- 764 **The date of service is more than 12 months old and the Medical Services Administration is unable to verify previous activity.** The documentation of prior activity is incomplete or differs from the original

claim. If appropriate, the claim should be resubmitted with an explanation of the difference or with additional/corrected information.

- 765 **The date of service is more than 12 months old.** The Medical Services Administration is unable to verify previous activity and the documentation of prior activity was not complete. If the required documentation is available, the claim should be rebilled indicating the appropriate Pay Cycle numbers and Claim Reference Numbers of previous claim submissions for this service. Chapter I contains information of the billing limitation.
- 766 **A claim adjustment to request additional monies for a service can be billed up to 12 months from the date of the original payment.** If there has been no active review (as explained in Chapter I), the claim must not be rebilled.
- 767 **If Medicare involvement prevented the claim from being billed to Medicaid within 12 months, refer to Chapter I for special billing instructions.** The provider should refer to the MEDICARE section of Appendix C for the details on the appropriate documentation that is required to process the claim. The claim should be rebilled with full documentation.
- 770 **Surgical second opinion program requirements have not been met.** This service must not be rebilled.
- 771 **The review of Medicaid records shows that this claim was previously paid.** The claim must not be rebilled.
- 772 **Program records indicate that this beneficiary has Medicare.** The provider must bill Medicare first and receive a response prior to billing Medicaid.
- If the beneficiary is enrolled in Medicare, the provider must bill Medicare, await resolution of the claim, then rebill the claim.
 - If the beneficiary is eligible for, but not enrolled in Medicare, the provider should encourage the beneficiary to contact the local Social Security Administration office for information regarding Medicare benefits. Once the beneficiary is receiving Medicare benefits, the provider may bill Medicare, await a response, then rebill the claim.

For Inpatient Hospital Charges Only: The beneficiary is currently enrolled in Part B Medicare only. The provider should refer to Chapter IV, page 25 of the Hospital Manual for instructions to initiate Medicare Part A coverage. The provider is reminded to keep Medicaid claims active according to the policies in Chapter I of the provider manuals.

- 773 **Medicaid reimbursement cannot be made for this service without further documentation from Medicare (e.g., Explanation of Benefits, voucher, written explanation).** The provider should rebill the claim and include the appropriate documentation. **LONG-TERM CARE PROVIDERS:** The Explanation of Benefits is unacceptable documentation. **HOME HEALTH AGENCIES:** Medicaid reimbursement cannot be made for this service. Medicare will cover 100% of the cost or charge for home health services. There is no Part A or Part B deductible or coinsurance; therefore, the agency must not bill Medicaid for these services.
- 774 **We have not received either an Informed Consent to Sterilization (MSA-1959) or Acknowledgment of Receipt of Hysterectomy Information (MSA-2218) form.** Please submit a completed form according to the instructions published in Remittance Advice Message 24-97 dated 05/22/97, or by sending the completed form with your claim to MSA. If the form was not completed as required, the service is not covered by Medicaid and can not be rebilled to MSA. This service cannot be billed to the beneficiary, his/her family or representative.
- 775 **The Informed Consent to Sterilization or Acknowledgment of Receipt of Hysterectomy Information form is invalid due to one or more of the following:**
- required information is missing,
 - information on the form does not match the claim,
 - the form is not appropriate for the procedure, or
 - the form is not accepted by the Program as a valid form (e.g., MSA-1959 or MSA-2218).
- 776 **The diagnosis code indicated does not match the diagnosis file.** The provider should verify the diagnosis code used, correct, and rebill the claim.
- 777 **The information on the claim does not agree with or match the information on the submitted documentation or prior authorization form.** All data should be verified, including prior authorization number, procedure codes, names, dates, places of service, and payments. If appropriate, corrections should be made and the claim rebilled. If the data is correct, the service must **not** be rebilled.
- 778 **Medical necessity for the services billed is not reflected by the diagnosis code.** All data should be verified, including the diagnosis code subclassification digits, where indicated. If appropriate, corrections should be made and the claim rebilled. If the data is correct, the service must **not** be rebilled.

- 779 **Unnecessary hospital days, or services contrary to Program requirements, are not reimbursable.** This claim must not be rebilled until the provider has received the rebilling instructions.
- 780 **This beneficiary ID Number does not match the name and birthdate on the claim.** The provider should verify the beneficiary ID Number with either the Medicaid ID Card/Eligibility Notice or ACCESS. The claim should be corrected and rebilled.
- 781 **The claim has been billed using the mother's beneficiary ID Number and the services are for a child that is over six months old.** The provider should rebill the claim using the child's ID Number.
- 782 **This beneficiary does not have Medicare Part A or Part A benefits are exhausted.** The hospital charges for laboratory and/or radiology services must be included on a separate claim with other Part B charges. The provider should bill one claim showing all Part A charges and a second claim showing all Part B charges including the hospital laboratory and/or radiology charges.
- 783 **The Medical Services Administration's records indicate that the beneficiary's beneficiary-pay amount exceeds the total amount billed on this claim.** The service must not be rebilled.
- 784 **Multiple procedures or services have been billed on separate claims.** To be paid for this procedure or service, it is necessary to claim adjust the previously paid claim. A copy of the Remittance Advice page showing the paid claim must be sent with the claim adjustment.
- 785 **The amount to be paid for these services exceed the monetary amount allowed for nonprior authorized dental services (under 21 program), OR, the services are for a denture-related case and require prior authorization (expanded adult dental - age 21 and over program).** The service must not be rebilled.
- 786 **The service(s) billed on this claim was not included on the prior authorization form.** The service must not be rebilled.
- 787 **The beneficiary ID Number and/or name on the claim does not match the beneficiary ID Number on the prior authorization and/or documentation.** All data should be verified. If appropriate, corrections should be made and the claim rebilled. If the data is correct, the service must not be rebilled.
- 788 **The first paid surgical claim line is the line that MUST be used to adjust the multiple surgery payment even if it was billed properly as the major surgery.** The first paid surgical claim line MUST be exactly the same on the adjustment as it was on the previous billing except for

the charge. The procedure code, type, etc., **must** be the same. The charge must be the **total** dollar amount for the total surgery. A detailed explanation must accompany the claim adjustment including the reason for the adjustment and the order in which it should have been billed. A copy of the Remittance Advice page on which the claim was previously paid **MUST** be attached. Any operative notes or reports that will assist in determining payment must be attached. Individual consideration should be requested by indicating a Modifier Code "22" in Item 43J.

- 789 **The other insurance code indicates payment made, yet there is no other insurance payment shown on the claim.** The claim should be corrected and rebilled.
- 790 **The required documentation regarding other insurance action is not complete.** The provider should refer to the CLAIM COMPLETION, Other Insurance Code section of Appendix C for the appropriate documentation requirements. The claim should be corrected and rebilled.
- 792 **The beneficiary is not eligible and there is no pending application on file.** The service must **not** be rebilled.
- 793 **The other insurance policy has master medical coverage.** The service must be billed to the other insurance carrier.
- 795 **A manual review indicates these services are covered and benefits are currently available from another insurance carrier.** The provider should rebill the other insurance carrier for reimbursement. After the provider receives a response from the other insurance carrier, the claim should be rebilled.
- 796 **This compounded prescription cannot be processed as the ingredients are not sufficiently identified by name, manufacturer, National Drug Code, strength, form, and quantity.** The claim should be rebilled indicating complete documentation of the ingredients of the compound.
- 797 **There is an invalid relationship between the procedure code, diagnosis code, or drug code and the description of the services rendered.** All data should be verified. If appropriate, corrections should be made and the claim rebilled. If the data is correct, the service must not be rebilled.
- 798 **These services have been billed incorrectly under the mother's ID Number.** These services must be rebilled using the newborn's name, birth date, and ID Number.
- 800 **The payment is for the quantity shown.** The explanation code is for informational purposes only.

- 802 **Other insurance or Medicare money manually distributed.**
- 803 **This provider type is not allowed for the beneficiary's age. The claim must not be rebilled.**
- 804 **Effective for dates of service 10-01-98 and after, services rendered to Ingham County State Medical Plan beneficiaries are the responsibility of the Ingham Health Plan (Phone # 517-887-4301). Claims should be mailed to the:**
- Ingham County Health Department
Billing and Reporting Unit
5303 S. Cedar
Lansing, MI 48911
- 805 **State Medical Program (SMP). Effective 10-01-98 and after, payments for State Medical Plan (formerly General Assistance) services will be marked as "Indigent Medical Care Program" for the State of Michigan. Continue to submit claims for services to State Medical Program beneficiaries to the Medical Services Administration (MSA).**
- 807 **This claim adjustment has been created by the Medical Services Administration because the beneficiary's HMO enrollment status is under review. If the edit has been forced (appears with an asterisk), the Medical Services Administration has recovered payment for a retroactive HMO disenrollment. This explanation code is for informational purposes only.**
- 809 **The service billed is part of the Mental Health or Substance Abuse Capitation and cannot be billed directly to the MSA. These services should be billed to the Mental Health or Substance Abuse contractor in the beneficiary's catchment area.**
- 810 **The National Drug Code (NDC) billed has been terminated by the manufacturer. If the wrong NDC has been billed, you should rebill using the correct NDC.**
- 811 **The beneficiary is not in a long-term care setting and the unit dose system billed is not reimbursable.**
- 812 **Unit dose systems for liquids are not reimbursable.**
- 813 **The quantity entry and package size for the National Drug Code (NDC) billed are inconsistent. The pharmacy should check the quantity entry on the claim to make sure that decimals were billed for**

fractional package sizes (e.g., 18.1 gms) or that the quantity relates to the NDC package (e.g., billing 21, not 28, for an oral contraceptive sold in packages of 21).

- 814 **This National Drug Code (NDC) is being manually priced.**
- 821 **The product cost is paid based on the lower of charge or the AWP minus 15.1% for pharmacies owning five or more stores or for pharmacies with no retail customers serving long-term care beneficiaries. The explanation code is for informational purposes only.**
- 822 **The product cost is paid based on the lower of charge or the AWP minus 13.5% for pharmacies owning one to four stores. The explanation code is for informational purposes only.**
- 823 **The product cost is paid based on the lower of charge or manufacturer direct price. The explanation code is for informational purposes only.**
- 824 **The product cost is paid based on the lower of charge or a Maximum Allowable Cost (MAC) price. The Michigan Medicaid Drug List contains the MAC prices. Payment for a drug entity will not exceed the MAC price unless prior authorization is approved. The explanation code is for informational purposes only.**
- 825 **The claim was paid based on the lower of charge or estimated retail price or retail Maximum Allowable Cost (MAC) price. The explanation code is for informational purposes only.**
- 834 **The provider has not supplied MSA with a copy of the bond required by the Health Care Finance Administration (HCFA).**
- 840 **The claim indicates a date of service of February 1, 1985, or after. The claim is reimbursed using the DRG policies. The explanation code is for informational purposes only.**
- 842 **The services on this claim are reimbursed on a percent-of-charge basis.**
- 843 **The services on this claim, for this DRG, are reimbursed on a percent-of-charge basis. The explanation code is for informational purposes only.**
- 844 **The claim indicates a low-cost outlier.**

- 845 **The alternative weight for the DRG reimbursement for this hospital was used in determining the reimbursement amount. The explanation code is for informational purposes only.**
- 846 **The inpatient hospital claim is for a transfer beneficiary and is paid the daily DRG rate. The explanation code is for informational purposes only.**
- 847 **The claim indicates a low-day outlier. The claim is reimbursed at a percent-of-charge basis not to exceed the full DRG payment. The explanation code is for informational purposes only.**
- 848 **The claim indicates a high-day outlier. The explanation code is for informational purposes only.**
- 849 **The claim indicates a high-cost outlier. The explanation code is for informational purposes only.**
- 850 **The beneficiary was readmitted within 15 days of a previous discharge. Only the outlier payment is approved. The explanation code is for informational purposes only.**
- 854 **The Medicare coinsurance and deductible amounts for this DRG are being reviewed.**
- 855 **The DRG assignment is being manually reviewed.**
- 856 **This DRG requires prior authorization.**
- 857 **This DRG is being manually reviewed to determine the medical necessity and/or appropriateness of the admission.**
- 858 **Individual consideration has been requested for reasons other than transfer or readmission.**
- 859 **The wrong provider ID was used.**
- 860 **The claim does not contain sufficient information for a reimbursement determination.**
- 861 **The claim is reimbursed on a per diem basis. This explanation code is for informational purposes only.**
- 862 **Medicaid's internal group number for the hospital has caused the claim to pend.**
- 863 **The beneficiary was transferred to another facility/unit and the hospital has requested individual consideration for the full DRG payment.**

- 867 **This claim was rejected because the beneficiary was admitted and discharged on the same day and no accommodation day was billed.** The claim should not be rebilled unless there are both ancillary charges and accommodation day charges incurred.
- 868 **The beneficiary was admitted and discharged on the same day and an accommodation day was billed.**
- 869 **The Qualified Health Plan's (QHP) rate cell could not be determined.**
- 870 **Medicaid Qualified Health Plan (QHP) coverage has been purchased by Childrens Special Health Care Services.**
- 874 **The wrong Qualified Health Plan (QHP) ID number was used for the beneficiary's eligibility.**
- 875 **The combination of tooth number/letter is invalid for the procedure code billed.** If appropriate, the claim should be corrected and rebilled.
- 876 **A Medicare rate cell was used to pay the Qualified Health Plan (QHP) capitation rate for the beneficiary.** The explanation code is for informational purposes only.
- 880 **The total amount billed on this claim is \$0.00.** The explanation code is for informational purposes only.
- 881, 882 **This beneficiary has possible Medicare coverage and the claim was billed with a Medicare status code that indicates the beneficiary is not eligible for Medicare.** The provider should verify that the correct status code was used, make any necessary corrections and rebill the claim. If the claim indicates the correct code and was rejected, the provider should refer to Appendix C for additional information regarding Medicare resources.
- 883 **The beneficiary is enrolled in a Qualified Health Plan/Health Maintenance Organization/Clinic Plan on the date of service but the hospital admission might be before the enrollment date.**
- 891 **This claim is reimbursed at the operating per diem plus capital costs per case.** The explanation code is for informational purposes only.
- 895 **This claim is reimbursed under the standard rate DRG methodology.** The explanation code is for informational purposes only.
- 896 **This claim is an additional page of a multipage claim. No reimbursement is to be made.** This explanation code is for informational purposes only.

- 897 **The claim is for Resident County Hospitalization services for a beneficiary not in Wayne County.**
- 898 **The claim is pending for determination of Medicaid reimbursement after Medicare's payment.**
- 899 **The claim is pending for determination of Medicaid reimbursement.**
- 915 **Services in the inpatient hospital setting are not benefits of the State Medical Program. The claim must not be rebilled.**
- 930 **This beneficiary is eligible for the Resident County Hospitalization Program as authorized by a county other than Wayne County. The hospital used the provider ID Number for the Wayne County PLUS CARE Program. The hospital must rebill using the correct provider ID Number.**
- 931 **This beneficiary is eligible for the Resident County Hospitalization program as authorized by Wayne County. The hospital did not use the provider ID Number for the Wayne County PLUS CARE Program. The hospital must rebill using the correct provider ID Number.**
- 932 **The inpatient hospital claim indicates Source of Admission Form Locator 4 (Transfer from another hospital), or 6 (Transfer from Another Health Care Facility), and no admission authorization number is indicated on the claim. The explanation code is for informational purposes only.**
- 933 **The physician's claim requires an authorization number for the admission. This explanation code is for informational purposes only.**
- 934 **The date of admission is prior to the date of the admission authorization number.**
- 935 **The admission date is more than 30 days after the date of the admission authorization number.**
- 936 **The admission/readmission/transfer authorization number is missing.**
- 937 **The admission/readmission/transfer authorization number is invalid.**
- 938 **The admission/readmission/transfer authorization number on the claim was not assigned to this beneficiary.**

- 939 **These inpatient hospital claims are temporarily being held for processing in a future payroll.** The explanation code is for informational purposes only.
- 940 **The admission date on the claim does not match the from date.**
- 942 **The secondary surgical procedure requires an admission authorization number.** The explanation code is for informational purposes only.
- 943 **The secondary diagnosis requires an admission authorization number.** The explanation code is for informational purposes only.
- 944 **The primary surgical procedure requires an admission authorization number.** The explanation code is for informational purposes only.
- 945 **The primary diagnosis requires an admission authorization number.** The explanation code is for informational purposes only.
- 946 **The elective admission requires an admission authorization number.** The explanation code is for informational purposes only.
- 947 **A Beneficiary Status Code of 30 (Still a Beneficiary) was used on the inbeneficiary hospital claim.**
- 948 **The outpatient claim indicates emergency room services, Procedure Code 169032, and subsequent admission to the inbeneficiary hospital setting.**
- 949 **Professional charges are not allowed on an inpatient claim.** The professional charges must be billed on the Michigan Health Benefits Claim (or Dental Invoice, as appropriate). The inpatient charges should be rebilled on the inpatient hospital invoice.
- 950 **This claim is being manually reviewed.**
- 953 **The office copayment has been deducted for the State Medical Program beneficiarys.** The explanation code is for informational purposes only.
- 955 **The National Drug Code is missing or invalid.**
- 956 **The product billed is not made by an allowable manufacturer.** The product must not be rebilled.
- 959 **The extended stay authorization number for a psychiatric or rehabilitation admission does not match the period being billed.**

- 960 **The authorization number does not match this psychiatric stay.**
- 961 **The number of days authorized does not match the number of days billed for this psychiatric stay.**
- 973 **The provider has billed amounts (e.g., professional charges, Medicare charges, coinsurance/deductible) that are inconsistent for a Medicare coinsurance claim. The claim should be corrected and rebilled.**
- 975 **The provider has billed amounts (e.g., professional charges, Medicare charges, coinsurance/deductible) that are inconsistent for a Medicare coinsurance and deductible claim. The claim should be corrected and rebilled.**
- 979 **Home health services were billed for a beneficiary who is in the nursing home, or enrolled in a hospice program (Level of Care Code 16), or enrolled in Medicaid's Home & Community-Based Services Waiver for the Elderly & Disabled (Level of Care Code 22). The claim must not be rebilled.**
- 980 **Medicaid reimbursement cannot be made for services rendered by this provider type. The service must not be rebilled to Medicaid.**
- 981 **Medicaid reimbursement cannot be made to this provider type for this service. The claim must not be rebilled to Medicaid.**
- 983 **This procedure/service cannot be billed in combination with any other procedure/service billed on this date of service. The procedure/service must not be rebilled.**
- 984 **The procedure code requires documentation and documentation was not received with the claim. The claim should be rebilled with appropriate documentation attached.**
- 990 **This claim requires documentation and documentation was not in the Remarks section of the claim or attached to the claim. The claim should be rebilled with appropriate documentation.**
- 993 **This claim is being held for future processing.**

Appendix F
OBRA '90 DUR Requirements

impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612. Pursuant to 5 U.S.C. 606(b), the amended regulation, therefore, is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

Although the amended regulation will affect some small entities, this certification can be made because VA believes that the overwhelming majority of small entities have already submitted all the necessary periodic certifications. The department does not believe that requiring the remainder to submit them before October 1, 1993 will cause a significant economic impact. Therefore, the amended regulation will have no significant economic impact on small entities, i.e., small businesses, small private and nonprofit organizations and small governmental jurisdictions.

The Catalog of Federal Domestic Assistance number for the program affected by this regulation is 64.121.

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: September 18, 1992.

Edward J. Derwinski,
Secretary of Veterans Affairs.

PART 21—VOCATIONAL REHABILITATION AND EDUCATION

Subpart F-1—Veterans' Job Training

For the reasons set out in the preamble, 38 CFR part 21, subpart F-1 is amended as set forth below.

1. The authority citation for part 21, subpart F-1 continues to read as follows:

Authority: Pub. L. 96-77, 87 Stat. 443.

In § 21.4632 paragraph (c)(4) and its authority citation are added to read as follows.

§ 21.4632 Payment restrictions.

(c) Release of payments. . . .

(4) VA will not release any payments for training provided by an employer if VA receives the employer's certification for that training after September 30, 1993.

(Authority: Sec. 8, Pub. L. 96-77, 87 Stat. 443)

[FR Doc. 92-36453 Filed 10-30-92; 8:48 am]
BILLING CODE 8330-01-0

8-340999 0025(01)(30-OCT-92-12:23:13)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 486

(MB-050-IFC)

RIN 0938-AP07

Medicaid Program; Drug Use Review Program and Electronic Claims Management System for Outpatient Drug Claims

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim rule implements provisions of section 4401 of the Omnibus Budget Reconciliation Act of 1990 by specifying requirements for a Drug Use Review program, including the establishment of Drug Use Review Boards, and for an Electronic Claims Management system for outpatient drugs.

DATE: Effective date: These regulations are effective on January 1, 1993.

Comment period: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 4, 1993.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB-050-IFC, P.O. Box 20676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code MB-050-IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a 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) 243-7800).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit comments to: Laura Oliven, HCFA Desk

Officer, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Thomas Fulda, (410) 966-3343.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Title XIX the Social Security Act (the Act) authorizes grants to States for medical assistance (Medicaid) to needy individuals. The Medicaid program is jointly financed by the Federal and State governments and administered by the States. Within Federal rules, each State decides eligible groups, types and ranges of services, payment levels for most services, and administrative and operating procedures. A State submits to HCFA a written statement, called a State plan, that describes the nature and scope of its Medicaid program. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program. The plan is amended whenever necessary to reflect changes in Federal or State law, changes in policy, or court decisions.

B. Legislative Background

Under section 1906(a)(1)(E) of the Act, States may provide coverage of outpatient prescription drugs as an optional service. Section 1909(a) of the Act provides for FFP in State expenditures for these drugs. Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508, enacted on November 8, 1990) redesignated section 1927 of the Act as section 1928 and added a new section 1927 to the Act.

Section 1927(g) of the Act provides that, for FFP payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, not later than January 1, 1993, a drug use review (DUR) program that consists of prospective drug review, retrospective drug use review, the application of explicit predetermined standards, and an educational program. The purpose of the DUR program is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and that they are not likely to result in adverse medical results. Section 1927(g)(1)(A) of the Act directs that the program be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of

fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients or associated with specific drugs or groups of drugs. Section 1927(g)(1)(B) of the Act requires that the program assess data on drug use against predetermined standards consistent with peer-reviewed literature and three specified compendia. The assessment must include, but is not limited to, monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse.

Section 1927(g)(1)(C) of the Act specifies that the Secretary must pay to each State 75 percent of the sums expended by the State plan during calendar years 1991 through 1993 that the Secretary determines are attributable to the Statewide adoption of a DUR program that conforms to the statutory requirements.

Section 1927(g)(1)(D) of the Act specifies that States are not required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures currently at 42 CFR 483.80.

Section 1927(g)(2)(A) of the Act contains the requirements for prospective drug review. The statute requires that the State plan provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under the Medicaid program. The review must include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

Section 1927(g)(2)(A)(ii) of the Act requires that, as part of the prospective drug review program, applicable State law establish standards for counseling of Medicaid recipients by pharmacists. The statute directs that State law must require pharmacists to offer to discuss, with each recipient or caregiver who presents a prescription, matters that the pharmacist, exercising his or her professional judgment (consistent with State law respecting the providing of such information), deems significant, including specified information. The statute requires that the discussion be in

person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls. The statute does not require that a pharmacist provide consultation when a recipient or the recipient's caregiver refuses the consultation. The statute further requires the pharmacist to make a reasonable effort to obtain, record, and maintain specific patient profile information.

Section 1927(g)(2)(B) of the Act contains the requirements for retrospective drug use review. It requires that the DUR program provide for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and individuals receiving Medicaid benefits, or associated with specific drugs or groups of drugs.

Section 1927(g)(2)(C) of the Act requires that the DUR program assess data on drug use against explicit predetermined standards. It also requires that, as necessary, the program introduce remedial strategies to improve the quality of care and to conserve Medicare funds or personal expenditures.

Section 1927(g)(2)(D) of the Act requires that, in order to improve prescribing or dispensing practices, States provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems.

Section 1927(g)(3) of the Act requires that States establish a DUR Board, either directly or through contract with a private organization. It contains requirements regarding the qualifications of Board members and the composition of the Board and specifies the activities of the Board. It also requires the State to prepare an annual report for submission to the Secretary that describes the activities of the DUR Board, including specified information.

Section 1927(h) of the Act requires the Secretary to encourage each State Medicaid agency to establish a point-of-sale electronic claims management (ECM) system for processing claims for covered outpatient drugs. The ECM system must be capable of performing on-line, real-time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists and other authorized persons in applying for and receiving payment. The statute specifies that, if the State acquires, through applicable competitive procurement process, the most cost-effective telecommunications network and automatic data processing services

and equipment, FFP at a matching rate of 90 percent will be made for expenditures made in calendar quarters during fiscal years 1991 and 1992 for the development of the ECM system.

Section 1927(i) of the Act concerns covered outpatient drugs dispensed by health maintenance organizations from the requirements of section 1927 of the Act. Section 1927(j) further requires that the State plan provide that covered outpatient drugs dispensed by a hospital using drug dispensary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of section 1927 of the Act.

II. Provisions of this Interim Rule

In developing these regulations, we have essentially relied on the language of sections 1927(g) and (h) of the Act as established by Public Law 101-508. We also sought and received advice from various national provider associations, States, pharmaceutical companies, drug utilization review firms, and others. We considered their comments as we developed this interim rule.

Note that sections 1927(g) and (h) of the Act use the term "drug use review" to describe the total program (prospective review, retrospective review, and education) and in speaking of the retrospective review activity. These same sections use the term "drug review" to mean the prospective review activity. We maintain that distinction in terminology in the following discussion.

A. Scope of Regulations

Current regulations at § 488.1 set forth the basis and purpose of 42 CFR part 488, "Utilization Control." We have revised § 488.1(a) to add that part 488 prescribes specific requirements for an outpatient DUR program. We have revised § 488.1(b), which lists the statutory basis for the requirements in part 488, by adding the statutory basis for the DUR program. We have also revised Table 1, which shows the relationship between sections of the Act and the requirements of part 488, to include this information for subparts J and K of part 488. Subpart J has been in existing regulations, but, through an apparent oversight, it was not included in the table. As discussed below, subpart K is being added to part 488 by this rule.

We are establishing a new subpart K, entitled "Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims," in part 488. In § 488.700, we set forth the scope of this subpart.

We state that this subpart prescribes requirements for—

- An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;
- The establishment, composition, and functions of a State DUR Board; and
- An optional point-of-sale ECM system for processing claims for covered outpatient drugs.

B. Definitions

In § 456.702, we define the following terms for purposes of subpart K of part 456, using definitions already established in regulations:

- Abuse—as currently defined in § 455.2.
- Criteria—as currently defined in § 400.1.
- Fraud—as currently defined in § 455.2.
- Standards—as currently defined in § 400.1.

In addition, we have established the following definitions in § 456.702:

- "Adverse medical result" means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.
- "Appropriate and medically necessary" means drug prescribing and dispensing that is in conformity with predetermined standards established in accordance with § 456.703.
- "Gross overuse" means repetitive overutilization without therapeutic benefit.
- "Inappropriate and medically unnecessary" means drug prescribing and dispensing not in conformity with the definition of "appropriate and medically necessary."
- "Overutilization" means use of a drug in quantities or for durations that put the recipient at risk of an adverse medical result.
- "Predetermined standards" means criteria and standards, as defined in this section (§ 456.702), that have been established in accordance with the requirements of § 456.703.
- "Underutilization" means that a drug is used by a recipient in insufficient quantity to achieve a desired therapeutic goal.

We believe that the definitions of "adverse medical result," "overutilization," "underutilization," and "gross overuse" reflect the meaning generally given these terms by the health care community. The definitions of "appropriate and medically necessary," and "inappropriate and medically unnecessary" define these terms in relation to predetermined standards established in accordance with this rule. We believe that, by

including both criteria and standards in the definition of "predetermined standards," we provide a framework for drug therapy guidelines, while allowing State Medicaid programs adequate flexibility to accommodate legitimate variations in prescribing practices.

Other terms are defined in the regulation sections in which they are used and are discussed in this preamble when discussing the contents of those sections.

C. Drug Use Review Program

In § 456.703(a), we specify that, in order for FFP to be paid under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of subpart K. This is based on section 1927(g) of the Act, which requires the establishment of a DUR program. We further specify that the goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

In § 456.703(b), we specify that prospective drug review and retrospective drug use review under the DUR program (including interventions and education) is not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in 42 CFR part 483. Note that this exception applies to the drugs, not to the pharmacies that dispense them. This provision for the rule is based on section 1927(g)(1)(D) of the Act, which specifies that States shall not be required to perform additional drug use review with respect to these drugs. We also specify, in accordance with the exemption at section 1927(j)(1) of the Act, that prospective drug review and retrospective drug use review are not required for drugs dispensed by health maintenance organizations (HMOs). These exemptions, however, do not affect the State's right to impose additional requirements. Therefore, we specify that the State is not precluded from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State makes the drugs subject to all the requirements applicable to the type of review. (Note further, that the term "covered outpatient drugs" is generally defined at section 1927(k)(2) of the Act, subject to the limitation at section 1927(k)(3), which, among other exclusions, excludes from the definition those drugs included in the per diem rate of nursing

facilities. Thus, review under the DUR program is not required for such drugs. Again, this does not preclude the State from making such drugs subject to DUR. Such review, however, would not be considered a part of the DUR program required by this subsection.)

In § 456.703(c), we require that the State plan provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. This reflects the requirement in section 1927(j)(1) of the Act.

In § 456.703(d), we specify, based on the requirement in section 1927(g)(1)(B) of the Act, that prospective drug review must assess drug use information against predetermined standards. In § 456.703(e), we specify that acceptable sources of predetermined standards are those—

- Developed directly by the State or its contractor;
- Obtained by the State through contracts with commercial vendors of DUR services;
- Obtained by the State from independent organizations, such as the United States Pharmacopoeial Convention, or entities receiving funding provided by the Agency for Health Care Policy and Research (an agency of the Public Health Service), HCFA, or State agencies; or
- Any combination of the above.

We specify, in § 456.703(f), that the predetermined standards used in the DUR program must meet the following requirements:

1. The source materials for their development must be consistent with the peer-reviewed medical literature and the following compendia:
 - American Hospital Formulary Service Drug Information.
 - United States Pharmacopoeia-Drug Information.
 - American Medical Association Drug Evaluations. We define "peer-reviewed medical literature" as scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts.
2. Differences between source materials were resolved by physicians and pharmacists developing consensus solutions.
3. They are non-proprietary and readily available to providers of service. Systems and algorithms using the

predetermined standards may remain proprietary.

4. They are clinically-based and scientifically valid.

5. Retrospective review based on clinical criteria uses predetermined standards to determine the population at risk and applies standards appropriate to this population, across providers to determine the provider outliers whose prescribing practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these outliers.

6. They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems.

7. The predetermined standards for prospective and retrospective DUR are compatible.

8. They are subjected to ongoing evaluation and modification either as a result of actions by their developers or as a result of recommendations by the DUR Board.

The first requirement reflects the language of section 1927(g)(1)(B) of the Act, with the addition of a definition of "peer-reviewed literature." We believe that our definition is how this term is commonly understood. The second requirement takes into consideration the possibility that there may be differences between the compendia and peer-reviewed literature. The use by the developers of a professional consensus process involving pharmacists and physicians provides a means to resolve these differences. We believe providers should know what standards they are being judged against; therefore, we have included the third requirement. The fourth requirement recognizes the fact that criteria that are not scientifically valid and clinically-based would be substantively flawed and would be hard to apply to and unacceptable to clinicians. We established the fifth requirement because we believe there is a need to make clear that standards should not be used to decide what prescribing/dispensing practices are potential therapeutic problems. Clinical criteria are the appropriate basis for such decisions. Nonetheless, standards may be considered in deciding whether to intervene once the universe of potential therapeutic problems has been identified through the use of clinical criteria.

We established requirement number 8 because we believe testing is needed to determine the likely rate of problems to be uncovered by the use of a standard. If use of a particular standard results in an unusually large number of cases

being identified as potential problems, it may be that the standard is not sufficiently precise to identify truly significant problems. We have established requirement number 7 because if prospective and retrospective predetermined standards are obtained from different sources, they might contain different recommendations. We established requirement number 8 because it is expected that experience and changes in the state of medical knowledge will make modification or elimination of predetermined standards or the addition of new ones necessary.

We believe that, as part of the educational process, providers should know against what predetermined standards they are being judged. We believe the general public also has a right to know what predetermined standards are being applied. Therefore, in addition to the requirement in § 456.703(f)(3) that the predetermined standards be non-proprietary, in § 456.703(g), we specify that, upon their adoption, predetermined standards must be available to the public and that pharmacists and physicians must be informed about how they can obtain copies.

Section 1927(g)(3)(c) of the Act indicates that, as part of conducting educational interventions, written, oral, and electronic reminders containing patient-specific and drug-specific information should be used. It also specifies that these messages must be communicated in a manner designed to ensure the privacy of patient-related information. Because of this provision and the broader issue of patient confidentiality associated with conducting DUR through an electronic claims management system, we require, in § 456.703(h), that the State establish, in regulations or through other means, policies concerning confidentiality of patient-related data that are consistent with the applicable Federal confidentiality requirements of subpart F of part 431, the State Pharmacy Practice Act, and guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies. It should be noted that Federal confidentiality requirements would not apply to patient profile requirements at § 456.703(d) of this rule.

D. Prospective Drug Review (Point-of-sale or Point-of-Distribution Drug Review and Counseling Requirements)

Section 456.708 sets forth the requirements for prospective drug review, based on the prospective drug review requirements of section 1927(g)(2)(A) of the Act. In paragraph (a), we specify that the State plan must

provide for review of drug therapy before each prescription (other than those for drugs for certain nursing facility residents, drugs dispensed by HMOs, and certain covered outpatient drugs dispensed by hospitals) is filled or delivered to a recipient and that applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. We further require that the State provide pharmacies with detailed information as to what they must do to comply with prospective drug review requirements, including guidelines on counseling, profiling, and documentation of prospective drug review activities by the pharmacists. We specify that this information is to be based on guidelines provided by part 458, subpart K and other sources that the State may specify. We specify that the pharmacies, in turn, must provide this information to their pharmacists.

In § 456.708(b), we specify that the State plan must provide for point-of-sale or point-of-distribution review of drug therapy before each prescription is filled or delivered to the recipient or the recipient's caregiver. In accordance with the exceptions provided in sections 1927(g)(1)(D), 1927(j)(1), and 1927(j)(2) of the Act, we provide exceptions to this requirement for the following drugs, respectively:

- Drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in 42 CFR part 482.
- Drugs dispensed by HMOs.
- Covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs.

We specify that the review must include screening for potential drug therapy problems because of therapeutic duplication, drug-disease contraindication, adverse drug-drug interaction, incorrect drug dosage, incorrect duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. These requirements reflect the provisions of section 1927(g)(2)(A) of the Act. We recognize that screening for these drug therapy problems will be done without direct access to diagnosis information and details about disease conditions contained in medical records available in an inpatient environment. A pharmacist conducting prospective DUR can use the patient profile to obtain information from the patient about allergies, disease condition, and other

relevant information. In addition, based upon his or her professional judgment, the pharmacist may consult a physician(s), when appropriate, to obtain additional information. We do not believe the pharmacist will incur additional liability as a result of performing prospective DUR.

While the statute does not define "therapeutic duplication," "drug-disease contraindication," "adverse drug-drug interaction," "incorrect drug dosage," "incorrect duration of drug treatment," "drug-allergy interactions," and "clinical abuse/misuse," we describe these terms in § 456.706(b), based on what we believe are the meanings generally given these terms by the health care community. We describe these terms as follows:

- "Therapeutic duplication"—the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

- "Drug-disease contraindication"—the potential for, or the occurrence of, an undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition or the potential for, or the occurrence of, an adverse effect of the drug on the patient's disease condition.

- "Adverse drug-drug interaction"—the potential for, or occurrence of, an adverse medical effect as a result of the recipient using two or more drugs together.

- "Incorrect drug dosage"—the dosage lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days supply.

- "Incorrect duration of drug treatment"—the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

- "Drug-allergy interactions"—the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

- "Clinical abuse/misuse"—the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in § 456.702, and incorrect dosage and duration, as defined in paragraphs (b)(4) and (b)(5) [of § 456.706], respectively.

In accordance with the counseling requirements of section 1927(g)(2)(A)(iii) of the Act, we require, in § 456.706(c),

that standards for counseling by pharmacists of recipients or the recipients' caregivers be established by State law or other method that is satisfactory to the State. We believe that the standards should address questions such as whether an offer to counsel must be oral; whether or not posted signs may substitute for an oral offer to counsel; the applicability of this requirement to new and refill prescriptions; and the extent to which written material may or may not be substituted for the oral provision of information. Because we believe that the special nature of mail order pharmacy operations requires clarification as to how the counseling requirements apply to those entities, we require that the State law or State Medicaid agency policy include such clarification. We specify that the standards must meet the following requirements:

1. They require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. The standards need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses such consultation. The standards must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

2. They specify that the counseling includes those matters listed below that, in the exercise of his or her professional judgment (consistent with State law regarding the provision of such information), the pharmacist considers significant, as well as other matters the pharmacist considers significant.

- The name and description of the medication.
- The dosage form, dosage, route of administration, and duration of drug therapy.
- Special directions and precautions for preparation, administration, and use by the patient.
- Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
- Techniques for self-monitoring drug therapy.
- Proper storage.
- Prescription refill information.
- Action to be taken in the event of a missed dose.

Note that although section 1927(g)(2)(A)(ii)(b) of the Act includes, in the list of matters to be discussed, both "route" and "route of administration," we believe the use of both terms is redundant. Therefore, we include "route of administration" but not "route" in the regulation.

Consistent with the recordkeeping requirements of section 1927(g)(2)(A) of the Act, we specify, in § 456.706(d), that the State must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing at least the following information:

- Name, address, telephone number, date of birth (or age), and gender of the patient.
- Individual medical history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
- Pharmacist's comments relevant to the individual's drug therapy.

We have not defined "reasonable effort" in the above context. It is the responsibility of the State, through the State Board of Pharmacy or, in the absence of such effort, the State Medicaid program's DUR Board to define "reasonable effort."

E. Retrospective Drug Use Review

Section 456.706 sets forth the requirements for retrospective DUR, based on the retrospective DUR requirements of section 1927(g)(2)(B) of the Act and the application of standards requirements of section 1927(g)(2)(C). In paragraph (a), we require that the State plan provide for the establishment of a retrospective DUR program for ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. We specify that this examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. We also specify that this periodic examination must occur no less frequently than quarterly. Quarterly processing is the usual Medicaid agency practice to support postpayment utilization review activities. It facilitates the timely accomplishment of educational interventions.

Section 1827(g)(1)(B) of the Act further states that the examination of claims data is to be made through the mechanized drug claims processing and information retrieval systems "or otherwise". We interpret "mechanized drug claims processing and information retrieval systems" to include both the Medicaid Management Information System (MMIS) and separate electronic drug claims processing systems that are integrated with MMIS. Accordingly, we further require in § 458.708(a) that retrospective review be provided through the State's mechanized drug claims processing and information retrieval system (that is, MMIS) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use their existing systems provided that the results of the examination of drug claims as described in this section are integrated with their existing claims processing system. However, we request comments to provide a basis for defining "or otherwise" as used in the statute.

In paragraph (b), we specify that retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

- Therapeutic appropriateness.
- Overutilization and underutilization.
- Appropriate use of generic products.
- Therapeutic duplication.
- Drug-disease contraindication.
- Drug-drug interaction.
- Incorrect drug dosage.
- Incorrect duration of drug treatment.
- Clinical abuse or misuse.

We specify that "therapeutic appropriateness" is drug prescribing and dispensing that is in conformity with the predetermined standards. We specify that "appropriate use of generic products" is use of such products in conformity with State product selection laws. We believe these definitions reflect the meanings generally given these terms.

F. Educational Program

In § 458.711, we require that the State plan provide for ongoing educational outreach programs that educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. We specify that the program may be established by the DUR Board directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists' associations/societies, or other organizations. We further specify that the program must include, in

appropriate instances, the following types of interventions:

- Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards used in assessing drug use.

- Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

- Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.
- Intensified review or monitoring of selected prescribers or dispensers.

We specify that the DUR Board determines the content of education regarding common therapy problems and circumstances in which each of the interventions specified in § 458.711 (a) through (d) is to be used. These requirements are based on the requirements contained in sections 1827(g)(1)(D) and 1827(g)(3)(C)(iii) of the Act. The Medicaid agency is responsible for the education programs and for the actual interventions. The education and intervention functions may be carried out by a contractor responsible for retrospective DUR or by a contractor responsible for the DUR Board. It is left to State discretion as to whether the education and intervention functions are to be carried out by the same contractor or different contractors.

G. Annual report

In § 458.712(a), we specify, in accordance with section 1827(g)(3)(D) of the Act, that the State must require the DUR Board to prepare and submit, on an annual basis, a report to the Medicaid agency that contains information specified by the State.

In § 458.712(b) we specify that the Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 463 of this chapter.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at § 458.708(f) and with the access to the predetermined standards requirement at § 458.708(g).

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization review (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and the State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

We have included some requirements regarding the content of the annual report submitted to the Secretary not specified in the statute, in order to carry out the stated requirements effectively and efficiently. We ask for specifics about criteria and standards in use in order to have access to data that would make possible a national, as opposed to a State, evaluation of criteria. Conducting such a national evaluation would be done either by HCFA or outside researchers. We ask for clarification of the DUR and SUR review relationship. The retrospective DUR

- Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

With regard to retrospective DUR, we suggest that the Medicaid agency or its contractor apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

With regard to the education program (including interventions), we suggest that the Board perform the following activities:

- Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.
- Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy.
- Periodically re-evaluate and, if necessary, modify the interventions.

With regard to the education program (including interventions), we suggest that the Medicaid agency or its contractor perform the following activities:

- Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and intervention and furnish those reports to the Board.
- Carry out the educational programs and interventions specified by the Board.

In § 456.716(e), we specify that FFP is available for expenses associated with the operation of the DUR Board at the rate of 75 percent for funds expended by the State during calendar years 1991 through 1993. This is in accordance with the funding provision of section 1827(g)(1)(C) of the Act. We also specify that, after December 31, 1993, if the requirements for skilled professional medical personnel set forth in § 432.50 are met, FFP is available at the rate established by that section, that is, a rate of 75 percent. If the requirements for skilled professional medical personnel are not met, we specify, in accordance with the rate established at § 433.32(b)(7), that the rate for funds expended after December 31, 1993 is 50 percent.

I. Funding of DUR Program

Based on the funding provision of section 1827(g)(1)(C) of the Act, we specify, in § 456.716, that FFP is available at the rate of 75 percent for sums that the Secretary determines are

attributable to the Statewide adoption of a DUR program as described in subpart K and that were expended by the State during calendar years 1991 through 1993. We further specify, in accordance with the rate established at § 433.32(b)(7), that the rate for funds expended by the State after December 31, 1993, is 50 percent. We specify that payment is made under procedures established in part 433.

J. Electronic Claims Management System

Section 456.722 sets forth the requirements for an ECM system, based on section 1827(h) of the Act. Section 1827(h) requires the Secretary to encourage each Medicaid agency to establish, as its principal means of processing claims for covered outpatient drugs, a point-of-sale ECM system and contains requirements for such a system.

In paragraph (a), we specify that each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale ECM system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The ECM systems should assist pharmacists in applying for and receiving payment by electronically providing information, at point of sale, as to whether the recipient is eligible, the drug is covered, etc., thereby facilitating payment of claims. Since the statute specifies that the ECM system is to be the "principal" (not exclusive) means of processing claims, universal participation in the system is not required. Who must participate in an ECM system is to be determined by the State. Therefore, we also specify, in paragraph (a), that the State makes this determination. We further specify that, if the State exercises the option to establish an ECM system and wishes to receive FFP for its system, the system must meet the functional and additional procurement and system requirements discussed below. We request comments on how and to what extent these ECM requirements may affect the use of existing automated systems, the use of alternative techniques, such as "smart cards," and the participation of pharmacies in the Medicaid drug program.

In paragraph (b), we require that the ECM system developed by the State must include at least the following on-line, real-time capabilities:

- Eligibility verification, including identification of the following:
 - Third-party payers.
 - Recipients in managed care programs.
 - Recipients and providers in restricted service programs (for example, lock-in and lock-out).
 - Properly-enrolled providers.
- Claims data capture, including the following:
 - Processing of prescription drug claims.
 - Identification of prescribers.
 - Minimum data set for claims (as defined in Part 11 of the State Medicaid Manual).
- Claims adjudication, including the following:
 - Performing all edits and audits contained in the State's MMS applicable to prescription drugs.
 - Notifying the pharmacist (or another authorized person, such as the dispensing physician) about the claim status.
 - Taking steps up to but not including payment of the claim.

We provide that the real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State and claims may be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and the Medicaid agency. We provide this waiver because the large volume of claims from mail order and nursing home pharmacies make on-line, real-time processing impractical. It should be noted that, if the State allows batch claims processing, this does not exempt the pharmacy from any other requirements of this subpart.

In paragraph (c), we specify that in order to receive FFP for its ECM system, the State must meet the following requirements:

- The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G-O of OMB circular A-102. In accordance with section 1827(h)(2)(B) of the Act, we permit the substitution of a request for proposal (RFP) for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 86.305, and 45 CFR part 307. We require that a cost-benefit analysis accompany the RFP. Also, we provide that, if in its advance planning document a State establishes

review where prospective screening is done at the State level, prospective drug review screening will be done by individual pharmacies. Pharmacists will either have to rely on approved prospective drug review software programs or rely on written criteria, approved by the State, to properly perform manual prospective drug review.

Though an estimated 85 percent of pharmacies use computers, results of a survey of 12,456 pharmacists conducted in 1991 by the National Pharmacy Forum on Medicaid Drug Amendments showed significant differences in their ability to use computers for prospective DUR screening. The majority of pharmacists, for example, reported in that survey that they were able to screen for drug-drug interactions (85.8 percent), and drug-allergy interactions (82.3 percent) but very few pharmacists reported that they were able to screen for incorrect drug dosage (16.0 percent) and drug-disease contraindication (29.2 percent). Overall, 53 percent of the pharmacists surveyed indicated that they could not use their computers to screen for six of the nine types of prospective DUR screening required by OBRA 1990. The great majority of pharmacists will, as a result, have to update their prospective DUR software to meet the statutory requirements. We estimate the one time cost of upgrading prospective DUR software to be between \$1000 and \$2000 for the average pharmacy. In the event that the pharmacy's computer is not adequate to handle the demands of prospective DUR software, the pharmacy may also have to upgrade or replace their computer hardware. The \$1000 to \$2000 original estimate does not include any costs associated with upgrading the computer hardware. The majority of pharmacies have computers which are used for billing purposes, inventory control, prescription pricing, printing of the prescription labels, and generating handout information concerning drug interactions. The estimated initial cost for these computer systems is \$12,000 to \$18,000. Special computer programs, linking multiple stores, could increase the initial costs. In general, we believe it is unlikely that many pharmacies will have to significantly change their entire computer system to meet these DUR requirements. We would like to receive comments or additional information on this issue. It should be noted that pharmacists not wishing to upgrade their computer software may conduct prospective DUR screening manually, which must be based on approved

written standards that satisfactorily meet statutory requirements.

Section 1927(g)(2)(A)(ii) of the Act requires that applicable State law establish standards for counseling of recipients receiving prescriptions. The State law must require a pharmacist to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll free for long-distance calls), each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a toll free exchange, need not be required to offer toll free service. In addition, the State law must specify how counseling requirements apply to mail order pharmacies.

Little up to date information is available on the extent to which counseling is occurring in pharmacy practice. Seventeen States already require an offer of counseling by the pharmacist. Recent studies suggest that counseling occurs more frequently for new prescriptions than for refill prescriptions and that counseling is more frequent if done by a pharmacist than by a clerk. The effectiveness of counseling is also related to the training in counseling received by the pharmacist and the educational level of the recipient. At the present time we believe that counseling is provided for less than 50 percent of the total prescriptions dispensed and that the percentage of Medicaid recipients receiving counseling is lower than the general population.

The pharmacist must also make a reasonable effort to obtain and record patient information and maintain the patient profiles that are essential for the pharmacist to counsel the recipient concerning medication problems unique to the recipient. We expect that counseling and profiling requirements of OBRA 1990 will involve additional pharmacist time, which is costly. Our best estimate is that making the offer to counsel, reviewing a patient profile, and conducting counseling (exclusive of establishing a patient profile and interventions where the pharmacist takes an action such as telephoning the physician) could take two to four minutes at a cost of \$1 to \$2 per prescription. Assuming that counseling services are actually provided for 25 percent of all Medicaid prescriptions, and there are approximately 280 million Medicaid prescriptions filled each year, the annual cost for 70 million pharmacists to provide this service is \$70 million to \$140 million. We would welcome comments with regard to the accuracy of this cost estimate.

2. Retrospective DUR and Educational Outreach

Section 1927(g)(2)(B) of the Act contains the requirements for retrospective DUR. Nineteen states already have retrospective DUR programs. Retrospective DUR provides, through its mechanized drug claims processing and information retrieval systems, for the ongoing, periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and individuals receiving pharmacy benefits. Costs of establishing retrospective DUR programs for those States which do not already have them will depend on the size of the State's drug program. We estimate that implementation of retrospective DUR could cost an average of \$250,000 to \$300,000 annually per State, for a total national cost of \$12.5 billion to \$15 billion annually. We welcome comments with regard to the accuracy of this estimate.

Section 1927(g)(2)(D) of the Act requires that the State DUR board, either directly or through contracts with accredited health care educational institutions, State medical societies, or State pharmacists associations/societies or other organizations as specified by the State, provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices. The resulting intervention may involve written, oral, or electronic reminders containing patient-specific or drug-specific information along with suggested changes in prescribing or dispensing practices. Included will be face-to-face discussions, when appropriate and necessary, with prescribers and pharmacists who have been selected for educational intervention. The DUR Board will make policy recommendations concerning the circumstances under which each type of intervention will occur. We have no way of knowing how many practitioners will be selected for intervention or of knowing what types of intervention will be used. The level and type of intervention will determine the cost of the education/intervention component of retrospective DUR. We estimate that sending letters could cost from \$5 to \$8 each and more extensive encounters such as face-to-face interventions could cost as much as \$200 per encounter. The costs to States will vary with the number of interventions and the type

necessary to perform effective retroactive DUR. We welcome comments on the accuracy of these estimates.

3. Impact on the Pharmacy Dispensing Fee

The requirements for DUR and counseling that Public Law 101-508 imposes on pharmacists will increase the costs of operating a pharmacy and be reflected by surveys conducted by States to determine the cost of filling a prescription. This increased cost of operating a pharmacy may result in pressure to raise dispensing fees. Since these fees are set by the States, the additional costs incurred by pharmacies will not necessarily translate directly or immediately into increased Federal Medicaid costs. Historically, Medicaid dispensing fees have grown slowly, an average of under 3 percent per year between 1985 and 1991. The rate of increase has been higher (4.45 percent) in the last 2 years as many States increased fees that had been level for a number of years. Given the current budget climate and the States' likely resistance to granting increases, the net impact on Medicaid program expenditures is not expected to be large. At current Medicaid drug program spending levels, every 1 percent increase in the average dispensing fee translates into an estimated \$5 million to \$10 million in additional Federal funding. Thus, if the provisions of Public Law 101-508 cause dispensing fees to rise 2 percentage points above the average, the impact could be on the order of \$10 million to \$20 million and could offset the expected range of savings due to DUR implementation.

C. Impact on Recipients

The primary impact of DUR on the recipient should be to improve the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, dispensing and use of prescription drugs. According to one study that reviewed several potentially problem drugs, up to 30 percent of the patients receiving prescriptions for these drugs received an inappropriate prescription. DUR will be expected to catch some of these problems, but not all of them. Individual pharmacy DUR will not catch problems if conflicting prescriptions are filled at different pharmacies nor will it catch problems resulting from beneficiaries taking medication found in the home originally prescribed for someone else. The majority of these inappropriate prescriptions do not entail a significant health risk to the patient but some

inappropriate prescriptions, for various reasons, may be harmful or even potentially life threatening. Since DUR is an educational process, the benefit to the recipient should be a gradual reduction in the incidence of inappropriate prescribing and improved health outcomes for some beneficiaries. Since no reliable research data on likely benefits are known to us, we request information concerning this item. There may, however, be some reduction in pharmacy participation in the Medicaid program, resulting in some hardship on those beneficiaries who must travel longer distances to obtain pharmacy services.

D. Impact on States

States will incur increased costs to implement the DUR requirements of Public Law 101-508. Unless a State chooses to conduct prospective DUR as part of an optional ECM system, a State's cost for prospective DUR will be primarily for compliance monitoring and could cost approximately \$50,000 per State except in the States such as California and New York that have large drug programs. State costs, in those States that do not have retrospective DUR in place already, should not exceed \$250,000 to \$300,000 per State, except in the States with large drug programs. As previously indicated, estimating the cost of educational intervention required by the statute is not possible without knowing the likely level of each type of intervention. States also have the option of establishing ECM systems and also of conducting prospective DUR as part of such systems. We welcome comments and cost information from States that have already implemented ECM systems that include prospective DUR or from States that have received cost estimates for implementing similar systems.

E. Conclusion

The provisions of this interim final rule with comment are required by section 4401 of OBRA 1990. We believe any discretion we have exercised in defining certain terms will not impose a significant burden on participating pharmacies and prescribing physicians, particularly in comparison to the costs mandated by the statute or costs which States may voluntarily elect to incur.

We do recognize that the provisions to offer counseling and to maintain profiles may impose some additional burden on those pharmacies that are not already performing similar tasks. In addition, responding to educational outreach may require some response time on the part of both physicians and pharmacists, but we believe all parties should benefit.

The impact on States will vary. The 21 States that do not yet have retrospective DUR programs will be required to initiate both retrospective and prospective drug review systems by January 1, 1993. The 19 States with retrospective DUR programs will have to implement some form of prospective drug review program to comply with this interim final regulation with comment.

This regulation leaves pharmacies free to conduct prospective drug review either electronically or manually. Further, with regard to the requirements for Federal matching funds for a State's ECM system, it allows an exception to the on-line, real time eligibility verification requirements to mail order pharmacies and for prescriptions filled for nursing facility residents. These exceptions are attempts to reduce the burden or unnecessary costs to pharmacies to meet the DUR program requirements. We specifically request comments on other ways to reduce costs or burdens on participating pharmacies.

IV. Waiver of Proposed Rulemaking

Because the Secretary is exercising discretion in implementing section 1827 (g) and (h) of the Act, ordinarily we would publish a notice of proposed rulemaking and afford a period for public comment. However, section 4207(j) of Public Law 101-508 permits the Secretary to issue interim final regulations to implement the provisions of that law. Because States need sufficient lead time to recruit DUR board members, release RFPs, pass the required legislation, etc., so that the DUR program can be in place as of January 1, 1993, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period for public comment.

V. Response to Comments

Because of the large number of items of correspondence we normally receive concerning regulations, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the "DATES" section of this preamble, and we will respond to the comments in the preamble of that rule.

VI. Collection of Information Requirement

Regulations at §§ 496.705(d) and 496.712 contain information collection or recordkeeping requirements or both that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1990 (44

U.S.C. 3501 et seq.). The information collection requirements concern the collection of information for patient profiles of Medicaid recipients, preparation by State DUR Boards of annual reports to the State agency, and preparation by the State agency of annual reports to the Secretary. These are statutory requirements. The respondents who will provide the information include Medicaid recipients, who will provide information for profiles to pharmacists, State DUR Boards that will provide annual report information to the States, and States that will provide annual reports to the Secretary. Public reporting burden for the collection of the profile information is estimated to be 5 minutes for each initial encounter and 2 minutes for each subsequent encounter. Public reporting burden for the collection of the annual report information, which includes activities by the DUR Board and by the State agency, is estimated to be up to 60 hours per year per State. A notice will be published in the Federal Register after approval is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the "ADDRESSES" section of this preamble.

List of Subjects in 42 CFR Part 436

Administrative practice and procedure, Grant Programs—health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR part 456 is amended as set forth below:

PART 456—UTILIZATION CONTROL

1. The authority citation continues to read as follows:

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

2. In § 456.1, the introductory text of paragraph (a) is republished, a new paragraph (a)(3) is added, the introductory text of paragraph (b) is republished, a new paragraph (b)(5) is added, and the introductory text of Table 1 is republished and new subparts J and K are added to the table to read as follows:

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

(3) Specific requirements for an outpatient drug use review program.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship

between these sections of the Act and the requirements in this part.

(8) *Drug use review program.* Section 1927(g) of the Act provides that, for payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a drug use review (DUR) program. It also requires that each State provide, either directly or through a contract with a private organization, for the establishment of a DUR Board.

Table 1

[This table relates the regulations in this part to the sections of the Act on which they are based.]

Subpart J—Penalty for Failure To Make a Satisfactory Showing of An Effective Institutional Utilization Control Program (1903(g))

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims (1927(g) and (h))

3. A new subpart K is added to part 456 to read as follows:

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

Sec.	
456.700	Scope.
456.702	Definitions.
456.703	Drug use review program.
456.708	Prospective drug review.
456.709	Retrospective drug use review.
456.711	Educational program.
456.712	Annual report.
456.714	DUR/surveillance and utilization review relationship.
456.718	DUR Board.
456.719	Funding of DUR program.
456.722	Electronic claims management system.
456.725	Funding of ECM system.

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

§ 456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system

for processing claims for covered outpatient drugs.

§ 456.702 Definitions.

For purposes of this subpart—
Abuse is defined as in § 455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with § 456.703.

Criteria is defined as in § 456.1 of this chapter.

Fraud is defined as in § 455.2 of this chapter.

Gross overuse means repetitive overutilization without therapeutic benefit.

Inappropriate and medically unnecessary means drug prescribing and dispensing not in conformity with the definition of *appropriate and medically necessary*.

Overutilization means use of a drug in quantities or for durations that put the recipient at risk of an adverse medical result.

Predetermined standards means criteria and standards that have been established in accordance with the requirements of § 456.703.

Standards is defined as in § 456.1 of this chapter.

Underutilization means that a drug is used by a recipient in insufficient quantity to achieve a desired therapeutic goal.

§ 456.703 Drug use review program.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. The goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogative to allow for individualized drug therapy.

(b) *Exception for drugs dispensed to certain nursing facility residents and for drugs dispensed by health maintenance organizations.* Prospective drug review and retrospective drug use review (including inventions and education) under the DUR program are not required for drugs dispensed to residents of

nursing facilities that are in compliance with the drug regimen review procedures set forth in part 463 of this chapter and for drugs dispensed by health maintenance organizations. This does not preclude the State from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals.* The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart.

(d) *Use of predetermined standards.* A DUR program must assess drug use information against predetermined standards.

(e) *Source of predetermined standards.* The predetermined standards must be—

(1) Developed directly by the State or its contractor;

(2) Obtained by the State through contracts with commercial vendors of DUR services;

(3) Obtained by the State from independent organizations, such as the United States Pharmacopoeial Convention, or entities receiving funding from the Public Health Service, HCFA, or State agencies; or

(4) Any combination of paragraphs (1)(1) through (1)(3) of this section.

(f) *Requirements for predetermined standards.* The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts) and the following compendia:

(i) American Hospital Formulary Service Drug Information.

(ii) United States Pharmacopoeia-Drug Information.

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions.

(3) They are non-proprietary and readily available to providers of services. Systems and algorithms using the predetermined standards may remain proprietary.

(4) They are clinically-based and scientifically valid.

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk and applies standards, appropriate to this population, across providers to determine the provider outliers whose prescribing practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these outliers.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems.

(7) The predetermined standards for prospective and retrospective DUR are compatible.

(8) They are subjected to ongoing evaluation and modification either as a result of actions by their developer or as a result of recommendations by the DUR Board.

(g) *Access to predetermined standards.* Upon their adoption, predetermined standards must be available to the public. Pharmacists and physicians must be informed of the existence of predetermined standards and of how they can obtain copies of them.

(h) *Confidentiality of patent-related data.* In implementing the DUR program, the State must establish, in regulations or through other means, policies concerning confidentiality of patent-related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F; the State Pharmacy Practice Act; and guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

§ 466.706 Prospective drug review.

(a) *General.* Except as provided in §§ 466.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The pharmacies, in turn, must provide this information to their pharmacists. This information is to be based on guidelines provided by this

subpart and by other sources that the State may specify.

(b) *Point-of-sale or point-of-distribution review.* Except as provided in §§ 466.703 (b) and (c), the State plan must provide for point-of-sale or point-of-distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient's caregiver. The review must include screening to identify potential drug therapy problems of the following types:

(1) *Therapeutic duplication,* that is, the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

(2) *Drug-disease contraindication,* that is, the potential for, or the occurrence of—

(i) An undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition; or

(ii) An adverse effect of the drug on the patient's disease condition.

(3) *Adverse drug-drug interaction,* that is, the potential for, or occurrence of, an adverse medical effect as a result of the recipient using two or more drugs together.

(4) *Incorrect drug dosage,* that is, the dosage lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days supply.

(5) *Incorrect duration of drug treatment,* that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

(6) *Drug-allergy interactions,* that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

(7) *Clinical abuse/waste,* that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in § 466.702, and incorrect dosage and incorrect duration, as defined in paragraphs (b)(4) and (b)(5) of this section, respectively.

(c) *Drug counseling.* As part of the prospective-drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State. The State law must specify how counseling requirements apply to mail

order pharmacies. The standards must meet the following requirements:

(1) They require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. The standards need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses such consultation. The standards must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

(2) They specify that the counseling include those matters listed below that, in the exercise of his or her professional judgment (consistent with State law regarding the provision of such information), the pharmacist considers significant, as well as other matters the pharmacist considers significant.

(i) The name and description of the medication.

(ii) The dosage form, dosage, route of administration, and duration of drug therapy.

(iii) Special directions and precautions for preparation, administration, and use by the patient.

(iv) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(v) Techniques for self-monitoring drug therapy.

(vi) Proper storage.

(vii) Prescription refill information.

(viii) Action to be taken in the event of a missed dose.

(d) *Profiling.* The State must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(8) of this section.

(1) Name, address, telephone number, date of birth (or age), and gender of the patient.

(2) Individual medical history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(3) Pharmacist's comments relevant to the individual's drug therapy.

§ 488.708 Retrospective drug use review.

(a) *General.* The State plan must provide for a retrospective DUR program for ongoing periodic

examination (no less frequently than quarterly) of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. This program must be provided through the State's mechanized drug claims processing and information retrieval systems approved by HCFA (that is, the Medicaid Management Information System (MMIS)) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use existing systems provided that the results of the examination of drug claims as described in this section are integrated within their existing systems.

(b) *Use of predetermined standards.* Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

(1) Therapeutic appropriateness, that is, drug prescribing and dispensing that is in conformity with the predetermined standards.

(2) Overutilization and underutilization, as defined in § 488.702.

(3) Appropriate use of generic products, that is, use of such products in conformity with State product selection laws.

(4) Therapeutic duplication as described in § 488.706(b)(1).

(5) Drug-disease contraindication as described in § 488.706(b)(2).

(6) Drug-drug interaction as described in § 488.706(b)(3).

(7) Incorrect drug dosage as described in § 488.706(b)(4).

(8) Incorrect duration of drug treatment as described in § 488.706(b)(5).

(9) Clinical abuse or misuse as described in § 488.706(b)(7).

§ 488.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other

organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by § 488.708(c) for use in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

§ 488.712 Annual report.

(a) *DUR Board report.* The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) *Medicaid agency report.* The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at § 456.703(f) and with the access to the predetermined standards requirement at § 456.703(g). After the first annual report, only changes must be reported.

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the affect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 486.714 DUR/surveillance and utilization review relationship.

The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455.

§ 486.716 DUR Board.

(a) *State DUR Board requirement and member qualifications.* Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

(1) Clinically appropriate prescribing of covered outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.

(3) Drug use review, evaluation, and intervention.

(4) Medical quality assurance.

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed by the State on whose DUR Board they are serving.

(c) *Medicaid agency/DUR Board relationship.* The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) *DUR Board activities.* The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) *Application of predetermined standards: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(iii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

(2) *Application of predetermined standards: Medicaid agency role.* The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.

(ii) If prospective DUR is conducted using an electronic claims management

(ECM) system, apply software approved by the Board.

(iii) If prospective DUR is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(3)(A) of the Act.

(3) *Retrospective DUR: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(4) *Retrospective DUR: Medicaid agency role.* The Medicaid agency or its contractor should apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

(5) *Education program (including interventions): Board's activities.* The DUR Board should perform the following activities:

(i) Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.

(ii) Make recommendations as to which mix of the interventions set forth in §§ 486.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy.

(iii) Periodically re-evaluate and, if necessary, modify the interventions.

(6) *Education program (including interventions): Medicaid agency's role.* The Medicaid agency or its contractor should perform the following activities:

(i) Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and interventions and furnish those reports to the Board.

(ii) Carry out the educational programs and interventions specified by the Board.

(e) *Funding for the Board.* FFP is available for expenses associated with the operation of the DUR Board in carrying out its responsibilities, and payment is made under procedures established in part 433 of this chapter as follows:

(1) If the requirements for skilled professional medical personnel at § 432.80 of this chapter are met, at the rate of 75 percent.

(2) If the requirements for skilled professional medical personnel at § 432.80 of this chapter are not met, at the rate specified in § 456.719.

§ 456.719 Funding for DUR program.

FFP is available for sums that the Secretary determines are attributable to the Statewide adoption of a DUR program as described in this subpart, and payment is made under procedures established in part 433 of this chapter as follows:

(a) For funds expended by the State during calendar years 1991 through 1993, at the rate of 75 percent.

(b) For funds expended by the State after December 31, 1993, at the rate of 50 percent.

§ 456.722 Electronic claims management system.

(a) *Point-of-sale system.* Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The State determines who must participate in an ECM system and who may decline to do so. If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) *Functional requirements.* The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. The real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State to permit claims to be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and Medicaid agency.

(1) Eligibility verification, including identification of the following:

(i) Third-party payers.

(ii) Recipients in managed care programs.

(iii) Recipients and providers in restricted service programs (for example, lock-in and lock-out).

(iv) Properly enrolled providers.

(2) Claims data capture, including the following:

(i) Transfer of claims information from the pharmacy to the Medicaid agency or the Medicaid agency's contractor.

(ii) Identification of prescriber.

(iii) Minimum data set (as defined in Part 12 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

(c) *Additional requirements.* In order to receive FFP for its ECM system, the State must meet the following requirements:

(1) The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G-O of OMB circular A-102. The request for proposal (RFP) may be substituted for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 96.205, and 45 CFR part 307. A cost-benefit analysis must accompany the RFP. If in its advance planning document, a State establishes that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, procurement of network services and equipment (but not software modifications) must be competitively procured.

(2) States wishing to do prospective DUR as part of their ECM must do the following:

(i) Submit a cost benefit analysis showing the cost-effectiveness of such a system. A State's decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.

(ii) Establish a central State-wide electronic repository for capturing, storing, and updating data for all prescriptions dispensed and for providing access to such data by all authorized participants.

(iii) Design the system to access data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in § 456.705.

(3) ECM is considered a subsystem and must be fully integrated with the remainder of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

§ 456.725 Funding of ECM system.

(a) For funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management system (that is, the most cost-effective telecommunications network and automatic data processing services and equipment) that meets the requirements of § 456.722, FFP is available at a matching rate of 90 percent. After fiscal year 1992, ECM subsystems are funded at the standard applicable MMIS enhanced rates, subject to the requirements of part 433, subpart A of this chapter.

(b) FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.

(Catalog of Federal Domestic Assistance Program No. 83.776, Medical Assistance Program)

Dated: June 18, 1992.

William Tuby,
Acting Administrator, Health Care Financing Administration.

Approved: June 25, 1992.

Leslie W. Sullivan,
Secretary.

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Work Statement for Contract Amendment for Adding Rebate Negotiations and Maintenance to the FHSC Contract

October 1, 2001 – September 30, 2001

Expanded Prior Authorization List:

Effective October 1, 2001, FHSC will identify, analyze, and recommend therapeutic classes with products that have minimal clinical differences, same or similar drug actions, have the same or similar outcomes, or have multiple effective generics available. This function includes but is not limited to data analysis, system updating and reprogramming, support systems, physician training, provider and beneficiary mailing and notifications, and program promotional materials. This flat fee does not include postage.

FHSC has requested a flat fee of \$235,000.00. MDCH concurs with the \$235,000.00.

Rebate Contracting and Administration

Effective October 1, 2001, FHSC on the behalf of the Michigan Department of Community Health will negotiate a supplemental rebate for Michigan Medicaid [FFS and Managed Care] and a state level rebate for the Elder Prescription Insurance Program, the Children's Special Health Care Services Program, the State Medical Program, and non-Medicaid Mental Health Program and other state programs that may be included in the future. This function includes but is not limited to the negotiation process, data and systems support. In addition, this process includes FHSC providing Dan Hardin on a full time basis to complete this negotiation process.

FHSC has requested a flat fee of \$ 185,000.00. Michigan concurs with the \$185,000.00.

MAC Pricing Generic Drugs

Effective October 1, 2001, FHSC will recommend MAC amounts for the Michigan Pharmaceutical Product List. This function includes updating Michigan's MAC price list on a continuous basis to reflect the best available wholesale price. This process involves providing a baseline review of wholesale prices to provide Michigan with a recommended MAC. FHSC would also maintain the MAC file and update as needed.

FHSC has requested a flat fee of \$ 165,000.00. Michigan concurs with \$165,000.00.

Maintenance of Expanded Prior Authorization List, Rebate Negotiations and Contracts, and MAC Pricing

Effective October 1, 2001, all maintenance activities for the expanded prior authorization list, rebate supplemental and state level negotiations and contracts and MAC pricing will be performed by FHSC at no additional cost to the State of Michigan. The cost for these activities will be absorbed in the \$0.2049 presently being paid to FHSC for the claims processing. However, MDCH will provide a bonus incentive to FHSC based on the amount savings acquired from such activities. This incentive bonus will be structured as follows:

Michigan expects a minimum savings of \$50 millions dollars. If FHSC meets this savings amount, no additional monies will be paid for claims administration other than the \$0.2049.

If FHSC obtains savings of \$51 to \$75 million, FHSC may increase its claims payment administration fee by 10 percent.

If FHSC obtains savings of \$76 to \$100 million, FHSC may increase its claims payment administration fee by 20 percent.

**Work Statement for Contract Amendment for Adding Rebate Negotiations and
Maintenance to the FHSC Contract**
October 1, 2001 – September 30, 2001

Drug Rebates

Effective first calendar quarter of 2002 [January 1 March 31, 2001], Michigan will implement the CMS Rebate Administration program as defined in the Contract on page 58-60 and in FHSC Contract response on pages C1.59 –C1.65 for all CMS rebatable pharmaceutical products including physician office products, OTC, and miscellaneous. FSHC will invoice and negotiate rebates for the psychotropic carve out and the Medicaid FFS and Managed Care.

FHSC will include in this process the invoicing and negotiations for the state level rebates for CSHCS, the State Medical Program, non-Medicaid Mental Health and other State funded programs.

FHSC agrees to \$0.025/per paid claim rate for this program.

Michigan Claims Volume

All prices above are based on the premise that Michigan will increase the volume from 13,000,0000 to 30,000,000. If this volume increase does not occur, FHSC may request price changes.

Other Contract Prices and Agreements

All other contract prices and agreements remain the same.