Fields of Opportunities

STATE OF IOWA

CHESTER J. CULVER, GOVERNOR
PATTY JUDGE, LT. GOVERNOR

DEPARTMENT OF HUMAN SERVICES
EUGENE I. GESSOW, DIRECTOR

The Medicaid Drug Product Selection Committee requested additional clarification on the following Iowa Medicaid prescription drug program.

DEPARTMENT RESPONSE:

1. Explain the process of "grandfathering" a drug in when it is removed from the PDL.
   Response: Grandfathering allows members currently on a drug to remain on the drug. The pharmacy claims processing system identifies members on a particular drug by looking back in the claims system 180 days to see which members have had paid claims for the specific drug and allows the members to continue to get the same drug without restrictions. This grandfathering process remains in place for the duration of the member's eligibility.

   The change in drug status to nonpreferred would only stop pharmacy claims from paying for "new users" or those members that have not had the drug previously paid by Medicaid.

2. Is there a flow chart that shows the interaction of the P &T and DUR?
   Response: The Pharmaceutical & Therapeutics (P&T) Committee and Drug Utilization Review (DUR) Commission may solicit feedback from each other as needed to perform their functions or may make their recommendations directly to the Department independent of any feedback from the other Committee. See Attachment 1 for additional information on the two committees.

3. What is the range of approval times for PA?
   Response: Medicaid programs that use prior authorization (PA) programs are required by Federal Law to turnaround PA requests within 24 hours. No PAs for Iowa Medicaid exceed the 24-hour timeframe. They are also required to provide for dispensing of at least a 72-hour supply in an emergency situation.

   When the Department quotes times for PA approval or denial, these times represent the average determination time. The average determination time is the average of the time to make a decision on all PA requests received within a specific time period. The determination time is calculated from the time the PA unit receives the PA request by fax until the prescriber is sent a response back by fax.

   The average determination time for SFY 2008 was as follows:

Determination Time	**%**
< 1 Hour	80.38%
1-2 Hours	8.86%
2-3 Hours	0.76%
3-4 Hours	0.41%
4-5 Hours	0.24%
5-10 Hours	0.22%
10-11 Hours	0.04%
11-15 Hours	2.67%*
15-16 Hours	5.29%*
16-24 Hours	1.13%*

*87% of these PA requests were received after hours.

4. What is the breakdown of costs/savings in the Medicaid prescription drug program?

Response: The chart below reflects the savings from the PDL and PA, net of administrative costs. Attachment 2 provides additional information on the methodology utilized to arrive at the savings.

State Fiscal Year	Total Savings from the PDL and PA	Contract Costs	Total Net Federal and State Savings to DHS (Total Savings – Contract Costs)	Total Net State Savings to DHS (Total Savings – Contract Costs)
SFY 06	$42.2 Million	$2.1 Million	$40.1 Million	$14.5 Million
SFY 07	$42.3 Million	$1.6 Million	$40.7 Million	$15.3 Million
SFY 08	$74.5 Million (Projected)	$1.5 Million	$73.0 Million (Projected)	$27.9 Million (Projected)
SFY 09	$81.2 Million (Projected)	$1.5 Million	$79.7 Million (Projected)	$29.9 Million (Projected)

5. How can transparency in the process be improved, better communication, more input from appropriate stakeholders?

Response: There are two issues with regard to transparency, contract and rebate transparency and PDL meeting process transparency.

1). *Contract and Rebate Transparency:* Pursuant to Section 1927 of the Social Security Act, terms of the rebate agreements must be held confidential except in limited circumstances. This includes the terms of the state supplemental rebate agreements. One hundred percent of all rebates come to the State, however the state must return the Federal government's share of the rebates.

2). *PDL Meeting Process Transparency*: The following is the current process of communication regarding the PDL to stakeholders, with the enhancements in italics. All P&T meetings are public meetings and only a small portion of the meeting is closed to discuss confidential pricing information as required by Federal law.

A. The PDL Agenda is posted to the website www.iowamedicaidpdl.com under P&T Committee and at the Hoover State Office Building bulletin board 30 days in advance of the meeting. *[The Department will develop a list serve anyone can be part of to receive notification by e-mail when the agenda is posted.]*

B. The same website above has an e-mail address info@iowamedicaidpdl.com where questions can be submitted. A response is provided within 24 hours. *[The Department can reiterate to those that sign up for the list serve that this option is available.]*

C. Public comment can be submitted in writing through the e-mail listed above and anyone can sign up on the website to provide oral public comment in person at the P&T meetings. Comment received by e-mail is also posted on the website. Written public comment is shared with P&T Committee members at each meeting. *[The Department can reiterate to those that sign up for the list serve that these options for public comments are available.]*

D. Informational Letters follow each P&T meeting to discuss all changes to the PDL implemented as a result of the meeting. These are posted to the website www.iowamedicaidpdl.com. All Medicaid providers also receive these by mail and the IME disseminates an electronic version to all provider organizations through the MAAC Committee list serve. Each Informational Letter has a contact e-mail and phone number at the end of the letter for any questions related to the letter.

E. The Department encourages all organizations to be active participants in all open meetings including the P&T and DUR.

6. What oversight is provided when changes in the PDL are made?--who monitors for things other than cost? Is there a way to measure cost shift to other parts of the system when the PDL changes?--DOC, DHS, etc.

   Response: The P&T Committee makes recommendations to the DHS in the maintenance of the PDL, by first considering the therapeutics and then cost. The Committee uses evidenced based literature to make these decisions. The P&T Committee members are all actively practicing and provide feedback on changes, both positive and negative, to the other Committee members from their own experience as well as their peers. Secondly, through written and oral public comment the Committee can assess the need to re-discuss specific issues that may have occurred as a result of a change on the PDL. Another monitoring mechanism of issues associated with the PDL change is the Pharmacy Call Center. Practitioners can call and relate questions and/or issues to the Call Center Representative who in turn tracks the issue and can escalate the issue if needed.

   In terms of measuring cost shift to other parts of the system when PDL changes re made, it is a difficult process to directly correlate a change in the PDL to other areas of care such as physician office visits, ER visits or hospitalization. The cause and effect analysis is difficult at this point due to the limited data available.

7. Is there a way to improve the notice for appeals process and the exception to policy process?

   Response: Most appeal and exception to policy requests for drugs are for non-preferred drugs or for drugs prescribed for conditions that are not FDA approved or supported by the medical literature. All denials of payment or prior authorization for drugs include notice of appeal rights, see Attachment 3. But no process will result in approval of drugs for conditions that are not FDA approved or supported by the medical literature. And the prior authorization process is more appropriate than an appeal or exception request for non-preferred drugs.

   Prior authorization for non-preferred drugs will be granted if:
   1. The requested drug meets federal rebate requirements for prescription drugs (or is a covered over-the-counter drug);
   2. Preferred drugs have been tried or are contraindicated; and
   3. There is a medical need for the non-preferred drug.

   As required by federal law, prior authorization requests are decided within 24 hours, while appeals can take 90 days and requests for requests for an exception can take 120 days.

   If prior authorization is denied for any reason, the Medicaid member is given notice of their right to appeal. But if a preferred drug has not been tried and is not contraindicated, or if there is not a medical need for the requested drug, an appeal or request for exception will not be successful. On the other hand, if prior authorization is denied only because a requested drug does not meet federal rebate requirements for prescription drugs (or is a non-covered over-the-counter drug), an exception to policy (with 100% state funding) may be appropriate. In such cases, the denial of the request for prior authorization includes notice of the exception to policy process.

   The quick and easy prior authorization process, which is well known to prescribers and pharmacies, should be the first resort for anyone denied a prescribed drug. As throughout the Medicaid program, members are given notice of their right to appeal with any adverse decision, including all denials of prior authorization for drugs. And the Department gives notice of the exception to policy process upon a denial of prior authorization when a request for an exception is appropriate. We believe that this adequately notifies members of the procedures available and that "improved" notice of the appeal and exception processes would simply divert members from the more appropriate, quicker, and simpler prior authorization process

8. Explain the change eliminated IPA from providing administrative support to the DUR?

   Response: IFMC, as the Medical Services Manager for the Iowa Medicaid Enterprise (IME), is responsible for staffing the DUR. IFMC indicated that in connection with its obligation to perform effectively under its contract with the IME it wanted to shift the subcontract from the Iowa Pharmacy Association (IPA) to Gould Health Services (GHS).

Since IFMC appeared to be exercising the professional judgment expected of it under its contract with the State, and since under that contract IFMC is responsible to the State for performance of DUR staffing responsibilities, and since it asked to substitute GHS, an acceptable subcontractor, IFMC's decision was approved.

9. Is there a way to increase pharmaceutical case management (PCM)? (Also referred to as Medication Therapy Management (MTM))

Response: The IME agrees with the benefits of MTM and PCM. Pharmaceutical Case Management (PCM) is an Iowa Medicaid service provided by physicians and pharmacists working together to closely manage the total medication regimens of their most complex patients. The services are provided to Medicaid members who are identified as being at high risk for medication-related problems. Eligible patients are those who take four or more regularly scheduled non-topical medications, are not nursing home residents, and who have at least one of twelve specified disease states. The innovative care delivered through this program is based on a model of care known to improve medication safety in hospital and clinic settings where pharmacists and physicians practice under the same roof and have access to patient care records.

The Iowa PCM program began in 2000 with funds appropriated by the Iowa legislature. The program, designed by an advisory committee of physicians and pharmacists, seeks to improve the quality of medication use in Medicaid eligible patients who are at high risk for experiencing adverse effects from their medications.

Pharmacists providing this service must have an Iowa license in good standing and have completed professional training regarding patient-oriented medication-related problem prevention and resolution. This training can be obtained by completion of a Doctorate of Pharmacy or completing a course from the Iowa Center for Pharmaceutical Care. The pharmacy or office where PCM services will be provided must have an area that allows private consultation.

Attachment 4 indicates the reimbursement trend from 2002-2008 for physicians and pharmacies. While reimbursement has remained relatively stable for physicians in this program, the amount of reimbursement, and thus program utilization, has gradually increased for pharmacies. The Department has been working on incorporating the beneficial aspects of this program with other IME initiatives including Chronic Disease Management and Complex Care Management.

The IME operates four care management programs including three Chronic Disease Management programs and Complex Care Management. The Chronic Disease Management programs include:

- Diabetes Mellitus, which was implemented 3.5 years ago and has served 433 Medicaid members.
- Congestive Heart Failure, which was implemented 2.5 years ago and has served 804 Medicaid members.
- Asthma, which was implemented 1.5 years ago and has served 284 Medicaid members.

Complex Care Management was implemented 3.5 years ago and has served 123 Medicaid members.

The IME has found these programs to be very effective at improving the quality of care and patient outcomes for Medicaid members.

10. Can IME provide response to 5 recs of IPA?

In response to the Legislative Interim Committee on Medicaid Drug Product Selection, IPA submits the following recommendations to Iowa Department of Human Services and the Legislative Interim Committee for its consideration:

A. Resist change to Iowa's Drug Product Selection Law.
Response: IME agrees and has recommended no change be made to this Legislation in the past.

B. Preclude the inclusion of brand name drugs on the PDL where there exists a generic equivalent for such drugs.

Response: The Department acknowledges this is a burden for pharmacies and the Department strives to reduce the number of brands on the list. As the brand goes to nonpreferred the Department allows a transition time where stores can use up the brand they have in stock, as well as an override process if they have additional product in stock beyond the transition time.

The cost benefits of generic use are not as black and white as commonly perceived and portrayed in the media, especially for Medicaid programs. State Medicaid programs participate in a federally negotiated rebate program with drug manufacturers. This means they receive a varying percentage of the cost of every drug back from the manufacturer. Due to such disproportionately large brand rebates, the net prices of certain brand drugs are significantly less than their generic counterparts.

The program has cost-avoided millions of dollars by selectively favoring these more cost-effective brands and shunning the more expensive generic. The lesson for state Medicaid programs is that they must follow their final net prices after all rebates and not the pre-rebate prices of drugs paid at the time of picking up the drugs at the pharmacy.

State Medicaid programs are allowed to set price caps on certain generic products. Each state can adopt their own approach and formula for setting these caps called SMACs (state maximum allowable cost). States vary in how aggressively they lower these generic prices. The lower these prices are set, the less likely it is that the brand version will cost less in comparison. Iowa does not currently have low enough generic price caps to undercut the net price of many brand drugs. The program could address this issue and minimize the preference of brand products if the process to set price caps was altered to remove the brand prices in setting the rates.

If the State had allowed the more costly generic versions to be dispensed instead, the Medicaid Program would have incurred an additional expense of just under $7.5 million, of which the State share would have been $2.87 million.

C. Explore ways of increasing transparency in the PDL process, both as it relates to administrative and financial activity.
Response: See response #5.

D. Separate contract vendors for the DUR and P&T processes.
Response: Many states have one committee and one vendor perform both DUR and PDL functions. The Department does not think this is a problem.

E. Expand MTM (Medication Therapy Management or Pharmaceutical Case Management) and implement chronic care disease management programs within the Medicaid program.
Response: See response #9

11. Is there a way to have a more holistic approach in selecting drugs for the PDL?
    Response: The P&T Committee makes recommendations to the DHS in the maintenance of the PDL, by first considering the therapeutics and then cost. The Committee uses evidenced based literature to make these decisions. This is the process undertaken by all P&T Committees.

12. Explain process available to reduce stock of former PDL drugs--transition time?
    Response: See response 10B.

13. The Department is providing additional information on drug purchasing pools and the Sovereign States Drug Consortium (SSDC), which Iowa is a member of.
    Response: In April 2003, the first multi-state supplemental drug rebate pool was formed. With a multi-state pool, states combine their covered lives and drug utilization to present a large market in securing rebates.

    The first pool was administered on behalf of its Member States by the pharmacy benefit administrator (PBA) that each state was using, First Health Services Corporation. In April 2004,

CMS approved this pool. In September 2004, CMS released a guidance letter on the formation of multi-state pooling arrangements. This letter is available at www.cms.hhs.gov/smdl/downloads/smd090904.pdf. Since that time CMS has approved a pool administered by the PBA for its Member States, Provider Synergies. In the fall of 2005, the states of Iowa, Maine, and Vermont concluded that they wished to form a state administered multi-state pooling arrangement, the Sovereign States Drug Consortium (SSDC). Unlike existing approved pools, the SSDC is state administered. The SSDC is not dependent on a single pharmacy benefit administrator but rather each member uses their internal and contractual resources to support their participation. Any state can potentially participate and the cost to participate is much lower than other pools.

The State of Vermont, Office of Vermont Health Access (OVHA) issued a Request for Proposal (RFP) on behalf of the Sovereign States Drug Consortium (SSDC) for services to solicit, negotiate, and procure Medicaid supplemental drug rebate bids on behalf of the states that are members of the SSDC. The SSDC chose Gould Health Services (GHS) for bid procurement services.

Attachment 1: Medical Assistance Pharmacy Committees

	Pharmaceutical & Therapeutics (P&T) Committee	**Drug Utilization Review (DUR) Commission**
Requirement for Establishing the Committee	State Statute: House File 619 (Iowa Code 249A.20a) authorized the establishment of the Iowa P&T Committee.	Federal Statute: OBRA 90 required States to implement retrospective DUR programs as well as an educational program.
Committee Appointment	The Governor appoints the members.	DHS appoints the members.
Committee Composition	Is comprised of 9 members: 1 dentist, 1 physician assistant, 3 pharmacists, and 4 physicians.	Is comprised of 9 members: 4 pharmacists, 4 physicians and 1 DHS representative.
Committee Function	Recommending Body to DHS on the PDL. The purpose of the P&T Committee is to advise and make recommendations to the DHS in the development and maintenance of the PDL, by first considering the therapeutics and then cost.	**Recommending Body to DHS on Drug Therapy including Prior Authorization (PA).** Each State is required to establish a Drug Use Review (DUR) board to ensure rational, cost-effective drug therapy for Medicaid members in Iowa.
Meeting Frequency and Forum	The P&T Committee meets on a quarterly basis. The final quarterly meeting is the Annual Review for all drug classes. Committee meetings are open to the public.	Commission meetings are held eight times a year. Committee meetings are open to the public.
Committee Interaction	- The P&T refers PA criteria development to the DUR. - May request feedback from DUR related to specific topics of discussion to aid in making their recommendation.	- The DUR defers selection of the most cost effective, clinically equivalent drugs in specific categories to be on the PDL to the P&T. - May request feedback from P&T related to specific topics of discussion to aid in making their recommendation.
Subcommittees and Workgroups	-Voluntary *Subcommittee* - Formed in September 2005 - Met six times through December 2005 - Provide input back to the P&T to assist in development of a 2005 Legislative report on options to increase savings on psychotropic drugs.	- Voluntary *Mental Health Work Group* - Formed in February 2005 - Meets ongoing - Provide input back to DUR on psychiatric issues to assist DUR with their recommendations to DHS on appropriate use in these areas.

Pharmaceutical & Therapeutics Committee Members

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Matthew Osterhaus, R.Ph., Vice Chairperson
Bruce Alexander, R.Ph.
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Attachment 2: Iowa Medicaid PDL Savings Methodology

The Iowa Medicaid Preferred Drug List (PDL) was implemented January 15, 2005. From this date forward, it became necessary for Iowa providers to request prior authorization for non-preferred drugs.

There are three major sources of savings within the PDL:

- federal (CMS) rebates
- supplemental rebates
- pre-rebate script costs

Federal CMS rebate shall mean, with respect to the Covered Product, the quarterly payment by Manufacturer pursuant to (name of Manufacturer's)
Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)
(1) or Section 1927(c)(3) of the Social Security Act (42 U.S. 1396r-8(c)(1) and 42 U.S.C.1396r-8(3)).

State Supplemental rebate payment is when a manufacturer agrees to provide a State Supplemental Rebate for each of its Covered Products. This is paid quarterly for Covered Products that are included in the Preferred Drug List. The manufacturer shall pay to the State the State Supplemental Rebate amount in accordance with the formula set forth below for calculation of state supplemental rebate payment. Nothing in this agreement shall be construed to relieve the Manufacturer of its obligation to make payments according to its Medicaid Drug Rebate Agreement for utilization by State Medicaid Recipients. The State shall remit the appropriate share of the State Supplemental Rebate payments made under this agreement to CMS as required under it approved state plan.

Calculation of State Supplemental Rebate Payment
The state supplemental Rebate per unit for each covered product shall be calculated each quarter as follows:

Ingredient Reimbursement
- Final CMS rebate per unit of cover product
- Net Cost
= State Supplemental Rebate per unit of covered product.

The quarterly State Supplemental Rebate payment required shall be calculated by multiplying the units of the covered product paid for by the State and dispensed to Iowa Medicaid recipients by pharmacies in the quarter by the State Supplement Rebate per unit of covered product for that quarter.

Concurrent with the clinical review, the Iowa Medicaid Enterprise pharmacy services contractor negotiates rebate offers from pharmaceutical manufacturers. A combined PDL and rebate program will save significantly more money than a program without a rebate component. Given that a group of medications is clinically equivalent, rebates can greatly reduce the cost of therapy within a therapeutic class. Although savings can be realized from movement to lower AWP products within a therapeutic class, the majority of savings associated with the PDL program are achieved through a rebate program.

Pre-rebate script costs are defined as the aggregate payments made by the state to outpatient pharmacies. It represents the sum of all individual prescription reimbursements as determined by various applicable payment formulas. The state of Iowa always pays the lower of AWP -12% or submitted usual and customary charge for brand drugs, and the lowest of AWP-12%, federal upper limit (FUL), state MAC, or submitted usual and customary charge for generics. Pre-rebate script costs can be further reduced by the on-line collections of other insurance payments and member co-pay obligations. PDL savings are then calculated by comparing the historical trend in pre-rebate costs prior to the PDL to those same costs after

the PDL. The total PDL savings are due to the combined effects of pre and post-rebate savings. The pre-rebate savings are primarily due to the combined influences of increased voluntary utilization of lower pre-rebate cost preferred drugs and prior authorization induced reductions in medically unnecessary prescribing.

Post-rebate savings are due to supplemental rebates and PDL-driven increases in CMS rebates.

Attachment 3: Notice of Decision and Right to Appeal

You Have the Right to Appeal

What is an appeal? An **appeal** is asking for a hearing because you do not like a decision the Department of Human Services (DHS) makes. You have the right to file an appeal if you disagree with a decision. You do not have to pay to file an appeal. [441 Iowa Administrative Code Chapter 7].

How do I appeal? Filing an appeal is easy. You must appeal in writing. To appeal in writing, do one of the following:

· Complete an appeal electronically at http://www.dhs.state.ia.us/forms/appealrequest.htm, or
· Write a letter telling us why you think a decision is wrong, or
· Fill out an Appeal and Request for Hearing form. You can get this form at your county DHS office

Send or take your appeal to the Department of Human Services, Appeals Section, 5th Floor, 1305 E Walnut Street, Des Moines, Iowa 50319-0114. If you need help filing an appeal, ask your county DHS office.

How long do I have to appeal? You must file an appeal:

· Within 30 calendar days of the date of a decision or
· Before the date a decision goes into effect

If you file an appeal more than 30 but less than 90 calendar days from the date of a decision, you must tell us why your appeal is late. If you have a good reason for filing your appeal late, we will decide if you can get a hearing. If you file an appeal 90 days after the date of a decision, we cannot give you a hearing.

Can I continue to get benefits when my appeal is pending? You may keep your benefits until an appeal is final or through the end of your certification period if you file an appeal:

· Within 10 calendar days of the date of a decision or
· Before the date a decision goes into effect

Any benefits you get while your appeal is being decided may have to be paid back if the Department's action is correct.

How will I know if I get a hearing? You will get a hearing notice that tells you the date and time a telephone hearing is scheduled. You will get a letter telling you if you do not get a hearing. This letter will tell you why you did not get a hearing. It will also explain what you can do if you disagree with the decision to not give you a hearing.

Can I have someone else help me in the hearing? You or someone else, such as a friend or relative can tell why you disagree with the Department's decision. You may also have a lawyer help you, but the Department will not pay for one. Your county DHS office can give you information about legal services. The cost of legal services will be based on your income. You may also call Iowa Legal Aid at 1 800 532 1275. If you live in Polk County, call 243 1193.

Statement of Nondiscrimination

By law, DHS will not discriminate against you on the basis of: age, color, creed, disability, national origin, political beliefs, race, religion, or sex. If you feel we have discriminated, you can ask for a Discrimination Complaint form from any DHS office or the DHS Diversity Program Unit.
To file a complaint of discrimination, you may also write to any of the addresses below. If you need help, you may call your county DHS office.

Iowa Department of Human Services
Diversity Program Unit 1st Fl

1305 E Walnut
Des Moines IA 50319-0114

Iowa Civil Rights Commission
400 E 14th St
Des Moines IA 50319-1004

U.S. Department of Health & Human Services
Office for Civil Rights Region VI
601 E 12 St Rm 248
Kansas City MO 64106-2808

Attachment 4: Pharmaceutical Case Management Reimbursement

		State Fiscal Years							
		2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**Total**
Physician									
W3100	Initial	$2,355.49	$945.75	$1,442.75	$1,284.00	$4,756.28	$3,739.67	$375.00	$14,898.94
W3200	Preventative	$73.50	$0.00	$24.25	$24.25	$74.94	$724.70	$0.00	$921.64
W3300	New Problem	$196.40	$0.00	$426.80	$232.80	$552.48	$3,360.08	$480.00	$5,248.56
W3400	Follow-up	$742.00	$659.60	$2,444.40	$2,161.16	$3,747.48	$7,959.08	$2,097.96	$19,811.68
		$3,367.39	$1,605.35	$4,338.20	$3,702.21	$9,131.18	$15,783.53	$2,952.96	$40,880.82
Pharmacist									
W4100	Initial	$28,537.50	$20,022.50	$13,990.00	$18,675.00	$24,777.34	$28,899.23	$16,616.03	$151,517.60
W4200	Preventative	$1,850.00	$1,825.00	$1,825.00	$1,875.00	$4,709.40	$3,397.78	$4,849.04	$20,331.22
W4300	New Problem	$6,276.00	$10,160.00	$10,800.00	$13,880.00	$16,586.20	$28,664.77	$20,795.16	$107,162.13
W4400	Follow-up	$15,440.00	$24,080.00	$29,068.15	$43,480.00	$42,723.60	$66,470.96	$52,630.12	$273,892.83
		$52,103.50	$56,087.50	$55,683.15	$77,910.00	$88,796.54	$127,432.74	$94,890.35	$552,903.78
Grand Total		$55,470.89	$57,692.85	$60,021.35	$81,612.21	$97,927.72	$143,216.27	$97,843.31	$593,784.60