Office Of Inspector General
Office Of Audtt Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Region II
Jacob K Javits Federal Bulldlng
26 Federal Plaza
New York, NY 10278

October 2,2003

Report Number A-02-02-05001

Alfredo Escalera Navarro, M.D.
Executive Director
San Juan Health Department
P.O. Box 21405
San Juan, Puerto Rico 00928

Dear Dr. Escalera:

The attached report provides the results of our audit entitled *Review of Ryan White Title I funds Claimed by a Non-Profit Hospital Under Contract with the San Juan Eligible Metropolitan Area.* In response to a request from the Senate Finance Committee, the Department of Health and Human Services (DHHS), Office of the Inspector General (OIG) is conducting nationwide reviews of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title I and Title **II** grantees and their contractors. The Ryder Memorial Hospital (Ryder), a contractor of the San Juan Eligible Metropolitan Area (San Juan EMA) was selected as part of these reviews. A copy of this audit report will be forwarded to the action official noted below for review and any action deemed necessary.

Our audit objective was to determine whether Ryan White Title I payments totaling $2,564,680 to Ryder for medical services rendered to HIV/AIDS patients during the period March 1, 1998 through February 28,2001 were reasonable, allocable, and allowable. The primary Federal regulations and guidelines for determining costs applicable under grants and contracts with hospitals are found at 45 CFR Part 74, Appendix E. In general, these regulations require that all costs charged to Federal grants be reasonable for the performance of the award and be based on actual costs incurred.

We found that San Juan EMA reimbursed Ryder a total of $352,094 for services that we determined were not reasonable, allocable, or allowable. Specifically, this amount comprised $273,954 for medication services that we believe were not reasonable; $6 1,189 for laboratory service costs that were not allocable; and $16,951 for medical services that were not allowable.

For the medications we tested for program years 1999 through 2001, we found that Ryder billed $273,954 in excess of their cost. Contrary to Federal cost guidelines, Ryder billed, and the San Juan EMA provided reimbursement for, medications in amounts that were substantially above their cost. Specifically, Ryder billed medications to the San Juan EMA at the Average Wholesale Price plus 10 percent while having obtained these medications at lower prices, in many instances at PHS 340B discount prices. In other words, Ryder was buying drugs at a

reduced price through one Federally sponsored program, and getting reimbursed at a significantly higher rate from another Federally sponsored program.

Ryder did not follow Federal regulations that require costs charged to Federal programs be based on actual costs incurred. Specifically, Ryder added $61,189 to the costs charged by outside laboratories, which performed laboratory analysis. Ryder calculated its reimbursement amount by adding an unreasonable 30 percent surcharge onto the costs charged by the outside laboratories. The surcharge was added because Ryder did not have an accounting system that allocated actual costs attributable to the CIS program for its laboratory collection and handling services. Consequently, there is no assurance that the $61,189 surcharge accurately reflects Ryder's costs for preparing the laboratory specimens for analysis.

We also documented four instances where the Ryder pharmacy dispensed medications without a valid prescription from a health care practitioner licensed to administer the drug product. Federal law prohibits dispensing prescription drugs without a valid prescription. Ryder billed the San Juan EMA a total of $9,975 for the medication dispensed in the four instances we documented.

The Ryan White Care Act includes a provision to ensure that its funds are used only after private health insurance, other Federal, or state health insurance and benefit programs are used. This provision commonly referred to as the "payor of last resort," is outlined in section 2605(a)(6) of the Public Health Service Act. We determined that Ryan White funds were used to pay for the laboratory services provided to 16 CIS patients who had Medicare Part B health insurance coverage during November 2000. These laboratory services were billed to the San Juan EMA in the amount of $6,976.

In our opinion, these overpayments occurred because Ryder did not develop procedures for ensuring that costs claimed were reasonable, allocable, and allowable. Thus, we recommended in our audit report that San Juan EMA:

- Refund $352,094 to the Health Resources and Services Administration (HRSA) for the overcharges made by Ryder;

- Direct Ryder to implement procedures to ensure that costs charged to the Ryan White program are reasonable and based on the allocation of actual costs of the services;

- Identify additional overpayments to Ryder that may have occurred outside the scope of our audit ;

  Direct Ryder to implement procedures to ensure that prescription medications are only dispensed with a valid medical order; and

- Direct Ryder to establish control procedures to ensure that Ryan White Title I funds are the payor of last resort by implementing effective coordination of benefits procedures.

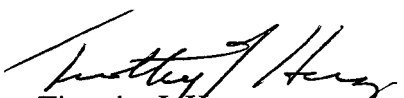
The San Juan EMA concurred with the findings and recommendations presented in our audit report and will work in coordination with HRSA and Ryder to implement corrective procedures.

The HHS action official named below will make final determination as to actions taken on all matters reported. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, OIG reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.) As such, within ten business days after the final is issued, it will be posted on the World Wide Web at http://oig.hhs.gov.

To facilitate identification, please refer to report number A-02-02-05001in all correspondence relating to this report.

Sincerely,



Timothy J. Horgan
Regional inspector General
for Audit Services

Enclosures – as stated

Direct Reply to HHS Action Official:

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF RYAN WHITE TITLE I FUNDS CLAIMED BY A NON-PROFIT HOSPITAL UNDER CONTRACT WITH THE SAN JUAN ELIGIBLE METROPOLITAN AREA

Inspector General
October 2003
A-02-02-05001

Office of Inspector General

http://oig.hhs.gov

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OBJECTIVE

The audit objective was to determine whether Ryan White Title I payments totaling $2,564,680 made by the San Juan Eligible Metropolitan Area (EMA) to Ryder Memorial Hospital (Ryder) for medical services rendered to Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) patients during the period March 1, 1998 through February 28, 2001 were for reasonable, allocable, and allowable costs. This review is part of a series of reviews conducted based on a request by the U.S. Senate Committee on Finance to examine the stewardship of Health Resources and Services Administration (HRSA) Ryan White CARE Act funds.

FINDINGS

The San Juan EMA reimbursed Ryder a total of $352,094 for services that we determined were not reasonable, allocable, or allowable, as outlined in Federal guidelines issued by the Office of Management and Budget. Specifically, this amount comprised $273,954 for medication services that we believe were not reasonable; $61,189 for laboratory service costs that were not allocable; and $16,951 for medical services that were not allowable. It is important to note that Ryder may have received additional overpayments in situations where patients had health insurance, but did not bill the primary payor, as required by the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, before billing the Ryan White program.

In our opinion, these overpayments occurred because Ryder did not develop procedures ensuring that:

- Only reasonable and allocable costs were claimed for providing medications and laboratory services to its Ryan White patients;
- Prescription medications were only issued with a valid medical order; and
- Ryan White Title I was the payor of last resort.

As a result, the San Juan EMA reimbursed Ryder a total of $352,094 for which the hospital was not entitled under Federal guidelines. The San Juan EMA could have used these funds to support other Ryan White program activities.

RECOMMENDATIONS

We recommend that the San Juan EMA:

- Refund $352,094 to HRSA for the overcharges made by Ryder;

- Direct Ryder to implement procedures to ensure that costs charged to the Ryan White program are reasonable and based on the allocation of actual costs of the services;

- Identify additional overpayments to Ryder that may have occurred outside the scope of our audit;

- Direct Ryder to implement procedures to ensure that prescription medications are only dispensed with a valid medical order; and

- Direct Ryder to establish control procedures to ensure that Ryan White Title I funds are used as the payor of last resort by implementing effective coordination of benefits procedures.

Ryder Memorial Hospital Comments

We provided Ryder with a copy of our draft report on November 12, 2002 to obtain its comments relative to our findings and recommendations. In its January 31, 2003 letter, Ryder generally disagreed with our findings and recommendations. Ryder maintained that its billings were fair, reasonable, allocable, and allowable because they were in accordance with the contract it had with the San Juan EMA. We have summarized Ryder's comments in Appendix B.

We have thoroughly reviewed the comments provided by Ryder and attended a meeting with Ryder officials to discuss our findings and recommendations. We conclude that the additional information and explanations Ryder provided do not afford a basis for us to revise the findings in our report. We provided additional remarks, based on Ryder's comments, in Appendix B.

San Juan EMA Comments

In its comments dated August 5, 2003, the San Juan EMA stated that it will abide by our findings and will make the corrections necessary to implement our recommendations. It summarized Ryder's position on the findings and pledged to work with HRSA and Ryder to solve the matter. The EMA acknowledged in its comments that Ryder does not agree with our conclusions that medication costs were unreasonable and the laboratory charges were improperly allocated. It also noted that its contract with Ryder includes a provision that obliges Ryder to comply with all applicable municipal, State, and Federal laws, regulations, and policies. The San Juan EMA comments are included in their entirety as Appendix C of this report.

OIG Response

We are pleased that the San Juan EMA is willing to make corrections to resolve our recommendations and to work with HRSA and Ryder to that end.

GLOSSARY OF ABBREVIATIONS AND ACRONYMS

AWP	Average Wholesale Price
CIS	Spanish acronym for Integrated Care for AIDS Patients Program (*Programa de Cuidado Integral del SIDA)*
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration - Federal agency that administers the Ryan White CARE Act
PHS 340B	Public Health Service 340 B prices
Ryan White CARE Act	Public Law 101-381 Ryan White Comprehensive Acquired Immune Deficiency Syndrome (AIDS) Resources Emergency (CARE) Act (enacted on August 18, 1990)
Ryder	Ryder Memorial Hospital, Inc. – subcontractor for the San Juan EMA
San Juan EMA	San Juan Eligible Metropolitan Area – program grantee
Title I	Title I of the Ryan White CARE Act provides emergency relief grants to cities for health support services for low-income and under-or-uninsured persons living with HIV/AIDS and their families

BACKGROUND

Ryan White Care Act

On August 18, 1990, Congress passed Public Law 101-381, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The enactment of this law followed reports of severe distress in major U.S. metropolitan areas that were becoming overburdened by the cost of care for a growing number of Americans living with AIDS who had little or no health insurance. The AIDS epidemic, which emerged in 1981, had created a need for primary medical care that was exceeding the capacity of local health departments, hospital emergency rooms, and other health care institutions.

The Ryan White CARE program, administered by the Health Resources and Services Administration (HRSA), supports the development of systems of care that are responsive to local needs and resources. It is founded on strong partnerships between the Federal Government, states, and local communities in need, and emphasizes less costly outpatient, primary care to prevent costly emergency room visits and hospitalizations.

Through Title I of the CARE Act, HRSA provides emergency relief grants to cities—referred to as Eligible Metropolitan Areas (EMAs) for health and support services for low-income and under-or-uninsured persons living with HIV/AIDS and their families. Services include health care and support services such as medical and dental care, prescription drugs, transportation, counseling, and home and hospice care.

Fifty cities, identified by HRSA as having a high number of persons living with AIDS are eligible for Title I grants. These cities are also eligible for supplemental grants, which are awarded to cities demonstrating additional critical needs. Since 1991, nearly $3 billion in Title I funds have been appropriated, by Congress for the Title I program.

The *Ryan White Care Act Title I Manual*, issued by HRSA, contains guidance for grantees regarding their responsibilities for monitoring Ryan White Title I funds. Section 2, Chapter 3 of this manual states that contract monitoring includes both program monitoring and fiscal monitoring. Specifically, Title I grantee (EMA) responsibilities include assessing:

- programmatic measures to determine the quality and quantity of the services being provided by a particular contractor, through such methods as reviewing program reports, conducting site visits, and examining client records or charts; and
- the contractor's uses of CARE Act funding to determine whether funds are used for approved purposes, through such methods as review and assessment of monthly expenditure patterns for particular contractors and processes to ensure adherence to Federal, state, and local rules and guidelines on the use of CARE Act funds. The HRSA manual points out that some EMAs conduct fiscal audits and record reviews, and most

require that contractors provide supporting documentation of expenditures and an annual financial audit by a qualified independent accountant.

San Juan Eligible Metropolitan Area

Puerto Rico has one of the highest incidences of AIDS in the United States. The San Juan EMA began participating as a Title I grantee at the inception of the CARE Act. At the time of our review, it had contracts with 19 agencies to provide HIV/AIDS services in the San Juan EMA.

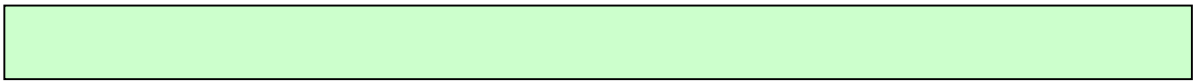
The San Juan EMA reimburses expenditures incurred by its contractors for rendering services to Ryan White Title I eligible patients. The most common contracted services are medications, laboratory, case management, and nursing. For the program year ended February 28, 2001, the San Juan EMA reimbursed contractors a total of $12,825,924 for Ryan White Title I services, with Ryder being the second largest recipient of those funds, at $1,016,652.

Ryder Memorial Hospital

Ryder is a non-profit organization founded in Humacao, Puerto Rico in 1914 by the American Missionary Association. Ryder is a general hospital that provides preventive, acute care, rehabilitation, and support services. The Integrated Care for AIDS Patients Program, known in Spanish as *Programa de Cuidado Integral del SIDA* (CIS), is one of the hospital's 17 programs.

The Ryder CIS serves approximately 210 patients. It was created in April 1991 and has received most of its funding from Ryan White Title I. CIS provides medication, laboratory, case management, physician specialist, mental health, nutritional supplements, and home health care services.

Patients gain access to Title I care services by a referral from a variety of sources including community-based organizations, physicians or other health professionals, immunological clinics, and hospitals outreach efforts. The patients are evaluated by a case manager responsible for determining their eligibility for Title I services. Once eligibility is established, the case manager is responsible for conducting an initial and an ongoing assessment of the patient's medical needs and their personal support system. The case manager develops a comprehensive individualized service plan and coordinates the services required to implement it.



Objective

The audit objective was to determine whether Ryan White Title I payments totaling $2,564,680 made by the San Juan EMA to Ryder for medical services rendered to HIV/AIDS patients during the period March 1, 1998 through February 28, 2001 were for reasonable, allocable, and allowable costs.

Scope

The San Juan EMA reimbursed Ryder a total of $2,564,680 during the period March 1, 1998 through February 28, 2001. We used applicable laws, regulations, guidelines, and the Notice of Grant Award to determine whether costs claimed by Ryder met reimbursement requirements.

The schedule below summarizes the amounts received by Ryder from the San Juan EMA during each of the program years in our review.

March 1, 1998 through February 28, 1999	$ 600,562
March 1, 1999 through February 29, 2000	947,466
March 1, 2000 through February 28, 2001	1,016,652
Total	**$2,564,680**

We did not assess the overall internal controls at Ryder. Our internal control review was limited to gaining an understanding of those controls related to the costs reimbursed by the San Juan EMA during the period March 1, 1998 through February 28, 2001.

Methodology

To accomplish our objective, we:

- Interviewed HRSA and San Juan EMA officials.

- Reviewed documentation at the San Juan EMA, including:
  - contracts with Ryder CIS program to provide Ryan White Title I services;
  - monitoring reports for Ryder CIS program; and
  - financial accounting records for reimbursement payments to Ryder.

- Reviewed Ryder's:
  - audit reports prepared to comply with the Office of Management and Budget (OMB) Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations* for the period under review; and
  - Ryan White Title I Proposal submitted to the San Juan EMA for program year 2001.

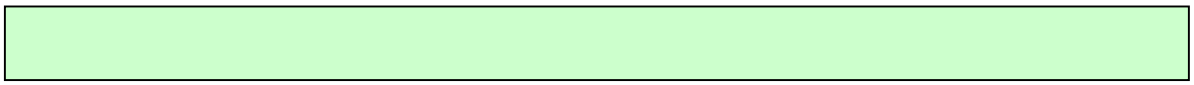
- Obtained an understanding of Ryder's:
  - program operations;
  - patient eligibility requirements; and
  - cost categories reimbursed, such as medications, laboratory, case management, physician specialist, mental health, nutritional services, home health care, and administrative expenses.

- Selected on a judgmental basis for each cost category monthly reimbursements with the highest dollar amounts and traced them to supporting documentation. We tested transactions totaling $1,360,372, as noted in the Appendix A.

- Interviewed and obtained documentary evidence from Ryder's professional staff, including laboratory and pharmacy personnel.

- Limited our testing to verify whether patients had primary health insurance to the month of November 2000 and determined if Ryan White funds were used as the payor of last resort. We also tested for duplicate payments on patients having Medicare Part B coverage.

We performed our work at the San Juan EMA office, the Ryder facility in Humacao, Puerto Rico, and OIG office in San Juan from April through August 2002. On November 12, 2002, we provided Ryder with a copy of our draft report to obtain their opinion on our findings and recommendations. Ryder's comments are included as part of this report. Our audit was conducted in accordance with generally accepted government auditing standards.



The San Juan EMA reimbursed Ryder a total of $352,094 for services that we determined were not reasonable, allocable, or allowable. Specifically:

- $273,954 for adding unreasonable costs and fees to medications;

- $61,189 for adding unallocable surcharges for laboratory services;

- $9,975 for dispensing medications without a valid prescription; and

- $6,976 for billing Ryan White rather than Medicare Part B.

In our opinion, these overpayments occurred because Ryder used an inappropriate cost basis and added unsupported surcharges to costs for the Ryan White program, rather than charging its actual costs for dispensing medications and providing laboratory services. We found Ryder's billing methodologies were not reasonable or consistent with Federal regulations

In addition, Ryder did not have controls to ensure that medications were only issued with a valid prescription and that Ryan White Title I was the payor of last resort. As a result, the San Juan EMA reimbursed Ryder a total of $352,094 for which it was not entitled during the 3-year period ended February 28, 2001. The San Juan EMA could have used these funds to support other Ryan White program activities.

CLAIMS FOR MEDICATION COSTS WERE NOT REASONABLE

Contrary to Federal cost guidelines, Ryder billed, and the San Juan EMA provided reimbursement for, medications in amounts that were substantially above their cost. Specifically, Ryder billed medications to the San Juan EMA at the Average Wholesale Price (AWP) plus 10 percent while having obtained these medications at lower prices, in many instances at PHS 340B discount prices. In other words, Ryder was buying drugs at a reduced price through one Federally sponsored program, and getting reimbursed at a significantly higher rate from another Federally sponsored program. As a result, Ryder

received $273, 954 in unreasonable reimbursements from the San Juan EMA for Ryan White medications.

Federal Cost Principles Require Costs to be Reasonable

In determining whether the costs charged by Ryder were reasonable, we applied the cost principles outlined in 45 Code of Federal Regulations (CFR) Part 74, Appendix E "*Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals*."

The general principle provisions of this regulation require that all costs charged to Federal grants be reasonable for the performance of the award. Specifically:

> *A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amount involved therefore reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made*.

Ryder Charged the San Juan EMA Significantly More Than It Paid to Purchase AIDS Medications

For the medications we tested for program years 1999 through 2001, we found that Ryder billed $273,954 in excess of their cost. The following are examples of monthly prescriptions that illustrate the extent of the overcharges for five of the medications reviewed. For the five medications shown in the following table, the overcharges represented 27 to 50 percent of the amount reimbursed.

Oct. 2000	A	$ 744.48	$ 477.46	$ 267.02	36
Dec.2000	B	$ 559.20	$ 308.51	$ 250.69	45
Nov.2000	C	$ 761.64	$ 384.33	$ 377.31	50
Jan. 2001	D	$ 314.84	$ 172.06	$ 142.78	45
Dec.2000	E	$ 342.69	$ 249.23	$ 93.46	27

The Overcharges Occurred Because Ryder Based its Cost Claims on Higher AWP Prices for the Medications and Added an Unreasonable 10 Percent Dispensing Fee

The San Juan EMA overpaid Ryder a total of $273,954 for the 3-year program period we reviewed because Ryder billed for the medications it purchased at a higher rate than it actually paid, and added a 10 percent dispensing fee. We attribute this condition to Ryder's failure to: 1) use its acquisition price as the cost of medications, and 2) establish fiscal procedures for determining the actual cost of dispensing medications to its patients.

Ryder billed and was reimbursed for the medications dispensed to CIS patients based on AWP plus a 10 percent dispensing fee. AWP is the manufacturer's suggested list price for a wholesaler to charge a pharmacy for a drug; however, based on the information available for our review, it was usually not the price Ryder paid to purchase the medications dispensed to CIS patients. We found that Ryder used a Federally sponsored program to purchase most of its CIS program medications at a reduced rate. This

discounted rate, known as the PHS 340B[1] price, is available to entities that provide services through various Federally supported health programs that serve as our nation's health care safety net.

In addition to using the incorrect cost basis, Ryder added a dispensing fee that was not based on a proper accounting of actual dispensing costs, but rather on an unreasonable percentage. This occurred because Ryder did not have an accounting system that accurately identified its costs for dispensing CIS medications. Ryder had only one drug supply area for storing its medications. This area contained the hospital's entire drug supply, including CIS program medications. We recognize there is a cost for storing and dispensing CIS program medications; however, we believe the amount associated with such functions would only be a small portion of the cost of operating Ryder's pharmacy.

Ryder Received $273,954 in Unreasonable Reimbursements

Ryder received unreasonable reimbursement totaling $273,954 in excess of its costs for the medication purchases reviewed, as follows:

- $212,337 for Crixivan and Viracept during the full 3-year program period, 1999 through 2001;

- $56,598 for Combivir, Epivir, Zerit, Kaletra, and Rebetron during program year 2001. We were not able to determine the overpayment amount for programs years 2000 and 1999 because pricing information for those years was not available at Ryder; and

- $5,019 for 17 other medications reviewed for December 2000.

Based on our discussion with Ryder officials, we understand this same billing methodology was used during program year 2002. If so, this methodology would not be reasonable or consistent with the cost principles identified in 45 CFR Part 74, Appendix E.

A summary of the comments provided by Ryder for the unreasonable medication costs appears in Appendix B along with our response. A complete copy of Ryder's comments will be maintained at our San Juan Field Office and will be made available to the San Juan EMA for their perusal.

SURCHARGES ADDED TO LABORATORY SERVICES WERE NOT BASED ON ALLOCATIONS OF ACTUAL COSTS

The cost principles in 45 CFR Part 74 Appendix E require that costs charged to Federal programs be based on actual costs incurred. Ryder did not follow this regulation in adding $61,189 to the costs charged by outside laboratories, which performed laboratory analysis. Ryder calculated its reimbursement amount by adding an unreasonable 30 percent surcharge onto the costs charged by the outside laboratories. The surcharge was added because Ryder did not have an accounting system that allocated actual costs attributable to the CIS program for its laboratory collection and handling services. Consequently, there is no assurance that the $61,189 surcharge accurately reflects Ryder's costs for preparing the laboratory specimens for analysis.

[1] "340B" refers to the section of the Federal legislation creating the discounted drug program.

Ryder Charges for Laboratory Services Were Determined Using an Unreasonable Surcharge Because Cost Allocations Were Not Performed

In billing the San Juan EMA for laboratory services, Ryder added an unreasonable 30 percent surcharge to the costs charged by outside laboratories, that actually performed the scientific analysis, to cover its costs for preparing and handling CIS program laboratory specimens. Ryder added the unreasonable surcharge because it did not have fiscal procedures for determining the actual cost it incurred related to preparation and handling of laboratory samples for CIS program patients. Because of the specialized nature of the tests conducted on CIS program patients, Ryder used the scientific analysis services of contracted reference laboratories, and thus only incurred minimal costs for its own laboratory. However, Ryder was not able to identify the specific costs incurred when preparing, collecting, and storing the sample specimens.

The following examples illustrate this condition:

Lab test	Reimbursed	Cost Charged by Contract Lab	Ryder's Surcharge
HIV Genotype	$455.00	$350.00	$105.00
HIV RNA by PCR	$232.70	$179.00	$ 53.70
HCV Genotype	$195.00	$150.00	$ 45.00
HIV PCR CD3/CD4	$162.50	$125.00	$ 37.50

Reimbursements Totaling $61,189 Were Not Allocations of Actual Costs

For each of the 3 years reviewed, Ryder billed and received reimbursement at 30 percent above the cost charged by contracted laboratories, amounting to $61,189 in charges that were not allocations of actual costs, as follows:

• Program year 2000-2001	$ 19,401
• Program year 1999-2000	30,348
• Program year 1998-1999	11,440
Total	$ 61,189

These reimbursements were not based on the actual cost incurred by Ryder in collecting and handling laboratory specimens for the CIS program. Rather, Ryder charged a 30 percent surcharge for the tests performed by outside reference laboratories. We noted that Ryder continued charging a 30 percent surcharge for these tests during program year 2002; therefore, there is a high probability that similar overcharges occurred in program years outside the scope of our review.

A summary of the comments provided by Ryder for the laboratory costs we determined to be not allocable to the Ryan White program appears in Appendix B along with our response.

DISPENSING DRUGS WITHOUT A VALID PRESCRIPTION

Contrary to Federal laws and regulations Ryder sometimes dispensed medications without a valid prescription. We documented four instances where the medication Rebetron was dispensed in a greater quantity than prescribed or based on a previously dispensed prescription. Ryder attributed these

dispensing errors to employee misunderstanding or oversight. We recommend that Ryder reinforce dispensing criteria with its pharmacy staff and refund $9,975 for the medications involved.

The Federal Food, Drug, and Cosmetic Act Requires a Valid Prescription to Dispense Drugs

Federal law prohibits dispensing prescription drugs without a valid prescription. Specifically, Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act provides that:

> *A drug intended for use … shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist.*

We documented four instances where the Ryder pharmacy dispensed medications without a valid prescription from a health care practitioner licensed to administer the drug product. We reviewed certain procedures used by Ryder's pharmacy to dispense the medication Rebetron during the period from August through December 2000. Our findings and Ryder's explanation for the dispensing errors are described below.

- On three occasions, patients were dispensed more Rebetron than prescribed. In these instances, Ryder pharmacists dispensed two therapy packs of Rebetron in excess of the amount prescribed. Physicians prescribe this medication, used for the treatment of Hepatitis C, for a month where the usage is one therapy pack per week, or four for a month. Ryder attributed this situation to a misunderstanding, since the medication previously prescribed, Intron, was prescribed at a rate of six packages per month.

- In the fourth instance, Ryder's pharmacy relied on a previous month's prescription for a CIS patient, which had already been dispensed. Ryder attributed this situation to an oversight by pharmacy staff.

To prevent future dispensing errors, Ryder should reinforce adherence to the Federal laws over dispensing medications, specifically ensuring that all medications are dispensed based on a valid prescription from a health care practitioner licensed to administer the medication.

Charges for $9,975 to the Ryan White Program for the Medication Dispensed Without a Valid Prescription is Unallowable

The amount billed by Ryder for medications dispensed without a valid prescription is an unallowable cost to the Ryan White program. Ryder billed the San Juan EMA a total of $9,975 for the Rebetron dispensed in the four instances we documented. It should be noted that these costs were excluded from our finding regarding the reasonableness of the Ryder's pricing and dispensing charges discussed on page 4 of this report. Therefore, we are questioning the entire $9,975 reimbursed by the San Juan EMA for these four medications.

A summary of the comments provided by Ryder for the unallowable medication costs appears in Appendix B.

RYDER DID NOT ENSURE THAT THE RYAN WHITE PROGRAM WAS THE PAYOR OF LAST RESORT

Contrary to the Ryan White CARE Act, Ryder sometimes billed the San Juan EMA Ryan White program for laboratory services provided to patients with other medical insurance. We found that Ryder billed $6,976 to the Ryan White program for laboratory services for CIS patients with Medicare coverage. Because Ryder did not have procedures to ensure appropriate coordination of benefits, specifically that the Ryan White program was the payor of last resort, the San Juan EMA was incorrectly billed for these services.

The Ryan White CARE Act Program Payor of Last Resort

The Ryan White Care Act includes a provision to ensure that its funds are used only after private health insurance, other Federal, or state health insurance and benefit programs are used. This provision, commonly referred to as the "payor of last resort," is codified in section 2605(a)(6) of the Public Health Service Act, which states:

> *Funds received under a grant awarded under this part will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service--- (A) under any State compensation program, under an insurance policy, or under any Federal or State benefits program.*

The Ryan White Funds Were Used for Services Provided To Patients with Medicare Coverage

We determined that Ryan White funds were used to pay for the laboratory services provided to 16 CIS patients who had Medicare Part B health insurance coverage during November 2000. These laboratory services were billed to the San Juan EMA in the amount of $6,976.

Ryder had not established a control procedure to ensure appropriate coordination of benefits for its CIS patients. Ryder indicated that several of its staff members, including the admitting social worker and attending nurses, inquired about a patient's insurance coverage, but that the correct information was not always conveyed to its billing office. In addition, Ryder believed that some patients incorrectly assume that they will be responsible for a co-payment if Medicare is billed; consequently, the patients may not be informing the attending nurses of their Medicare coverage. As a result, the claim is incorrectly submitted to the San Juan EMA for reimbursement.

Ryder Billed San Juan EMA for $6,976 in Laboratory Services that should have been billed to Medicare

Ryder billed for and received reimbursement totaling $6,976 from the San Juan EMA for laboratory services provided to 16 CIS patients during November 2000 that should have been billed to Medicare. Because Ryder did not have effective coordination of benefits procedures in place, we believe it is possible that the hospital incorrectly billed the San Juan EMA for CIS patients with Medicare or other health insurance coverage for other time periods and other services and in turn, received additional overpayments.

A summary of the comments provided by Ryder for the laboratory costs that should have been billed to Medicare appears in Appendix B.

RECOMMENDATIONS

We recommend that the San Juan EMA:

- Refund $352,094 to HRSA for the overcharges made to Ryder. This amount includes:

    - $273,954 for the overpayments made to Ryder for medications,
    - $61,189 for the overpayments made to Ryder for laboratory services,
    - $9,975 for improper payments made to Ryder for dispensing drugs without a valid prescription, and:
    - $6,976 for overpayments made to Ryder for laboratory services provided to Medicare patients.

- Direct Ryder to implement procedures to ensure that costs charged to the Ryan White program are reasonable and based on the allocation of actual costs for medications and laboratory services,

- Direct Ryder to implement procedures to ensure that prescription medications are only dispensed with a valid medical order,

- Direct Ryder to establish control procedures to ensure that Ryan White Title I funds are used as the payor of last resort by implementing effective coordination of benefits procedures, and

- Identify additional overpayments outside the scope of our audit.

San Juan EMA Comments

In its comments dated August 5, 2003, the San Juan EMA stated that it will abide by our findings and make the corrections necessary to implement our recommendations. It summarized Ryder's position on the findings and pledged to work with HRSA and Ryder to solve the matter. The EMA acknowledged in its comments that Ryder does not agree with our conclusions that medication costs were unreasonable and the laboratory charges were improperly allocated. It also noted that its contract with Ryder includes a provision that obliges Ryder to comply with all applicable municipal, State, and Federal laws, regulations, and policies. The San Juan EMA comments are included in their entirety as Appendix C of this report.

OIG Response

We are pleased that the San Juan EMA is willing to make corrections to resolve our recommendations and to work with HRSA and Ryder to that end.

APPENDICES

Summary of Costs Reviewed

The following schedule summarizes, for the 3-year period ended February 28, 2001 the Title I costs reimbursed to Ryder; amounts reviewed by the OIG; and, the amounts questioned by the OIG.

Cost Item	Reimbursed	Reviewed	Questioned
Medications	$1,575,633	$ 786,273	$ 283,929
Laboratory	487,800	487,800	68,165
Case Management	135,733	6,250	0
Physician Specialist	18,989	18,989	0
Mental Health	86,481	12,715	0
Nutrition	145,519	27,135	0
Home Health	59,118	4,684	0
Administration	55,407	16,526	0
Total	**$2,564,680**	**$1,360,372**	**$ 352,094**

Summary of Contractor's Comments to Findings and OIG Response

Finding #1 ***CLAIMS FOR MEDICATION COSTS WERE NOT REASONABLE***

In its comments dated January 31, 2003, Ryder did not agree that $273,954 should be refunded to HRSA. Ryder believes that the audit did not reflect the fiscal health and fairness of its community service and the high quality health care services provided. Ryder claimed that costs incurred were reasonable, allocable, and allowable, and in compliance with OMB Circular A-133, which it cited as the cost principles applicable to the Ryan White Title I program funds as managed by Ryder, a not for profit hospital. In addition, Ryder affirmed that it had adequate accounting procedures, which were routinely implemented. In its written comments, Ryder presented several major points to defend its cost claims; these comments are summarized below:

Contract with the San Juan EMA - Ryder contended that it billed for medications in accordance with the terms of its contract with San Juan EMA. Ryder maintained that program reimbursements were the result of a valid, binding, and enforceable contractual obligation with the San Juan EMA. Ryder indicated that the San Juan EMA required the change in reimbursement from the cost plus basis to a more standardized parameter; therefore, it adopted the AWP as the new basis for billing medication services in 1998.

Financial Position - Ryder explained that after nine months of not receiving reimbursements from the San Juan EMA, its financial position was compromised, and it was forced to threaten San Juan EMA with legal action, including cancellation of the contract and withdrawal from the Ryan White program. In a related argument, Ryder stated that it did not always purchase medications using PHS 340B prices because its lines of credit from pharmaceutical companies were often closed. Ryder maintained that as a result of these "dire" financial circumstances, it was only offered the "market price" for its medication purchases.

Medicare Cost Experience - Ryder stated that its audited cost report for its Medicare program patients illustrates both the direct costs and the related indirect costs for medications. The indirect cost percentages for Medicare ranged between 25.44 and 37.93 for the period 1998 through 2001. Ryder maintains that it is only able to break even when these higher Medicare indirect cost percentages are added to medication acquisition costs.

OIG RESPONSE

After reviewing Ryder's official comments to our report and the documentation included as part of it, we continue to conclude that Ryder received $273,954 in unreasonable cost reimbursements. While Ryder presented different reasons for ascertaining the reasonableness of reimbursement for its medications, we maintain that none of the statements presented justify the total amount claimed; and in fact, Ryder did not provide any evidence indicating the exact cost of dispensing medications to Ryan White Title I patients.

It is important to clarify the cost principles applicable to Ryder's Ryan White activities. Ryder's comments indicate that it believes that OMB Circular A-133 provides the applicable cost principles. We

do not agree. Circular A-133 sets forth standards governing independent audit requirements applicable to recipients of Federal awards; it does not contain cost principles. The Circular recognizes that the Federal cost principles applicable to a recipient of Federal funds depend on the organization type. In the case of Ryder's Ryan White activities, the applicable cost principles are contained in 45 CFR – Subtitle A – Part 74, Appendix E.

We offer the following response to the major points in Ryder's comments to our report:

Contract with the San Juan EMA - Ryder billed medications according to its proposal that was incorporated by reference in its cost reimbursable contract with San Juan EMA. However, we found Ryder's billing methodologies were not reasonable or consistent with Federal regulations. In this respect, this contract also mandated that Ryder comply with all municipal, state and Federal laws and policies, with emphasis on HRSA's regulations.

Although Ryder billed medication costs in accordance with its contract with San Juan EMA, we do not believe these costs are reasonable because: (1) they were not based on actual costs incurred by Ryder to purchase the medications, as discussed on page 4 of this report; and, (2) there was an unreasonable 10 percent surcharge added to the AWP for the dispensing of medications.

Financial Position - In its comments, Ryder contended that it was forced to pay market prices for certain medications, because its financial position affected its credit standing with pharmaceutical manufacturers. We found that in most instances we evaluated, Ryder was able to purchase these medications at PHS 340B prices, which are below market. For example, our analysis disclosed that the medication Crixivan was available at PHS 340B prices in eight of the nine instances evaluated for the program year 2000-2001. In addition, documentation analyzed for the medication Viracept disclosed that PHS 340B prices were available in seven of the nine instances evaluated. These two drugs alone represented approximately 50 percent of the medication costs for the program year 2000-2001. Consequently, we maintain our conclusion that Ryder's charges for medications were not reasonable, since they were not based on the actual costs incurred to purchase them.

Medicare Cost Experience - Ryder referenced its higher Medicare cost allocation rates in defending its 10 percent surcharge added to the AWP to determine the cost of Ryan White medications. We do not believe that the Medicare allocation rates are applicable to the Ryan White Title I program for the reasons discussed below:

- We determined that Ryder did not have an accounting system which adequately identified its total Ryan White Title I costs. We recognize that Ryder had a cost accounting system to identify both direct and indirect costs for the Medicare program; however, it did not provide sufficient evidence that the volume, cost, and dispensing differences of Ryan White Title I medications were adequately identified and considered. Specifically:

    - We found that medications included in the Ryan White program were expensive drugs, usually dispensed only to HIV/AIDS patients, and provided to patients once a month in sealed bottles. In contrast, regular medications dispensed in a hospital setting generate more indirect cost because the personnel involvement is higher in selecting, packing, and distributing small quantities;

- The fact the HIV/AIDS medications in question were expensive also factors into the materiality of the 10 percent surcharge. By multiplying the AWP price by 10 percent, we believe a material amount of cost was added. Federal regulations require a special accounting treatment for material indirect costs issues. (See 45 CFR – Subtitle A – Part 74; Appendix Section v).

Ryder's comments emphasized that there is a cost involved with dispensing medications, and we have acknowledged such a cost in our report. We are questioning the methodology Ryder used to bill its surcharge, the use of the AWP cost for medications, and documentation supporting such costs. We conclude that Ryder did not provide adequate supporting evidence that would cause us to revise this finding.

Finding #2 ***SURCHARGES ADDED TO LABORATORY SERVICES WERE NOT BASED ON ALLOCATIONS OF ACTUAL COSTS***

Ryder did not agree that $61,189 in laboratory reimbursements should be refunded to HRSA. Referencing the same arguments used on the finding involving medications, including its contract with the San Juan EMA, Ryder further stated that although the norm in the local health industry, mandated by Medicare, is to receive reimbursement based on costs, contract negotiations can and should allow health care institutions and providers to maintain an economically stable situation that guarantees continuation of vital services.

Ryder maintained that the 30 percent surcharge added to the costs of the laboratory tests performed by outside laboratories is reasonable, allowable, and allocable. For comparative purposes, Ryder provided its Medicare laboratory indirect cost rate for the time period of our review.

OIG RESPONSE

After reviewing Ryder's comments, including the enclosures, we continue to maintain that Ryder received $61,189 in reimbursement for costs related to laboratory services that were not allocable. We offer the following response to the major points in Ryder's comments to our report:

Contract with San Juan EMA - Ryder maintained that it billed laboratory services according to the proposal that was incorporated by reference in its cost reimbursable contract with San Juan EMA. With respect to laboratory services, the proposal indicated that Ryder would bill them based on a fee schedule plus 10 percent, and that this was the methodology used by Ryder when billing the Ryan White program for tests conducted in Ryder's own laboratories. In the case of laboratory tests performed by outside reference laboratories, we found that the amount charged by Ryder was 30 percent above its actual costs.

Medicare Cost Experience **-** Ryder provided its Medicare indirect cost rates to provide a comparison of costs for indirect laboratory services. We recognize that Ryder had a cost accounting system to identify both direct and indirect costs related to the Medicare program; however, Ryder did not provide any evidence that the amounts claimed for Ryan White Title I were accurately identified. We found that the Medicare allocation rates apply to laboratory tests performed by Ryder's own laboratory department, but did not apply to laboratory tests performed by outside reference laboratories. The Medicare allocation rates represent the costs (i.e., housekeeping, plant operation, etc.) incurred by Ryder in supporting its own laboratory department for instances when the actual test analysis on the specimen is performed in-house.

Our review included laboratory tests performed by outside reference laboratories under contract with Ryder -- tests that were highly specialized in nature and high in cost. We found that for Ryder's Ryan White activities, its CIS personnel performed the actual collection, and were paid by Ryder with direct Ryan White funds. In fact, the contracted laboratories also provided the laboratory supplies used for these specialized tests. Consequently, Ryder's indirect involvement was limited to preparing, collecting, and storing the sample specimens until retrieved by personnel from the reference laboratories.

Finding #3 ***DISPENSING DRUGS WITHOUT A VALID PRESCRIPTION***

Ryder concurred that $9,975 pertaining to medications dispensed without a valid prescription must be returned to the program. Ryder claimed that human error was the cause for this finding and not the lack of procedures.

OIG RESPONSE

We are pleased to note Ryder's concurrence that medications totaling $9,975 were dispensed without a valid prescription. We must emphasize the need for Ryder to establish control procedures to comply with Federal laws and regulations in the dispensing of medications.

Finding #4 ***RYDER DID NOT ENSURE THAT THE RYAN WHITE PROGRAM WAS THE PAYOR OF LAST RESORT***

Ryder concurred that laboratory services for $6,976 were erroneously billed to the Ryan White program, instead of being billed to the Medicare program. Ryder claimed that a human error was the cause for this finding and not the lack of procedures.

OIG RESPONSE

We are pleased to note Ryder's concurrence that they need to establish control procedures to ensure that the Ryan White program is the payor of last resort.

SAN JUAN EMA COMMENTS TO OIG REPORT

Municipality of San Juan, Capital City

August 5, 2003

Timothy J. Hogan
Regional Inspector General
Office of Audit Services Region II
Department of Health & Human Services
Jacob Javitz Federal Building
26 Federal Plaza
New York, NY 10278

RE: Review of Ryan White Title I Funds at Ryder Memorial Hospital – San Juan Eligible Metropolitan Area
March 1, 1998 through February 28, 2001
Report Number A-02-02-05001

Dear Mr. Horgan:

As requested, we hereby comment on the draft of the above referenced document dated June 30, 2003.

The Inspector General determined that the San Juan Eligible Metropolitan Area, hereinafter "San Juan EMA", reimbursed Ryder Memorial Hospital, hereinafter "Ryder", $352,094 for services that were determined not reasonable, allocable or allowable. Specifically, $273,954 for medication services that the Inspector General believes were not reasonable; $61,189 for laboratory service costs that were not allocable; and $16,951 for medical services that were not allowable.

The Inspector General is recommending the following measures:

1. Refund $352,094 to the Health and Services Administration, hereinafter "HRSA", for the overcharges made by Ryder.
2. Direct Ryder to implement procedures that ensure that costs charged to the Ryan White program are reasonable and based on the allocation of actual costs of the services.
3. Identify additional overpayments outside the scope of the audit.
4. Direct Ryder to implement procedures to ensure that prescription medications are only dispensed with a valid medical order.
5. Direct Ryder to establish control procedures to ensure that Ryan White funds are the payor of last resort.

Ryder recognized that $16,951 refunded for medical services were not allowable due to the fact that $9,975 were medications dispensed without a valid prescription and $6,676 were erroneously billed to the Ryan White program instead of being billed to the Medicare program. Furthermore, Ryder concurred with the Inspector General that they need to establish control procedures to ensure that Ryan White program is the payor of last resort. Therefore, we have no comments related to the Inspector General's claim of $16,951 because we understand that Ryder acknowledged said assessment and will refund the $16,951 to HRSA.

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On the other hand, Ryder did not agree that the $273,954 and $61,189 assessed for adding unreasonable costs and fees to medications and for adding unallocable surcharges for laboratory services, respectively, should be refunded to HRSA. It also claimed that costs incurred were reasonable, allocable, allowable, in compliance with OMB Circular A-133 and in accordance with terms of its contract with the San Juan EMA. The Inspector General concluded that Ryder's billing method were not reasonable or consistent with federal regulations. Ryder claimed that their billing method is in accordance with Ryder's contract with the San Juan EMA therefore, acceptable.

We would like to bring to your attention, the contract between the San Juan EMA and Ryder, which emphatically obliges Ryder to comply with all the municipal, state and/or federal laws, regulations and policies, including HRSA's regulations. Therefore, if Ryder did not comply with any applicable municipal, state and/or federal law, regulation or policy, it was not based nor acting under the provisions of the contractual agreement with the San Juan EMA.

Furthermore, we will abide with the Inspector General's findings. Consequently, we welcome the Inspector General's recommendations and we look forward to make the appropriate corrections. HRSA will have our full collaboration and commitment as to establish the procedures and/or controls within the federal laws and the regulations issued there under.

Once again, we look forward to work with HRSA and Ryder in solving this matter in the most efficient and convenient manner.

Sincerely yours,

Cristina Ochoa, CPA
Deputy Executive Director

[redacted]

This report was prepared under the direction of Timothy Horgan, Regional Inspector General. Other principal Office of Audit Services staff that contributed includes:

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