COST OF DISPENSING PRESCRIPTION DRUGS BY 340B ENTITIES TO MEDICAID RECIPIENTS — PHARMACY SURVEY REPORT FOR DISTRIBUTION
STATE OF COLORADO
NOVEMBER 14, 2013

Government Human Services Consulting
CONTENTS

• Executive Summary .................................................................................................. 2
  • Summary of Preliminary Findings ........................................................................ 3
  • Limitations ........................................................................................................... 4

• Background Information .......................................................................................... 6
  • Introduction .......................................................................................................... 6
  • Colorado Pharmacy Program Overview .................................................................. 7
  • 340B Entity Requirements and Types of Entities ................................................. 7
    1. Regulatory Compliance and Inventory Control Requirements ....................... 7
    2. Patient Relationship ......................................................................................... 8
    3. Auditing and Dispensing Requirements ........................................................... 8
    4. Federally Qualified Health Centers ................................................................... 8
    5. FQHC Patient Populations ............................................................................... 9
    6. Differences in FQHC Pharmacy Operations .................................................... 9
    7. Role of the Pharmacist in the FQHC ................................................................. 10
    8. Hospital-Affiliated 340B Pharmacies ............................................................... 10
    9. Unique Aspects of Hospital-Affiliated Outpatient Pharmacies ......................... 10

• 340B Cost of Dispensing Survey ............................................................................. 12
  • Survey Instrument Development .......................................................................... 12
  • Methodology ......................................................................................................... 12
  • Survey Population ................................................................................................ 13
  • Survey Distribution and Follow-Up ....................................................................... 13
  • Survey Response Rate and Non-Response Bias .................................................... 13
  • Costs and Expenses Elements ............................................................................. 14
  • Inflation Adjustments ............................................................................................ 16
  • Analysis and Findings ........................................................................................... 17
  • Regression Analysis of Pharmacy Characteristics ................................................. 17
  • Qualitative Information Gathered ........................................................................ 20
  • Summary ............................................................................................................... 20

• Conclusions ............................................................................................................. 22
Executive Summary

The State of Colorado (State) engaged Mercer Government Human Services Consulting (Mercer) to conduct a survey to provide the Colorado Department of Health Care Policy and Financing (Department) with cost analysis information to study the cost of dispensing prescription medications to Medicaid recipients within the State by entities that participate in the 340B program (as defined below). This report is provided as a decision support tool to enhance the Department’s understanding and evaluation of dispensing in the 340B environment for future provider reimbursement updates.

The objective of the survey was to aid the State in understanding the uniqueness of the pharmacies participating in the 340B program and to understand how their dispensing costs may differ from non-340B Medicaid pharmacy providers in Colorado. The 340B pricing program requires drug manufacturers to provide outpatient drugs to eligible entities that provide pharmacy services under 42 CFR 256, as amended, commonly known as “340B pharmacies” at significantly reduced prices. To participate in the 340B program, eligible organizations must register and be enrolled with the 340B program and comply with all 340B program requirements.

This report examines the unique operational models and costs related to dispensing a prescription through 340B-covered entities, including regulatory compliance requirements unique to program participation. These requirements include maintenance of patient records, audit programs, and other regulatory provisions relating to specific inventory controls unique to participating in the 340B program. In addition, this report also discusses reimbursement for encounterable services by Medicaid and appropriate cost reporting under federal law. This report distinguishes variables relevant to the cost of dispensing in both the federally qualified health centers (FQHCs) and hospital affiliated outpatient pharmacies.

The State requested that entities responding to the survey include financial information based on the most recent audited fiscal year completed by the 340B pharmacy providers, with the majority period of service reported for calendar year 2012. In addition, the survey requested information, such as the amount of prescriptions filled and the breakdown by payer, square footage of the pharmacy department and entity as a whole, and questions targeted at deriving information to better understand the uniqueness of each entity in terms of the populations it serves and additional costs it may incur related to participating in the 340B program.
The survey information was analyzed by statisticians, applying indexes, trends, and allocations where appropriate, ultimately resulting in the estimated costs of dispensing (CODs) included in this report. However, because survey questions did not ask for the level of detail in order to exclude costs that are otherwise not allowable under the Office of Management and Budget (OMB) Circulars A-21, A-87, and A122, the results were substantially higher than anticipated. Additionally, the validation of cost observations against the entities’ separately submitted cost reports was not under the scope of this report, nor was the determination of the reporting entities’ adherence to mandatory federal cost reporting and cost allocation requirements, including salaries and services otherwise provided under all-inclusive encounter rates.

**Based on these survey limitations, Mercer does not recommend that the Department implement a change to the COD fees for 340B entities based on the results of this report but, rather, use the information to develop a cost reporting methodology that provides the necessary level of detail to allow for costs to be appropriately allocated among the FQHCs, hospitals, and pharmacy services.**

**Summary of Preliminary Findings**

Based on the unaudited results supplied by pharmacies across the State that participated in the survey, and taking into consideration the limitations of the survey instrument as discussed, Mercer calculated an average cost of dispensing a prescription for the 340B pharmacy respondents at $39.50. However, the results were highly variable, with 95% confidence interval (CI)\(^1\) of the mean of ($27.57, $51.44). In light of the small sample size, a decision was made not to winsorize\(^2\) this average. Another reason for the decision not to winsorize was the COD values that appeared to be outliers, or which were less plausible, were concentrated on the high end of the spectrum.

Two respondents were hospital-based pharmacies associated with the University of Colorado Hospital (UCH), and eight respondents were affiliated with Denver Health and Hospital Authority (DH). These ten entities were analyzed as a hospital group and compared to the remaining respondents (FQHC group). In addition, a comparison was made between UCH and DH facilities.

For entities belonging to UCH or DH, the average COD was $47.20 ($28.91, $65.50). For the FQHC entities, the average COD was $28.51 ($14.90, $42.12). The average COD for hospital-based pharmacies was almost two-thirds greater than for all others. UCH was the primary driver of the high COD with an average COD of $95.17 (the two

---

\(^1\) The confidence interval of 95% means that if the survey were to be conducted 100 times, the results would be the same 95 out of 100 times.

\(^2\) A winsorization approach can be used to minimize the impact of outliers by setting the cost of dispensing that is below the 5th percentile to 5th percentile and those that were higher than 95th percentile to 95th percentile. This approach was used in previous COD reports.
UCH entities had CODs of $87.09 and $103.25, respectively); the average COD for the DH entities was $35.21 ($34.59, $35.83).

The study found that input from select entities accounted for a significant variation in the observed prescription dispensing costs for 340B providers. Some of this variation was the result of accounting practices that were unique to certain entities or systems. Administrative and facility costs for both the FQHC group and the hospital group remain higher than expected when compared to costs reported by retail pharmacies. These costs were reported in aggregate for each facility (entire entity, not only pharmacy costs) and with the available data, and may not be appropriately allocated to the pharmacies following federal cost allocation requirements, artificially driving up the COD results. Please see the following section for additional information.

Limitations
Recent experience with COD surveys in Colorado has provided relatively low response rates but on a much larger population size. Based on stakeholder feedback from prior COD surveys, as well as discussion with the Department, the survey questions for the 340B COD survey were written to be more user-friendly for the respondent, yet still provide usable information with which to calculate the cost of dispensing. Although the resulting response rate for the survey was satisfactory, the responses may not appropriately capture the pharmacy-specific costs due to the complex nature of FQHC and hospital operations. Specifically, each response provided administrative and facility costs that were reported for their entire entity, not specific to pharmacy costs. Many entities are not able to report these costs specific to the pharmacy department. UCH and DH, the larger hospital entities, reported costs that resulted in dramatically higher COD figures than other respondents, likely due to the issue noted above. Although attempts were made to properly allocate these costs, it is believed that these figures may be artificially elevating the COD results.

Additionally, there were three distinct factors that resulted in a number of highly significant limitations to this study that must be taken into account when considering the results of the cost of dispensing analysis:

- First, the population sample was not random, nor large enough to limit the effect of outliers or other statistical anomalies.
- Second, the survey questions and COD calculations are designed to assess pharmacy-related costs, and as such, may not sufficiently address the complexity of many of the clinics that responded, as pharmacy operations are only a portion of the entities’ services.
- Last, the cost reporting required by the Department does not require consistent application of cost allocations and/or reporting of expenses across all pharmacies, resulting in large variances across respondents when comparing reported costs.
Given these significant limitations, Mercer recommends that the results of this survey be taken as a preliminary investigation into 340B dispensing costs in the State of Colorado, as discussed further in the Conclusions Section of this report.

All results in Mercer’s analysis were based on a sample that was limited in the following distinct aspects:

- The sample relied on a voluntary survey rather than a sample chosen through a randomization procedure. As such, a simple random sample of eligible pharmacy entities was not obtained.
- All 340B respondents were 340B entities with in-house pharmacies. Two also had contracts with external pharmacies for 340B services. No respondents were external pharmacies contracted with a 340B entity.
- Although the sample population represents a reasonable response rate among 340B-covered entities (63% of Colorado 340B-covered entity pharmacies), the sample size is still small, providing limited statistical significance and little protection against outliers and other statistical variations.

For the analysis, Mercer relied on survey data and information, as well as other sources of data as described in this report. Mercer relied on these data without independent audit. Although Mercer has reviewed the data for reasonableness and consistency, the data has not been audited or otherwise verified. It should also be noted that Mercer’s review of data may not always reveal data reporting issues. The results of the analysis are dependent on this assumption that data provided by respondents is both accurate and complete.
Background Information

Introduction
The Centers for Medicare and Medicaid Services (CMS) federal regulations pertaining to state Medicaid pharmacy dispensing fees require states to develop a reasonable dispensing fee reimbursement for pharmacy providers. The State and the Department, in conjunction with Colorado pharmacy stakeholders, desire to better understand the cost structure of dispensing prescription medications to Colorado Medicaid recipients via entities participating in the 340B program or contracted with 340B pharmacy providers. As a result, the State engaged Mercer to conduct a study regarding the average cost for 340B providers to dispense prescription medications to State Medicaid recipients.

In order to help these nonprofit or public health care organizations that serve predominantly uninsured or medically underserved populations, the “340B Program” was established by the Veterans Heath Care Act of 1992 that put Section 340B of the Public Health Service Act into place. In short, this allows approved entities to acquire prescription drugs at a reduced price. Although the 340B price is defined in statute as a ceiling price, 340B-covered entities can negotiate below ceiling prices with manufacturers. For the purpose of this analysis, contract pharmacy and prime vendor arrangements are not discussed, as all respondents had in-house pharmacy services.

340B-covered entities receive funding under Section 330 of the Public Health Service Act and often seek additional state, federal, and private grant opportunities to accomplish their missions. 340B-eligible facilities include family planning projects, Ryan White Care Act, or early HIV intervention services, Aids Drug Assistance Programs (ADAP), black lung clinics, comprehensive hemophilia diagnostic treatment centers, Native Hawaiian health centers, certified tuberculosis clinics, disproportionate share hospitals, certified sexually transmitted disease clinics, FQHCs and FQHC look-alikes, migrant health centers, Health Care for the Homeless programs, school-based programs, health centers for residents of public housing, and Tribal or Urban Indian Organizations.
Colorado Pharmacy Program Overview
The Colorado Medicaid program provides coverage for most prescription drugs. Under the Department’s fee-for-service pharmacy program, current reimbursement for pharmacy ingredients cost is determined by the lesser of:

- The usual and customary charge to the public minus the client’s copayment.
- The allowed ingredient cost minus the client’s copayment.

The allowed ingredient cost is the lesser of actual acquisition cost (AAC) or submitted ingredient cost. If no AAC price is available, then reimbursement will be determined by the lesser of:

- Wholesale acquisition cost.
- Submitted ingredient cost.

For drugs purchased through the 340B drug pricing program, the submitted ingredient cost is equal to the 340B purchase price.

The pharmacy program pays a professional dispensing fee, in addition to the ingredient cost determined above, for drugs dispensed to Medicaid recipients. The current pharmacy dispensing fee for the State for retail pharmacies, 340B pharmacies, institutional pharmacies, and mail order pharmacies is tiered based upon annual total prescription volume. The current dispensing fees are tiered as follows:

- Less than 60,000 total prescriptions filled per year = $13.40.
- Between 60,000 and 90,000 total prescriptions filled per year = $11.49.
- Between 90,000 and 110,000 total prescriptions filled per year = $10.25.
- Greater than 110,000 total prescriptions filled per year = $9.31.

340B Entity Requirements and Types of Entities

**Regulatory Compliance and Inventory Control Requirements**
Although significant attention has been paid to 340B pharmacies in recent years, both in terms of potential revenue opportunities for covered entities and savings opportunities for Medicaid agencies, an overview of the different 340B entity types and regulatory compliance requirements will help to understand the reason why the Department chose to specifically examine these entities. For the purpose of this study, covered entities are evaluated and distinguished as FQHCs and hospital-affiliated outpatient pharmacies.
Prior to discussing the unique features of each dispensing environment, the overarching administrative and operational requirements mandated by the Health Resources and Services Administration (HRSA) for participation in the 340B program are discussed below.

**Patient Relationship**
The 340B-covered entity must have an established relationship with the individual and maintain records of the individual’s health care. The individual must receive their health care by someone employed by the covered entity or one doing so under contract or other arrangement, so the responsibility for the care provided remains with the covered entity.

Although there are limited exceptions for state-operated or funded ADAPs, an individual will not be considered a “patient” of the entity for the purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

**Auditing and Dispensing Requirements**
Covered entities must maintain accurate records documenting that no double dipping or diversions by reselling/transferring of drugs to ineligible patients is occurring and ensure the stock and claims used for 340B-eligible patients are correctly adjudicated. These inventory and billing procedures can be either physical, in which a pharmacy maintains two separate medication inventories, or virtual, in which a software program registers and records 340B transactions.

**Federally Qualified Health Centers**
FQHCs maintain a specific clinic designation type from the Bureau of Primary Health Care, a division of the HRSA and CMS. These clinics provide services to all persons, regardless of their ability to pay, and charge on a sliding scale basis, making them crucial components of the health care delivery system for low-income populations.

Unlike other models of health care delivery, FQHCs’ focus is not only on improving the health of individual patients but on improving the health status of the entire community. This community-oriented focus means that these health centers differ from most traditional health care providers in a number of ways. Needs assessment, program development, evaluation, and even the definition of “community”, are all framed in terms of both community health needs and patient health.³

---

**FQHC Patient Populations**

FQHCs often serve persons with one or more chronic physical conditions, including asthma, hypertension, chronic obstructive pulmonary disease, dyslipidemia, and diabetes, as well as a wide range of mental health conditions. Safety-net providers that participate in HRSA programs serve populations in which these conditions have a higher prevalence compared with other populations of similar age and gender, making medication safety and effectiveness at least as salient for them as for other providers.4

Furthermore, many of these conditions frequently occur in comorbid patterns in which patients have multiple concurrent diagnoses. Treatment of these comorbid patients often requires more in-depth therapy management services, as appropriate medication therapies are crucial in the treatment of these disease states. Nearly two-thirds of American health care dollars are spent on the 25% of the population suffering from comorbid chronic medical conditions. Therefore, the appropriate, efficient management of these patients and their medication regimens is paramount to promoting community health.5

The populations served by FQHCs and similar clinics tend to be both sicker, and by definition, poorer than the populations served by many other facilities. As such, these individuals face greater challenges in achieving improved health outcomes than the general population. These can include a host of socio-economic factors, including access to transportation, literacy, housing, childcare, and other factors that can impact patients’ ability to adhere to care plans and prescription regimens. For patients, the (340B) program provides convenient access to affordable prescription medications, as well as comprehensive pharmacy services that include counseling, monitoring, referral, and collaboration with a care team.6

**Differences in FQHC Pharmacy Operations**

There are a number of unique features of an FQHC that require a clinical and operational model significantly different from the traditional retail or community pharmacy. Among these unique features are requirements to provide culturally and linguistically appropriate health services, providing hours of operation that encourage access

---


to care, an appropriate mix of services available to the target populations it serves, and a patient mix with greater health care needs.

**Role of the Pharmacist in the FQHC**

The FQHC care and staffing model relies heavily on the provision of clinical pharmacy services to help improve health outcomes for the clinics’ patients. The American College of Clinical Pharmacy has defined clinical pharmacists (PharmDs or registered pharmacists with additional training) as “experts in the therapeutic use of medications…and a primary source of scientifically valid information and advice regarding the safe, appropriate, and cost-effective use of medications.”

As previously discussed, patient populations served at these pharmacies may differ from those of the traditional community or retail pharmacy. FQHC pharmacies frequently work with patients with not only chronic, complex, and comorbid medical conditions, but also with severe and persistent mental health diagnoses, and substance and alcohol abuse histories. For many FQHC patients, pharmacotherapy is the foundation of their treatment programs, so appropriate therapy management and a somewhat more involved role of a clinical pharmacist is crucial.

**Hospital-Affiliated 340B Pharmacies**

The definition of “covered entities” includes six categories of hospitals: disproportionate share hospitals (DSHs), children’s hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals (CAHs). Hospitals in each of the categories must be (1) non-profit, (2) owned or operated by or under contract with state or local governments, and (3) with the exception of CAHs, meet payer-mix criteria related to the Medicare DSH program.

**Unique Aspects of Hospital-Affiliated Outpatient Pharmacies**

Outpatient hospital pharmacy services differ from the retail or community-based pharmacy in several ways. Outpatient hospital pharmacies are more likely to dispense medications to patients with new medicines and acute illness, including oncology drugs to cancer patients, patients on drugs with narrow therapeutic indexes and chronic disease states, elderly and psychiatric patients, and caregivers for pediatric patients. In addition, it is often the responsibility of the outpatient hospital pharmacist to assist clinicians, where necessary, with therapeutic and logistical prescribing decisions and the review of all medicine orders.

---

In many cases, an outpatient hospital pharmacy may serve as the dispenser of new medication regimens to recently discharged patients, or those patients who have just seen one or more prescribing clinicians that may have made significant changes to the patient’s medication therapy regimen. In such cases, the outpatient hospital pharmacy often serves as the final point of contact between the patient and the health system, so it is vitally important that a patient understands their therapies and the expectations associated with them.
340B Cost of Dispensing Survey

Survey Instrument Development
The 2013 Colorado Medicaid 340B COD survey focused on collecting the actual costs incurred by pharmacies within the State that provide prescription drugs to Medicaid recipients under the 340B program. The State-approved survey was sent to both 340B entities and pharmacies contracted with 340B entities. The study population encompassed various types of entities including, but not limited to, community health centers, CAHs, DSHs, and FQHCs. The State survey tool was designed following review of dispensing fee surveys, conducted both at the national and individual state levels, and based on the unique circumstances of the 340B entities as identified by the Department and suggestions provided from Colorado pharmacy stakeholders.

The design, creation, and performance of the survey entailed the following:

• Development of the survey tool, including instructions for completion.
• Creation of an online web-based survey.
• Establishment of an email support mailbox and a provider help line.

Methodology
The study methodology included the following tasks:

• Held a project kick-off meeting with the Department and the Colorado pharmacy stakeholders to review the survey objectives, tools, and timelines to complete the survey and prepare a final report.
• Developed and tailored survey tool based on the project objectives, information from the kick-off meeting, monthly project update meetings, and stakeholder feedback.
• Requested a list of 340B entities enrolled as Medicaid providers with the State, including but not limited to, FQHCs and pharmacies contracted with 340B entities. The request included pharmacy contact, mailing, email address information, and Colorado provider identification numbers. The resulting list identified the universe of pharmacies (study population) in the State to be surveyed.
Developed and distributed, via email, a notification containing a link to an online survey tool, instructions, and cover information to the study population. The purpose of the cover information was to highlight the importance of the survey and the submission of the requested information for the 340B dispensing fee analysis.

- Responded to technical concerns by survey recipients and resolved issues.
- Received completed surveys from pharmacies and sent follow-up reminder emails to pharmacies that had not submitted the survey by the due date.
- Screened survey responses for reasonableness and completeness of the data.
- Imported and/or entered data into a central database and performed initial cost analysis of the data.
- Conducted a statistical analysis of the cost data to determine an average cost and percentile distribution of cost of dispensing a prescription to Medicaid recipients within the State via 340B entities.
- Prepared the draft report and submitted it to the Department.

The draft report was reviewed with the Department and, subsequently, finalized with changes as agreed upon by the Department and Mercer.

**Survey Population**
A list of pharmacies participating in the 340B program and enrolled as a Colorado Medicaid provider was obtained from the Department and served as the data source to identify the study population.

The COD study population included 27 pharmacies classified as 340B entities and 76 pharmacies contracted with a 340B entity, primarily retail entities.

**Survey Distribution and Follow-Up**
An email notification announcing the survey was sent to all pharmacies included in the study population on April 4, 2013. Providers were requested to access the survey via the provided link and to submit a survey for each provider identification number on file with the Department. An additional email was sent on April 25, 2013, reminding the study population to submit a survey if they had not already done so.

**Survey Response Rate and Non-Response Bias**
Of the 27 surveys sent to 340B entities, 18 responded, with 17 providing a usable response, representing a 63% response rate. None of the 76 entities contracted with 340B providers responded to the survey. Usable responses were defined as responses that provided data on all the following survey items or data that allowed these items to be calculated:

- Prescription area square footage.
• Total square footage.
• Total number of prescriptions.
• Total prescription sales.
• Total sales.
• Pharmacy department payroll and related costs.
• Total pharmacy department costs.
• Total facility costs.
• Total other store/location costs.

**Costs and Expenses Elements**
The expenses included in the COD calculation are classified as:

• Payroll and related expenses.
• Pharmacy department expenses.
• Facility expenses.
• Other expenses.

The expenses related to filling a prescription need to be identified and allocated to the pharmacy department relative to the rest of the pharmacy areas. The allocation can be made based on area ratio, sales ratio, or at 100% for direct pharmacy department expenses. Area ratio is calculated by dividing the pharmacy department square footage by total square footage. Sales ratio is calculated by dividing prescription sales, including prescription over-the-counter sales, by total sales for the reporting period.

Expenses included in the COD calculation for payroll, payroll-related expenses, and all other expenses specific to the pharmacy department, are allocated at 100% to the pharmacy department.

All other pharmacy department expenses, allocated at 100%, include:

• Prescription containers, label, and other pharmacy supplies.
• Professional liability insurance for pharmacists.
• Pharmacy department licenses, permits, and fees.
• Dues, subscriptions, and continuing education for the pharmacy department.

---

8 Mercer did not collect data related to marketing, advertising, or promotional expenses based on Mercer’s interpretation of the CMS definition of dispensing fee cost and consistent with Medicare cost reporting principles (CMS Pub.15-1).
• Delivery expenses (only prescription-related).
• Bad debts and uncollected copays.
• Computer systems (related only to the pharmacy department).
• Transaction fees.
• Other allowable pharmacy department-specific costs not identified elsewhere.

Facility expenses allocated, based on area ratio, include:

• Rent.
• Building mortgage.
• Utilities (gas, electric, water, and sewer).
• Real estate taxes.
• Facility structure and liability insurance.
• Maintenance and cleaning.
• Depreciation.
• Other allowable facility-specific costs not identified elsewhere.

Other expenses allocated, based on sales ratio, include:

• Professional services (for example, accounting, legal, and consulting).
• Telephone and data communication.
• Computer system and support.
• Other depreciation and amortization on equipment.
• Office supplies.
• Other insurance.
• Franchise fees.
• Interest.
• Other allowable costs not included elsewhere.

Total pharmacy operational expenses, including overhead and labor costs, are obtained by summing salary expenses, prescription and pharmacy department expenses, facility expenses, and other store expenses allocated to the pharmacy department. The cost of dispensing a prescription is obtained by dividing the total pharmacy operational expenses by the total number of prescriptions reported in the time period.
After dividing total pharmacy, total facility, and total other costs by the total number of prescriptions dispensed, total pharmacy costs represented the largest share of costs, followed by payroll, administrative, and facility costs, as seen in Figure 1.

**Figure 1. Distribution of Costs (divided by number of total dispensed prescriptions)**

![Distribution of Costs](image)

**Inflation Adjustments**

The Consumer Price Index (CPI) published by the Bureau of Labor Statistics was used to standardize total pharmacy operational expenses, including overhead and labor costs, to the same time period ending on December 31, 2012. Fiscal year end dates reported by pharmacies ranged from May 2012 to April 2013.

Table 1 shows the fiscal year-end date, mid-point CPI index, terminal month CPI index, inflation factor, and number of pharmacies with the corresponding year-end date included in the analysis.

**Table 1. Inflation Factors Used to Standardize Costs to December 2012**

<table>
<thead>
<tr>
<th>Fiscal Year-End Date</th>
<th>Mid-Point CPI</th>
<th>Terminal Month CPI (December 2012)</th>
<th>Inflation Factor</th>
<th>Number of Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/31/2012 (November 2011)</td>
<td>226.230</td>
<td>229.601</td>
<td>1.015</td>
<td>1</td>
</tr>
<tr>
<td>06/30/2012 (December 2011)</td>
<td>225.672</td>
<td>229.601</td>
<td>1.017</td>
<td>2</td>
</tr>
<tr>
<td>12/31/2012 (June 2012)</td>
<td>229.478</td>
<td>229.601</td>
<td>1.001</td>
<td>12</td>
</tr>
<tr>
<td>01/31/2013 (July 2012)</td>
<td>229.104</td>
<td>229.601</td>
<td>1.002</td>
<td>1</td>
</tr>
</tbody>
</table>
Analysis and Findings
Descriptive statistics and measures of central tendency, namely means and medians, are used to determine an average COD a prescription in the State. Refer to Tables 2–3 for summary statistics relating to COD data.

**Table 2. Means, Medians, and Percentile Distribution of COD**

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean</th>
<th>Median</th>
<th>25th Percentile</th>
<th>75th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>All 340B</td>
<td>$39.50</td>
<td>$34.88</td>
<td>$28.29</td>
<td>$36.02</td>
</tr>
<tr>
<td>UCH/DH</td>
<td>$47.20</td>
<td>$35.24</td>
<td>$34.75</td>
<td>$36.79</td>
</tr>
<tr>
<td>Non UCH/DH</td>
<td>$28.51</td>
<td>$24.36</td>
<td>$16.43</td>
<td>$36.02</td>
</tr>
<tr>
<td>UCH only</td>
<td>$95.17</td>
<td>$95.17</td>
<td>$87.09</td>
<td>$103.25</td>
</tr>
<tr>
<td>DH only</td>
<td>$35.21</td>
<td>$35.06</td>
<td>$34.67</td>
<td>$35.45</td>
</tr>
</tbody>
</table>

**Table 3. Low, Median, and High COD by Facility Type**

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Low COD</th>
<th>Mean COD</th>
<th>High COD</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>$13.44</td>
<td>$39.50</td>
<td>$103.25</td>
</tr>
<tr>
<td>FQHC</td>
<td>$13.44</td>
<td>$28.51</td>
<td>$57.31</td>
</tr>
<tr>
<td>Hospital</td>
<td>$34.54</td>
<td>$47.20</td>
<td>$103.25</td>
</tr>
</tbody>
</table>

**Regression Analysis of Pharmacy Characteristics**
Sixteen univariate regressions were performed to identify variables that had a relationship to COD. Six variables appeared to have a statistically significant relationship. Those with statistical significance at the level of α=0.05 were entered as predictors in a multivariable regression to see how they performed together. Together, none of the predictors reached statistical significance. A stepwise multivariable regression was run using only the variables that were significant predictors in univariate analyses; variables with statistical significance at p < 0.05 were entered and those with p < 0.10 were retained (Table 4).

**Table 4. Probabilities from Regressions**
<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariate p</th>
<th>Multivariate p</th>
<th>Stepwise Multivariate p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Square feet of pharmacy</td>
<td>0.467</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Square feet of non-pharmacy</td>
<td>0.002*</td>
<td>0.854</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of 340B prescriptions</td>
<td>0.939</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of 340B prescriptions billed to Colorado Medicaid</td>
<td>0.845</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Revenue from 340B prescriptions</td>
<td>0.003*</td>
<td>0.711</td>
<td>N/A</td>
</tr>
<tr>
<td>Total prescriptions</td>
<td>0.921</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Total Medicaid prescriptions</td>
<td>0.426</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Total third party payer prescriptions</td>
<td>0.288</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Total cash pay prescriptions</td>
<td>0.165</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Total revenue</td>
<td>&lt; 0.001*</td>
<td>0.208</td>
<td>N/A</td>
</tr>
<tr>
<td>Total pharmacy revenue</td>
<td>0.002*</td>
<td>0.576</td>
<td>N/A</td>
</tr>
<tr>
<td>Pharmacy payroll</td>
<td>0.160</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pharmacy costs</td>
<td>0.006*</td>
<td>0.916</td>
<td>N/A</td>
</tr>
<tr>
<td>UCH or DH</td>
<td>0.104</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>UCH entity</td>
<td>&lt; 0.001</td>
<td>0.126</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>DH entity</td>
<td>0.490</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Of all variables entered into the stepwise regression, only one variable achieved statistical significance — whether the entity was a UCH entity. A regression model was run using UCH entity as a predictor variable. The model performance, R-squared, measures how well the model fit the data and denotes the percentage of variation in average COD accounted for by the predictor used in the model. The regression coefficient represents a unit change in average COD per unit change in the predictor variable. In this case, it is the change in average COD when an entity is a UCH facility versus an entity that is not a UCH facility.

The results were significant at the level of α=0.05, as the p-value was <0.0001. Overall, the model explained 81.4% of the variance in average COD per prescription.

The regression coefficient was applied to the survey data submitted. On average, the COD is approximately $63.08 higher for a UCH entity than for a non-UCH entity. Please see Table 5 for additional results from the regression analysis.
Table 5. Regression Analysis using UCH Entity as Predictor of Average COD

| COD Inflated | Coefficient | Standard Error | t     | p>|t|  | [95% Confidence Interval] |
|--------------|-------------|----------------|-------|------|---------------------------|
| UC hospital  | 63.0846     | 7.7774         | 8.11  | <0.0001 | (46.5073, 79.6619) |
| Intercept    | 32.0811     | 2.6676         | 12.03 | <0.0001 | (26.3971, 37.7691) |

A correlation matrix was performed with average COD per prescription and a variety of other variables. The strength of a correlation is primarily represented by its correlation coefficient (r), which can run from a perfect negative correlation (-1) to a perfect positive correlation (1), with zero meaning there is no correlation.

A strong correlation existed between the average COD per prescription and whether an entity was a UCH entity (r=0.9024, p<0.0001), total revenue (r=0.8931, p<0.0001), and total area (r=0.9030, p<0.0001). Not surprisingly, total area and total revenue were strongly correlated (r=0.9910, p<0.0001). These results indicate that UCH entities, entities with greater total revenues, and entities with greater total areas tend to have a higher average COD per prescription than smaller pharmacies that are not affiliated with UCH. In addition, there was a strong correlation between the average COD and pharmacy revenue (r=0.6914, p=0.0021). The correlations between the average COD per prescription and pharmacy area (r=0.1894, p=0.4665) or percent of total revenue derived from pharmacy revenue (r=-0.2371, p=0.3595) were not significant.

An analysis of COD by type of facility and 340B prescription volume was performed. The analysis showed that DSHs had the highest average COD when compared to consolidated health centers and FQHCs (which have the lowest average COD). DSHs deal with a higher percentage of indigent patients, so they may have higher costs that lead to their higher average COD.
## Table 6. Summary of Average COD by Facility Type and 340B Volume

<table>
<thead>
<tr>
<th>Variable</th>
<th>Yes/No</th>
<th>Number</th>
<th>Mean ($)</th>
<th>Median ($)</th>
<th>25th Percentile ($)</th>
<th>75th Percentile ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consolidated Health Center</td>
<td>Yes</td>
<td>9</td>
<td>32.33</td>
<td>34.88</td>
<td>28.29</td>
<td>35.24</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8</td>
<td>47.57</td>
<td>35.39</td>
<td>29.47</td>
<td>61.94</td>
</tr>
<tr>
<td>DSH Hospital</td>
<td>Yes</td>
<td>5</td>
<td>59.29</td>
<td>36.79</td>
<td>34.75</td>
<td>87.09</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>12</td>
<td>31.26</td>
<td>34.71</td>
<td>24.04</td>
<td>35.45</td>
</tr>
<tr>
<td>FQHC</td>
<td>Yes</td>
<td>7</td>
<td>28.51</td>
<td>34.71</td>
<td>16.43</td>
<td>36.02</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>10</td>
<td>47.20</td>
<td>35.24</td>
<td>34.75</td>
<td>36.79</td>
</tr>
<tr>
<td>340B Rx Filled &lt;50,000</td>
<td>Yes</td>
<td>5</td>
<td>48.50</td>
<td>35.24</td>
<td>34.59</td>
<td>57.31</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>6</td>
<td>31.66</td>
<td>35.06</td>
<td>34.75</td>
<td>35.65</td>
</tr>
<tr>
<td>50,000–99,999</td>
<td>Yes</td>
<td>6</td>
<td>39.85</td>
<td>29.45</td>
<td>23.72</td>
<td>36.79</td>
</tr>
<tr>
<td>100,000+</td>
<td>Yes</td>
<td>6</td>
<td>39.85</td>
<td>29.45</td>
<td>23.72</td>
<td>36.79</td>
</tr>
</tbody>
</table>

## Qualitative Information Gathered

In addition to the financial and statistical data described above, there were five questions included in the survey for which the respondents were requested to respond to that were not financial or statistical in nature. These qualitative questions were included in the survey to aid the Department in understanding the unique nature of the operations of 340B entities. Due to the confidential nature of this information, it is not presented within this report.

## Summary

Based on Mercer’s analysis of the unaudited data, with the significant limitations mentioned within this report, the calculations of the data as submitted result in an average COD of $39.50 across all 340B-covered entity pharmacies that responded to the survey. The cost observations ranged from three to ten times higher than those reported in the retail or community pharmacy setting.

In addition to values that were higher than expected, the COD results were quite variable, ranging from $13.44 to $103.25. The reported costs at the twenty-fifth and seventy-fifth percentiles with a 95% confidence interval were $27.57 and $51.44. Mercer believes the uncontrolled variables mentioned throughout this report played a significant role in the wide variance in COD results reported herein.
After reviewing the initial results, Mercer completed additional analysis to estimate the average COD separately, based on whether an entity was a UCH or DH entity. The results varied such that the average (95% CI) COD for UCH or DH entities was $47.20 ($28.91, $65.50) and $28.51 ($14.90, $42.12) for all other entities. Average COD was much greater for the two UCH facilities ($95.17) than for the eight DH facilities ($35.21).

Due to the large discrepancy in average COD among hospitals, particularly UCH facilities, and all other entities, Mercer suggests the State evaluate what an appropriate dispensing fee should be in each environment, based on additional data collection and review of federal regulations on allowable costs. The entities associated with UCH reported pharmacy payroll expenses that were higher than most other entities. In their commentary, UCH also reported it is responsible for maintaining and administering the formulary for the Colorado Indigent Care Program (CICP). According to its response, the administration of CICP requires UCH to provide a higher level of necessary training and oversight to maintain staff capable of executing the tiered copay structure of CICP. These costs, if included in the reported amounts, may also be attributing to the large COD results shown in this report. In order to determine the exact nature of the costs driving up the COD for UCH, further investigation or validation would be warranted.

Last, it should be noted there is a proposed rule, dated February 12, 2012, that will modify federal Medicaid regulations surrounding coverage, reimbursement, and rebates for prescription drugs and over-the-counter products to implement provisions of the Patient Protection and Affordable Care Act. A portion of this rule proposes to require states to include their methodology for determining Medicaid reimbursement, including 340B ingredient cost and cost of dispensing fee in their State Plans. This suggests the State will be required to outline the methodology for the COD in the State Plan, and any changes to the COD, or the methodology used to calculate that fee, would require a State Plan Amendment.
Conclusions

As mentioned earlier, there are significant limitations that should be taken into consideration when reviewing the resulting COD amounts discussed in this report. Additional detailed information should be obtained to appropriately validate the reported costs and that the required cost allocation techniques were utilized for both the FQHCs and hospital-based pharmacies. Therefore, Mercer does not recommend the Department implement a change to the cost of dispensing fees for 340B entities based on the results of this report.

Additional recommendations include the following:

1. Mercer recommends the financial information reported in the survey by both the hospital-based and FQHC pharmacies be validated through reviews of applicable cost report, or by another method, as deemed appropriate.
   - The validation process will allow the State to fully understand the reported information to ensure its accuracy and applicability to the State’s purpose, as well as to ensure the reported costs are allowable per CMS guidelines as a basis for COD reimbursement.
   - Entities, such as hospitals and FQHCs, which receive federal funding via contracts with State and local governments, are required by CMS guidelines to include only allowable costs when reporting incurred expenses. In reporting allowable costs, specific methodologies are to be used (also in accordance with CMS guidelines) to appropriately allocate only the allowable incurred costs to appropriate departments and line items within the entities’ reporting structures. These entities are typically required to submit cost reports on a periodic basis to the federal, and often State, governments. Only the allowable costs as defined by CMS are to be included in these cost reports.

2. Mercer recommends the Department mandate all FQHCs to adhere to a consistent, prescribed cost-report structure, including a dedicated pharmacy cost center for all FQHCs with 340B pharmacies and use of standard cost-allocation methods outlined in 42 CFR 413 and OMB A-122 for future report requirements of the FQHCs to the Department.
   - Per discussion with the Department, the current reporting structure allows for variances by FQHC, in methodologies and formats used to report financial information to the Department. These variances do not
provide the Department with an apples-to-apples comparison amongst the FQHC entities or provide validation that the reported costs are allowable per federal guidelines.

- The Department should gain a thorough understanding of federal guidelines for allowable costs and allocation methodologies, both from an encounter and COD basis. The prescribed reporting format should include and exclude costs as appropriate, based on these guidelines. The resulting format and approved methodologies should be delineated in policy, or at a minimum, in an instructional document accompanying the reporting template.

3. Mercer recommends that once a process is in place that allows for valid, allowable costs and consistent reporting, the Department revisit a review of the costs of dispensing for 340B entities.