

Drug Use Evaluation: Compounded Drugs

Research Questions:

- Quantify total compounded drug costs as a proportion of total drug costs and capture use and cost trends since 2014.
- Identify the most common and costly drugs compounded.
- Identify differences in costs or billing practices for most the common and most costly drugs and identify compounded claims that are for commercially available products.
- Identify the most common pharmacies billing compounded drugs.

Conclusions:

- There were 3167 unique compounded pharmacy claims representing 0.09% of total fee-for-service (FFS) drug claims from January 1, 2014 to June 30, 2015. The total amount paid to pharmacies was \$309,965 (0.13% of total FFS amount paid to pharmacies). The average amount paid per claim was \$97.87. There were 109 claims over \$500 and 69 claims over \$1000. The number of claims has increased 7% over the 18-month period. The amount paid to pharmacies is more variable and increased 42% over the 18 months. However, if an outlier data point on February 2015 is excluded, the increase in amount paid to pharmacies is reduced to 13%.
- Omeprazole with sodium bicarbonate suspension, “magic mouthwash” (i.e., viscous 2% lidocaine/Maalox™/ diphenhydramine) and antibiotics (e.g., vancomycin, gentamicin, ceftriaxone, cefepime, mupirocin, daptomycin) and their diluents (0.9% sodium chloride, sterile water for injection, dextrose 5% in water) are the most common compounds. Antimicrobials, lidocaine jelly and aripiprazole are the most costly compounded drugs.
- There is great variation between the minimum and maximum amount allowed billed for most drugs. Manual review of claims associated with the “maximum allowed amount billed” was correlated with inappropriate quantities and other questionable billing practices. The manual reviews identified 2 compounded drug claims of only 1 commercially available ingredient and 2 instances that appeared to be multiple commercially available oral drugs dispensed on one compound claim.
- The top 20 pharmacies accounted for 94% of compound claims cost and 71% of compounded drug claims submitted. The total cost per pharmacy is largely reflective of the type of practice and the drugs predominantly dispensed.

Recommendations:

- Produce a pharmacy education document for appropriate compounded claim billing for publication on the OHA website and for distribution to all pharmacies billing compounded drug claims to Oregon FFS.
- Implement data integrity edits to require a minimum of 2 ingredients and to disallow compounds with oral solids only.

- Implement specific billing quantity limits for high cost drugs (e.g., daptomycin [10], micafungin [10], ceftaroline [10], azithromycin [50], iron sucrose complex [10], lidocaine jelly [120]) and high volume drugs (omeprazole [60], sodium bicarbonate [600], baclofen [180], tacrolimus [30], 0.9% sodium chloride [2000]) to insure appropriate quantities are billed. Other drugs are to be added as identified to insure quantities are within recommended dose limits.
- Implement a generally allowed amount edit for compounded drug claims paid amounts exceeding \$1000, except set specific allowed amount limits for daptomycin (\$2500), micafungin (\$1500), ceftaroline (\$1500) and other exceptions identified upon implementation of the edit.
- Follow-up in 2 years for policy adjustments.

Background:

The danger of using compounded drugs was recently highlighted by the outbreak of central nervous system fungal infections linked to compounded epidural preservative-free methylprednisolone acetate.¹ However, compounding pharmacies also fill a critical niche as they prepare individualized, non-commercially available formulations for specific patient situations such as liquids where none are available and preservative-free, dye-free or gluten-free products when necessary.

Despite the highly publicized public health concerns, the United States Food and Drug Administration (FDA) has been unsuccessful in regulating compound pharmacies but does provide guidance for good conduct.^{3,4} Compounding pharmacies are generally regulated by state Boards of Pharmacy. In Oregon, the Board expects pharmacies to comply with the spirit of the current guidelines of the United States Pharmacopeia Chapters 796 and 797.² Pharmacies must register as a manufacturer and meet manufacturer requirements unless they limit compounding to a specific drug order or prescription (i.e., not in advance of unknown orders or prescriptions).² Pharmacists must compound only products that are not commercially available or that are temporarily unavailable.²

Currently, the OHP fee-for-service program (FFS) allows payment for compounded pharmacy claims when billed accurately using the National Council for Prescription Drug Program (NCPDP) Standards.⁵ A compound pharmacy claim is opened when a pharmacy processes it with a “2” in the “Compound Code” field.⁵ Compound drug claims have multiple details to allow for automated compound drug pricing. Each detail contains one ingredient in the compounded drug product. For non-rebated ingredients, there will be no reimbursement by FFS according to federal Medicaid law. Pharmacies can accept reimbursement for the compounded drug even though not all ingredients are reimbursed by submitting an “8” in the Submission Clarification Code.⁵ Only one dispensing fee, one other insurance payment and one copay applies per claim regardless of the type or number of ingredients. Pricing of the claim is as follows:

Sample Compound Drug Pricing

Step	Action
1.	Add the sum of the claim detail allowed amounts for individual ingredients. For example, \$3.00 + \$2.00 + \$10.00 + \$2.00 = \$17.00.
2.	Add the dispensing fee to the summed allowed amounts to get the full claim allowed amount. For example, \$10.14 + \$17.00 = \$27.14 allowed amount.
3.	Compare the billed amount of \$20.00 to the allowed amount of \$27.14
4.	Use the billed amount of \$20.00 as the allowed amount to price the claim since it is the lesser of the two amounts.
5.	Deduct Copay from the total allowed amount. For example, \$20.00 - \$3.00 = \$17.00.
6.	Deduct the Other Insurance Amount from the allowed amount. For example, \$17.00 - \$15.00 = \$2.00 (Total Claim Paid Amount).

It is suspected that a few pharmacies may be inaccurately reporting quantities or National Drug Codes (NDCs) when submitting compound pharmacy claims due to misunderstanding, or to maximize reimbursement. It is also suspected a few pharmacies may inappropriately submit compounded drug claims for commercially available drugs. The goals of this evaluation are to describe current compound prescription utilization and pharmacy billing practices to inform policy proposals.

Methods:

Include all FFS paid compound drug claims (Q-claims) from January 1, 2014 to June 30, 2015. Exclude patients with BMM, BMD, MED and MND benefit packages as we do not have complete drug data for them. The highest allowed cost for the top 10 ingredients by count and summed cost were manually reviewed to identify the source of variation.

Results:

There were 3167 unique compound claims representing 0.09% of total FFS drug claims during the study period. The total amount paid to pharmacies was \$309,965 (0.13% of total FFS drug claims). The average amount paid per claim is \$97.87. There were 109 claims over \$500 and 69 claims over \$1000. Figure 1 displays the monthly claim count trend and the amount paid to pharmacies. The number of claims has increased 7% over the 18-month period. The amount paid to pharmacies is more variable but increased 42% over the 18 months. However, the increase is reduced to 13% if the outlier point on February 2015 is excluded. The outlier point is due to 3 patients who received daptomycin from a single pharmacy during that month. One patient received 21 doses of ~850 mg per day, indicating a weight of 140 kg at the maximum dose of 6 mg/kg.

Figure 1: Compound Pharmacy Header Claim Counts and Amount Paid to Pharmacies

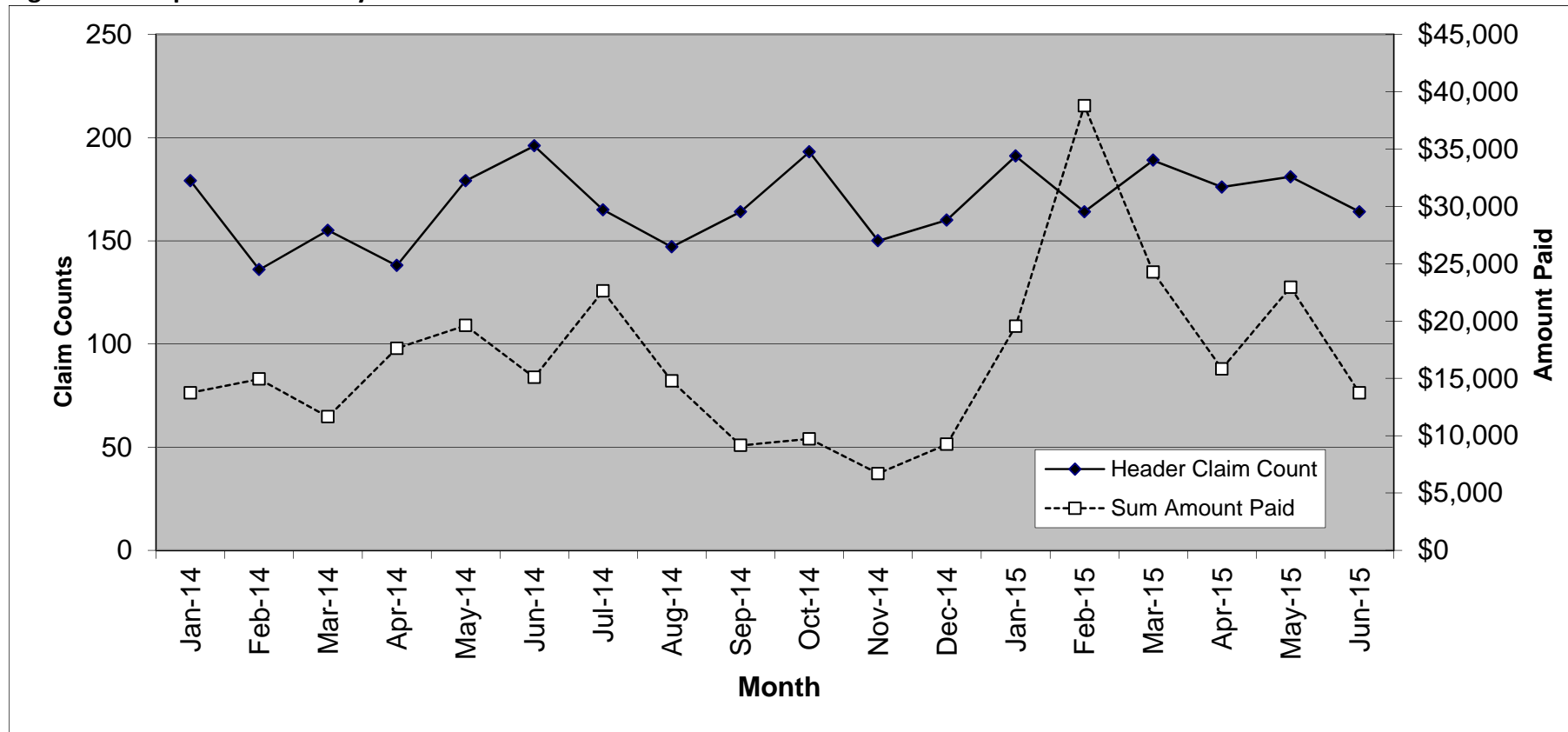


Table 1 displays the most frequent ingredients of compound claims. Suspensions of omeprazole and sodium bicarbonate are the most common compounds and “magic mouthwash” (i.e. viscous 2% lidocaine/Maalox™/ diphenhydramine) is the next most common compounded product. Antibiotics (e.g. vancomycin, gentamicin, ceftriaxone, cefepime, mupirocin, daptomycin) and their diluents (0.9% sodium chloride, water for irrigation, water for injection, dextrose5% in water) are also common.

Table 2 displays the most costly compounded claims. There are multiple details per claim that represent all ingredients in the compound and the sum of the allowed amount may not equal the total paid by FFS because other insurance payments, copays, the billed amount and dispense fees are not reflected in the simple sum (see “**Sample Compound Drug Pricing**” above). Antibiotics and antifungals dominate this table but it also includes the mental health carve-out drug aripiprazole.

Table 1: Top 20 FFS Compound Pharmacy Claim Details by Count

Rank by claim count	Generic Name	Count Claim Details	Average Detail Allowed Amount	Min Detail Allowed Amount	Max Detail Allowed Amount
1	OMEPRAZOLE	760	\$4.37	\$0.06	\$287.82
2	SODIUM BICARBONATE	702	\$22.47	\$0.00	\$331.80
3	0.9 % SODIUM CHLORIDE	499	\$13.89	\$0.24	\$198.36
4	LIDOCAINE HCL	379	\$18.24	\$0.08	\$1,349.73
5	MAG HYDROX/AL HYDROX/SIMETH	344	\$1.15	\$0.02	\$205.06
6	DIPHENHYDRAMINE HCL	314	\$1.46	\$0.03	\$289.92
7	VANCOMYCIN HCL	214	\$50.26	\$1.97	\$202.50
8	WATER FOR IRRIGATION,STERILE	143	\$0.19	\$0.00	\$1.96
9	WATER FOR INJECTION,STERILE	137	\$42.00	\$0.01	\$5,179.39
10	NYSTATIN	110	\$37.38	\$0.51	\$2,653.44
11	TACROLIMUS	100	\$133.55	\$17.18	\$423.40
12	BACLOFEN	98	\$43.15	\$0.00	\$482.22
13	DEXTROSE 5 % IN WATER	92	\$6.61	\$0.15	\$64.76
14	COMPOUNDING VEHICLE SUSP NO.7	89	\$2.70	\$0.00	\$13.05
15	GENTAMICIN SULFATE	83	\$21.48	\$0.29	\$190.23
16	CEFTRIAZONE SODIUM	73	\$34.06	\$3.55	\$121.11
17	ENALAPRIL MALEATE	70	\$0.45	\$0.04	\$1.10
18	SODIUM CHLORIDE	68	\$3.62	\$0.95	\$14.77
19	SODIUM ACETATE	67	\$4.54	\$1.02	\$10.58
20	DEXTROSE 70 % IN WATER	67	\$1.19	\$0.59	\$4.63

There is great variation between the minimum and maximum amount allowed for most drugs. Some variation is expected given that pediatric quantities could be very small relative to adult quantities. Manual review of the claims confirmed some ingredients on this list may also represent both intravenous and oral formulations. However, the variation may also indicate inappropriate billing quantities. When claims details associated with the maximum detail allowed of the top 10 drugs by claim count were reviewed manually, only 2 were likely submitted with an appropriate quantity. One claim billed for 4500 omeprazole 20 mg capsules for a 30-day supply for a 3-year old. A second claim billed for 3 different NDCs for normal saline in the same compound claim. Only one detail allowed payment but for a billing quantity of 29,000 mL and the only other ingredient was 112 mL of magnesium sulfate 50% for 7 days. A third claim billed for a total of 5400 grams of zinc oxide, A&D ointment, lidocaine cream and aquaphilic ointment (the total paid on this claim was \$1,483.46). Finally, a fourth claim billed 38,400 units for all 7 oral ingredients (total of 268,800 units). Fortunately the pharmacy billed only \$99.99 because the calculated sum of the details was over \$10,000.

When the claim details associated with the maximum header allowed amounts of the top 20 drugs were reviewed manually, 8 had potential billing errors. One claim billed for 3200 mg of iron sucrose for an 8-day supply when the usual dose is 100 mg 3-times per week. One claim for oxacillin

billed for 110 grams for 9 days (12 grams per day versus the recommended 6 grams per day). A third claim billed for 450 mg of tadalafil for a 30-day supply for a 6-year old (15 mg/day). Two claims involving lidocaine jelly billed for 1000-3000 mL each. Several claims billed for multiple oral solids (aripiprazole 30 mg + lamotrigine 200 mg + fluoxetine 40 mg) on one claim. There was also an azithromycin claim for 2000 500 mg vials for a 7-day supply. Finally, there was a claim for an odd combination of ketamine and carboxymethylcellulose.

Table 2: Top 20 FFS Compound Pharmacy Claims by Maximum Allowed Amount on Claim Header

First Detail Generic Name	Second Detail Generic Name	Third Detail Generic Name	Claim Count	Average Allowed Amount on Claim	Minimum Allowed Amount on Claim	Maximum Allowed Amount on Claim
0.9 % SODIUM CHLORIDE	DAPTOMYCIN		47	\$2,188	\$346	\$5,391
0.9 % SODIUM CHLORIDE	MICAFUNGIN SODIUM		30	\$1,293	\$762	\$1,700
0.9 % SODIUM CHLORIDE	CEFTAROLINE FOSAMIL ACETATE		4	\$1,104	\$783	\$1,552
0.9 % SODIUM CHLORIDE	IRON SUCROSE COMPLEX		21	\$120	\$25	\$1,547
ZINC OXIDE	LIDOCAINE HCL	HYDROPHILIC CREAM	1	\$1,483	\$1,483	\$1,483
DEXTROSE 5 % IN WATER	OXACILLIN SODIUM		12	\$444	\$37	\$1,239
0.9 % SODIUM CHLORIDE	GANCICLOVIR SODIUM		2	\$1,030	\$827	\$1,233
TADALAFIL	COMPOUNDING VEHICLE NO.8		1	\$956	\$956	\$956
LINEZOLID			2	\$778	\$778	\$778
LIDOCAINE HCL 2% JELLY			10	\$122	\$0	\$750
LIDOCAINE HCL 2% JELLY	KETOPROFEN		16	\$240	\$135	\$692
0.9 % SODIUM CHLORIDE	AZITHROMYCIN		15	\$200	\$36	\$678
ERTAPENEM SODIUM	0.9 % SODIUM CHLORIDE		29	\$341	\$154	\$631
TACROLIMUS	SIMPLE SYRUP		100	\$141	\$16	\$618
0.9 % SODIUM CHLORIDE	MEROPENEM		20	\$180	\$52	\$599
0.9 % SODIUM CHLORIDE	NAFCILLIN SODIUM		12	\$415	\$148	\$595
CARBOXYMETHYLCELLULOSE	KETAMINE HCL		1	\$483	\$483	\$483
ARIPIPRAZOLE	LAMOTRIGINE	FLUOXETINE	32	\$368	\$309	\$422
WATER FOR INJECTION,STERILE	CEFTAZIDIME		2	\$286	\$174	\$399
Various compounding vehicles	SILDENAFIL CITRATE		28	\$74	\$14	\$391

Table 3 displays the top 20 pharmacies by the sum of the amount paid on compound claims. These pharmacies account for 94% of compounded claim costs and 71% of compounded claims submitted. The cost is largely reflective of the types of drugs predominantly dispensed. The top 2 pharmacies are largely intravenous and antibiotic practices, whereas the OHSU Doernbecher Children’s Hospital outpatient pharmacy mostly compounds pediatric suspensions.

Table 3: Top 20 Pharmacies by the Sum of the FFS Amount Paid.

January 2014 - June 2015

NPI	Pharmacy Name	Count Unique Claims (Header)	Percent of Total Compound Claims	Sum Amount Paid	Percent of Total Amount Paid on Compound Claims
1003826694	CORAM ALTERNATE SITE SVCS INC	190	6%	\$119,787	39%
1972640712	HOMECARE I.V. OF BEND LLC	74	2%	\$33,662	11%
1720062573	CARE RX PHARMACY	155	5%	\$24,589	8%
1619078698	CYPRESS POINT VENTURES LLC DBA	217	7%	\$23,997	8%
1225073448	CONSONUS PHARMACY SVCS LLC	143	5%	\$20,726	7%
1235240391	EVERGREEN PHARMACEUTICAL SERV	80	3%	\$17,293	6%
1053454645	OHSU DOERNBECHER OTPTNT PHARM	452	14%	\$10,000	3%
1265768774	JMSP LLC	55	2%	\$9,935	3%
1770713224	OREGON HEALTH SCIENCE UNIV PHA	283	9%	\$5,547	2%
1336223171	PROVIDENCE HLTH & SVCS OREGON	148	5%	\$4,044	1%
1740240589	FAIRLEY S PHARMACY	28	1%	\$3,546	1%
1255561478	HIERS ENTERPRISES	63	2%	\$2,886	1%
1073610358	HOME PARENTERAL CARE INC	10	0%	\$2,574	1%
1972518967	WALGREENS 05572	52	2%	\$2,374	1%
1548217136	BEAVERTON PHARMACY	64	2%	\$2,089	1%
1518927649	BOLGER PHARMACY DBA	42	1%	\$2,058	1%
1275698458	GATEWAY MEDICAL PHARMACY	48	2%	\$1,949	1%
1225464118	ISSE PHARMACY SERVICES	25	1%	\$1,624	1%
1417977976	EMANUEL RETAIL PHARMACY	99	3%	\$1,623	1%
1427132265	PROVIDENCE HLTH & SVCS OREGON	20	1%	\$1,468	0%
		2248	71%	\$291,771	94%

Limitations:

The claim details billed on the claim may not be reflective of all ingredients used in the compounded drug product. The database does not currently include claim details of \$0 payment. However, the manual reviews queried the complete claims data on-line. Still, pharmacies may not bill for all ingredients used in a compound if they are willing to forgo payment. As such, it is difficult to know if the single ingredient claims are truly for commercial products.

References:

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3. Markey E. H.R.2186 - 113th Congress (2013-2014): VALID Compounding Act. May 2013. <https://www.congress.gov/bill/113th-congress/house-bill/2186>. Accessed July 16, 2015.
4. Board of Pharmacy: Division 45 - Sterile and Non-Sterile Compounding. *Or Secr State Arch Div*. June 2015. http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_855/855_045.html. Accessed July 16, 2015.
5. Oregon Medicaid NCPDP Pharmacy Payer Sheet. *Or Health Auth - OHP Pharm Serv Program*. January 2011. <http://www.oregon.gov/oha/healthplan/tools/NCPDP%20D.0%20Payer%20Sheet.pdf>. Accessed July 16, 2015.