

# Impact on Health Plan Cancer Drug Costs in Different Delivery Models -

Identifying whether cancer drugs costs to health plans are affected by differences between original prescription and drugs actually used for treatment in two different drug acquisition models in practices (Direct Acquisition Model or External Delivered Model)

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## Summary

Health plans, specialty pharmacy providers, and cancer providers are engaged in cancer management initiatives, some of which include discussion about whether cancer providers should continue to acquire cancer drugs or whether an external vendor, such as a specialty pharmacy, should deliver cancer drugs to the cancer provider upon receipt of a prescription of the original cancer treatment plan. However, during active treatment, a cancer patient is usually assessed for health status and ability to receive the planned cancer treatment on the day of treatment. If that assessment leads to a change in the treatment prescription, that prescription change could result in a cost to health plans under one of the drug delivery models that does not occur under the other drug delivery model. This study reviewed the incidence of changes in treatment prescription versus actual treatment, as well as the potential cost to health plans of such changes under the Direct Acquisition Model and the External Delivered Model, as identified by ICD-9 coding conventions. Both the changes in treatments delivered and cost implications were found to be significant. The results are likely to change the perspective and strategies of future discussions between health plans, specialty pharmacies and cancer providers regarding drug delivery models. The results may be useful to health plans and physicians in discussing cost efficient methods of getting the right drug to the patient at the time of treatment.

## Key Points

- About one in 10 cancer treatments have variations in treatment between the original planned dosing and the actual day of treatment for the most common cancers: breast, lung, colon and prostate.
- Over 90 percent of those variations in treatment result in the planned dose not being given on the day of treatment.
- The rest of the variations result from dose increases or dose decreases.
- If drugs are pulled on the day of treatment from a general inventory maintained by the cancer provider (Direct Acquisition Model), only those drugs which are actually used are billed to the health plan by the cancer provider, so no waste of drug in comparison to the original prescription occurs.
- If drugs are delivered to the cancer practice for administration based upon the original planned prescription by the cancer provider (External Delivered Model), they are billed out to the health plan by the external vendor upon shipment, not upon actual utilization for the patient.
- If drugs are delivered from an external vendor to the cancer practice for a specific patient under the planned prescription and are not used for that patient – those drugs cannot be used for another patient, nor returned...they must be handled as “waste” and discarded by the cancer provider, resulting in a cost to both the health plan and the provider, in addition to the cost of the drugs actually used for treatment of the cancer patient.
- Based upon the results of this study, on a conservative basis, the cost of such potential “waste” to the health plan (in addition to the drugs actually used for treatment) under a External Delivered Model, could reach about \$5,000 per treating physician, and are possibly significantly higher under less conservative assumptions.
- There is a potential high impact of “waste” dollars in drug use even resulting from low (under 10 percent) variations resulting from same day treatment changes – for both chemotherapy drugs and ancillary drugs that are delivered to the cancer provider for use, but that “waste” does not occur when cancer drugs are used from within the cancer provider’s own acquired inventory.
- Drug shortages are a significant issue in oncology today, and delivery policies that cause large numbers of unused drugs to be destroyed would only exacerbate cancer drug shortages.

## Introduction

ABOUT 80 PERCENT OF CANCER CARE IS delivered in community oncology office settings (private or hospital owned). These are predominantly private physician offices, which, as small business-

es, keep a very tight rein over their expensive drug inventories. Patients coming in for treatment have their health status assessed in the physician office immediately prior to receiving any drug treatments, so the assessment of the patient and any decisions

made about changes in needed drugs for treatment are closely linked, both in terms of staff resources and knowledge of the actual drugs involved and the causes for the change.

**Drug Delivery Models in Flux:** Historically, all drugs have been acquired by the oncology office for cancer treatment, but with the advent of newer oral drugs and increased public and private payer focus on cost management in oncology, there has been some increase in the volume of drugs ordered by physician prescription and shipped to the office from an external pharmacy, usually driven by health plan policy or reimbursement structure. There has also been an increasing interest on the part of health plans and specialty pharmacy organizations in whether more drugs, if not all, should be delivered upon prescription to the oncology office. Physician practices are more closely evaluating individual drugs for both public and private payers, and occasionally making decisions to either send patients to another care system (such as a hospital outpatient center) or to acquire drug through an External Delivered Model if the cost of the drug is significantly higher than the reimbursement rate. Physician practices across the country are struggling financially, and many have recently been acquired by hospitals or merged into large group models. Each of these changes is initially driven by differences between cost and reimbursement policies of both public and private health plans, but as practices merge into larger organizations, can also then have an unintended adverse financial consequence for that same public or private health plan. Hospitals usually have different contract structures and pricing differences. Health plans are now starting to analyze relationships with those private physicians' practices that are still private, and consider what policies might encourage them to remain in practice rather than to seek integration into a more costly hospital setting. In some cases, those policies under review include consideration of the impact on both the health plan and the provider of different drug delivery models.

**Potential Changing Drug Delivery Models Cost Implications for Payers:** The National Association of Managed Care Physicians, facing questions from their membership (medical directors of health plans, employers and larger providers) about the costs and implications of different delivery models for oncology drugs, engaged the services of DGH Consulting, onPoint Oncology, LLC and Improve RX, LLC, to analyze the rate and volume of drug changes for cancer patients during treatment. While there are some variations in payment structure and other drug delivery models in use across the country, the Direct Acquisition Model and External Deliv-

ered Model are by far the most common currently in use. Payers pay for drugs to different entities under these two delivery models currently being employed or under consideration – and at different times in the treatment process. Those differences could be greatly affected by drug changes during treatment, but are not easily measurable by any current tracking process in either payer or specialty pharmacy systems.

**Impact is based upon delivery-related costs of drug cost only:** It is important to note that many health plans, as well as providers, are engaged in numerous other activities to manage the selection of appropriate treatment for cancer patients and their disease by the physician. While those initiatives can also affect the ultimate cost of treatment by managing drug or regimen choice, they do not affect the types of costs that could be incurred under the situation created by changing drug delivery models. Any changes related to prior authorizations, use of guidelines or pathways, or other oncology management programs would not be affected by the delivery method of the planned treatment. The only costs considered in this study relate to whether or not a planned treatment, once delivered, is actually used, and whether or not the method of delivery might result in a cost of unused product. While it would also be possible to use other price points for the purpose of quantifying the potential impact on a dollar basis, causing the numbers to vary somewhat, the fact that there is a dollar impact related to the potential for unused prescribed drug would not vary.

The two most common drug delivery models in use or under consideration for oncology care are described as follows:

**Direct Acquisition Mode:** Most oncology drugs are now acquired by the provider directly from a specialized oncology drug distributor and stored until actually used by a patient, at which point a claim is issued to the payer and submitted for payment. Physicians are paid for Medicare patients at a payment rate of Average Selling Price (ASP) plus 6 percent, which is modified quarterly by the federal government. Private health plans pay physicians on a wide range of payment rates, which can be based upon Average Wholesale Price (AWP) or ASP. ASP plus 10 percent was selected as a fairly common representative comparison for reimbursement rates under the Direct Acquisition Delivery Model for the purposed of this study.

**External Delivered Model:** Under this model, health plans contract with an entity external to the health provider (typically a specialty pharmacy) to acquire and deliver drugs to the health provider. The treating physician is expected to

Exhibit 1: Patients in Dataset 4/1/11 – 3/31/12, 1,368 total

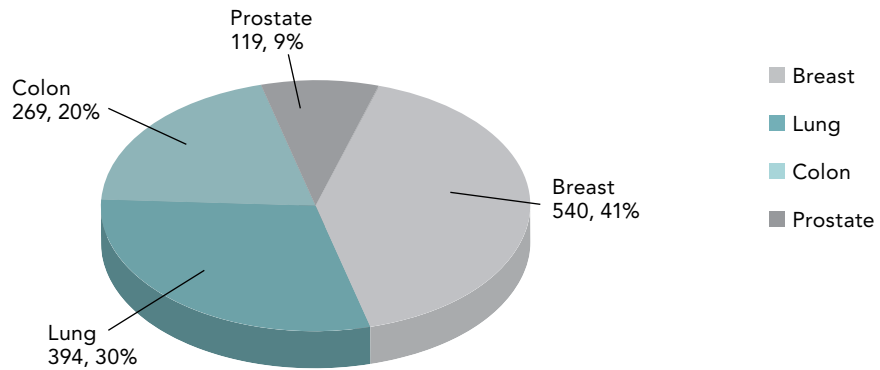
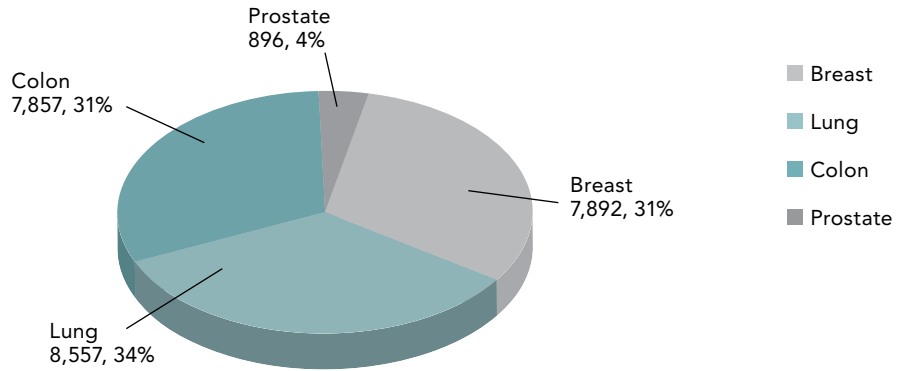


Exhibit 2: Doses in Dataset 4/1/11 – 3/31/12, 25,202 total



send a prescription to that designated specialty pharmacy for the planned cancer treatment and those drugs are then sent to the physician's office, usually within 24 to 72 hours in advance of the scheduled treatment day. Specialty pharmacies then bill the health plan for the ordered drugs at the time they are shipped from the specialty pharmacy, without the knowledge or ability to reconcile whether or not the drugs were actually used in the office setting. These delivered drugs arrive specifically labeled for the individual patient for whom they were ordered.

### Safe Handling Guidelines for Chemotherapy Administration

Cancer practices follow well-defined protocols for the safe administration of chemotherapy and supportive care medications, including clinical assessment regarding the appropriateness of the planned treatment on the day of treatment given the patient's

current health status. These guidelines also provide for the safe documentation of treatment changes on the day of treatment, as deemed necessary. Treating providers will not treat a cancer patient with any drugs without assessing the patient's health status and assessment of the appropriateness of the planned treatment on the day of treatment.

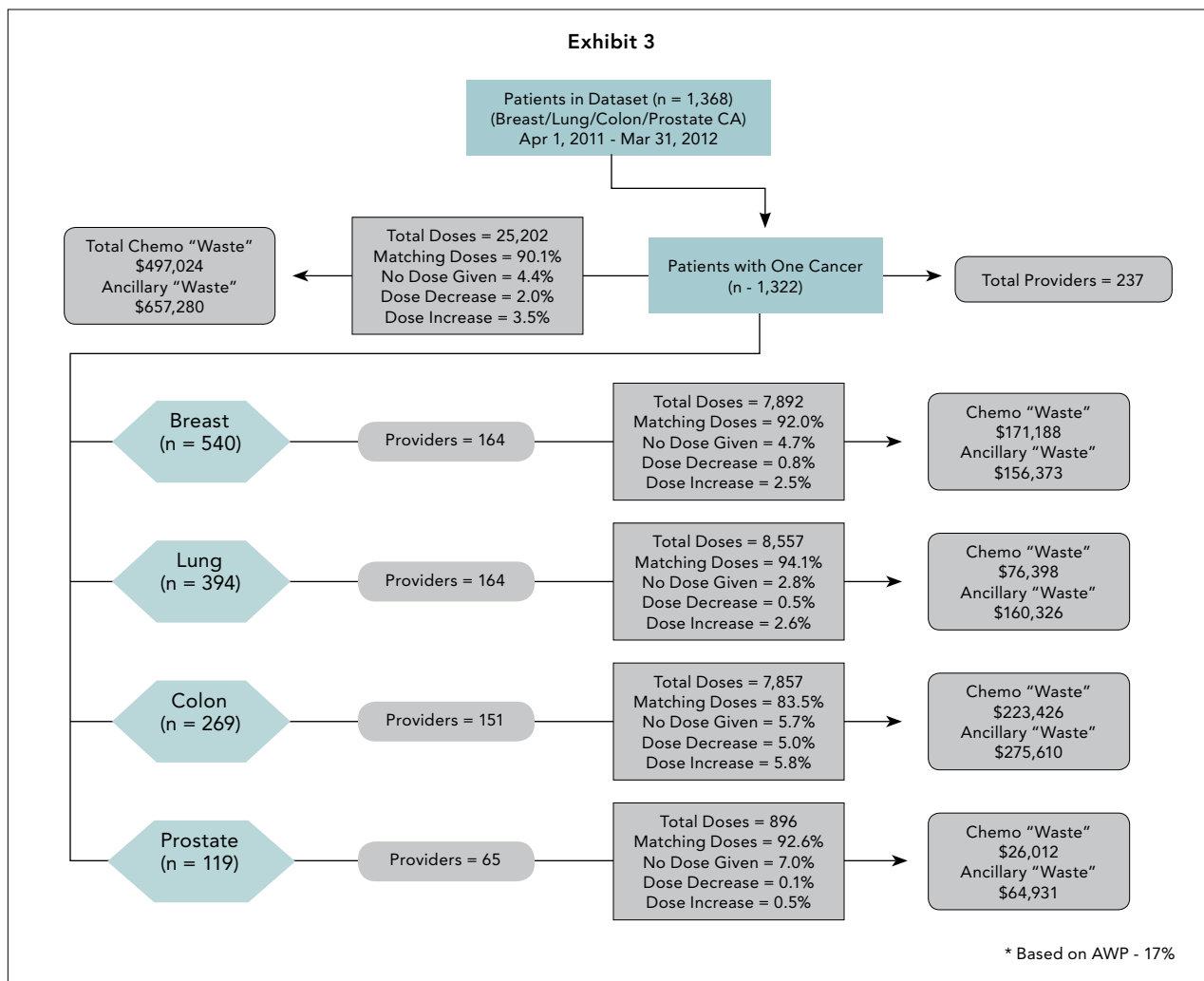
The American Society of Clinical Oncologists (ASCO) and the Oncology Nursing Society (ONS) have published guidelines for the safe handling of chemotherapy which are the national standard for safe practice. These ASCO/ONS Standards for Safe Chemotherapy Administration establish that:

22. On each clinical visit or day of treatment during chemotherapy administration, staff:

Assess and document clinical status and/or performance status

Document vital signs and weight

Verify allergies, previous reactions, and treatment-related toxicities



Assess and document psychosocial concerns and need for support; taking action when indicated.

This standard applies to all clinical encounters (including each inpatient day, practitioner visits and chemotherapy administration visits, but not laboratory or administrative visits).

23. At each clinical visit or day of treatment during chemotherapy administration, staff review the patient's current medications including over the counter medications and complementary and alternative therapies. Any changes in the patient's medications are reviewed and documented by a practitioner during the same visit.

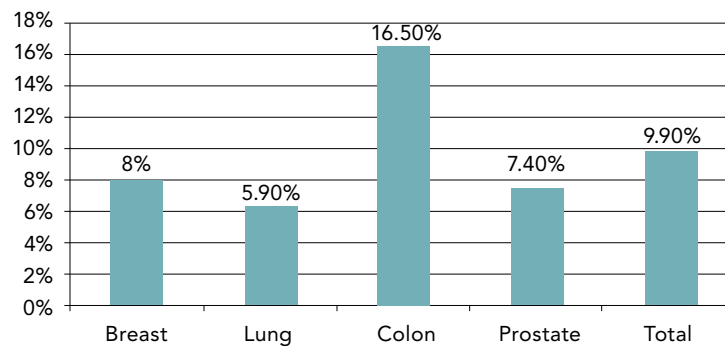
This standard applies to all clinical encounters (including each inpatient day practitioner visit and chemotherapy administration visits but not laboratory or administrative visits).<sup>1</sup>

**Regulatory Impact on Drug Management and Costs:** Federal and state pharmacy laws dictate whether drug ordered and labeled for a specific patient, if not used for the designated patient, may be returned to the source or re-allocated to another

patient. Federal and state pharmacy regulations, as well as individual manufacturer/distributor policies, also dictate whether or under what conditions a drug may be returned after delivery to the end point pharmacy or physician's office, with more restrictive policies for refrigerated rather than non-refrigerated drug. Most state pharmacy regulations prohibit any reuse of drugs issued for specific patients, and also preclude dispensing pharmacies from even accepting the return of prescribed drugs, as illustrated in this simple statement from the Missouri Division of Professional Regulation, "Under Missouri law, unused medication cannot be returned to a pharmacy for purposes of disposal/destruction."<sup>2</sup>

Most state pharmacy regulations require that a drug, once it leaves the pharmacy labeled for a specific patient based upon a doctor's prescription, must be destroyed if not used for that specific patient – not returned or reused for other patients. These regulations do cause concern because of the large numbers of drugs already being wasted from unused medications accumulating in individual homes and long-

Exhibit 4: Percent of Doses That Didn't Match Original MD Order – Dataset 4/1/11 - 3/31/12



term care nursing facilities. The National Conference of State Legislatures recently reviewed the problem and support efforts on different state levels to provide regulatory guidance for “take back” programs. However, in all circumstances, such take back programs focus on finding ways to accept unused prescribed drugs for controlled distribution to needy individuals, not for resale in the domain of the general public.<sup>3</sup> Those take back policies, while useful for uninsured patients who might not otherwise receive medications, do not allow for use of unused medications for commercial or Medicare populations.

### Methodology

To identify the impact of different drug delivery methods, a data set derived from electronic medical records (OncoEMR,<sup>®</sup> Altos Solutions, Pleasanton, CA and onPoint Oncology, LLC, Hudson, OH) was queried. The data set contained de-identified patient information such as dose, duration, sequence and key patient demographic data including diagnoses. Importantly, the originally ordered treatment plan including the anticipated drug and dose as well as the drug and dose actually administered to the patient on the day of treatment were available. Mismatches between the ordered drug and dose and the administered drug and dose provided the basis for comparisons of the two drug delivery models.

The data from the 12-month period of April 1, 2011 through March 31, 2012 were utilized. Patients receiving drug orders and administrations during the study period were divided into one of four cancer groups: breast, prostate, colon, and lung, as identified by conventional ICD-9 coding. Patients with diagnoses of multiple cancers were excluded. The drugs were divided into two groups: 1) chemotherapy/biologics and; 2) ancillary drugs, such as colony stimulating factors, anti-emetics, etc..

Three different scenarios were identified when a mismatch between ordered amount and administered amount occurred: ordered > administered, including situations where administered amount = 0 (ordered dose held); ordered < administered; and ordered = administered. The primary outcome measure was the mean cost difference between ordered drug amounts and administered drug amounts, when ordered was greater than administered. Under a delivered drugs model, drug is pre-ordered by the physician practice from an external source (i.e., specialty pharmacy) and cannot be returned if unused (ordered > administered). This was considered as potential ‘waste’. Thirty-day per patient drug waste was also calculated based on the observed utilization patterns for both Average Wholesale Price (AWP)–17 percent and Average Selling Price (ASP) + 10 percent and normalized to mean time on drug (in days, first to last).

Secondary measures included percent with any waste (ordered  $\neq$  administered), percent where ordered > administered, percent where administered amount = 0 (ordered dose held) and percent ordered < administered; and ordered = administered (matching doses). In addition,

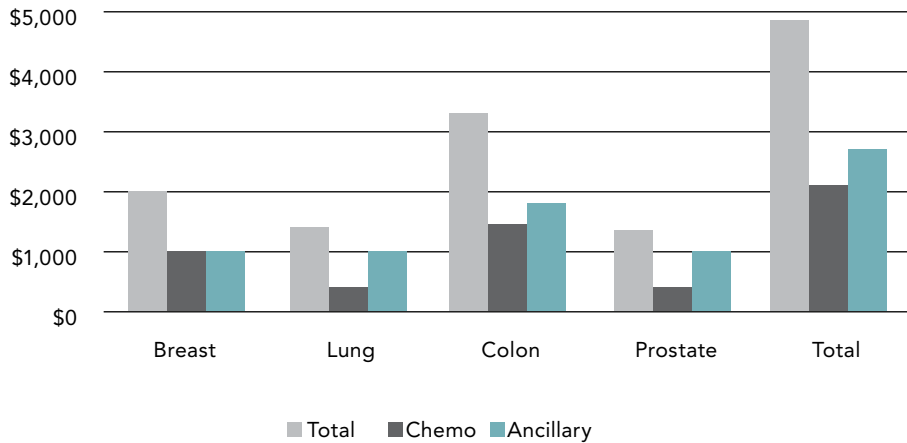
All administrations were reviewed by drug to ensure that consistent dosing units were used.

### Results

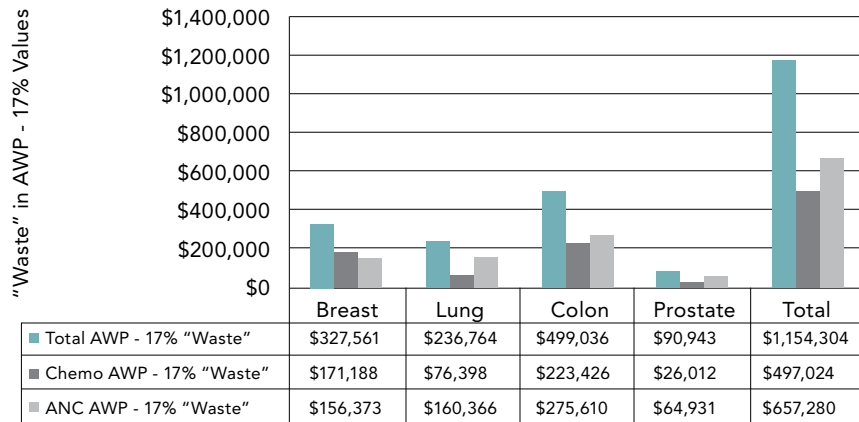
Over the 12 months of data aggregated for the study (April 1, 2011 to March 31, 2012) detailed dosing data was collected for 237 physicians practicing in locations across the country. The documented dosing data covered a total of 1,368 patients with diagnoses of either breast, lung, colon or prostate cancer (Exhibit 1).

Of the total 25,202 number of doses administered and documented during those twelve months, almost two-thirds (63 percent, 15,815) were for che-

**Exhibit 5: Potential Dollars of "Waste" per MD (at AWP - 17% value of doses) due to Unmatched Doses - Dataset 4/1/11 - 3/31/12**



**Exhibit 6: Potential Dollars of "waste" due to Unmatched Doses - Dataset 4/1/11 - 3/31/12**



motherapy treatments and the remaining third (37 percent, 9,387) were for ancillary drugs.

Most of those doses were evenly distributed between breast (31 percent), lung (34 percent) and colon (31 percent) with another 4 percent being used for prostate cancer. (Exhibit 2)

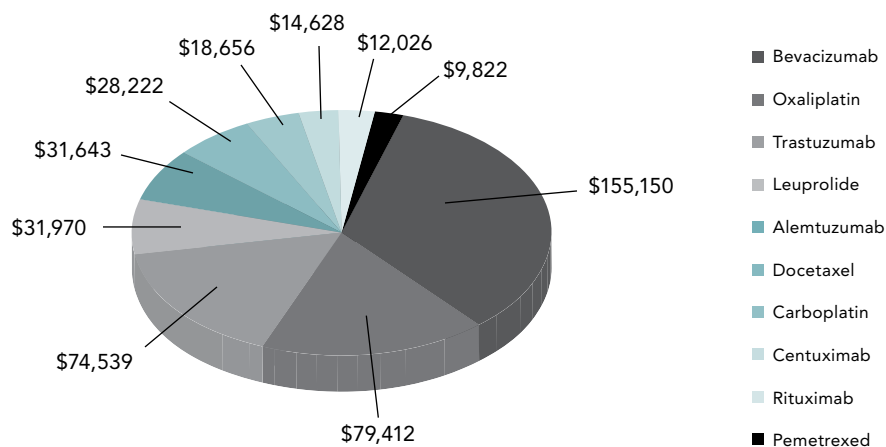
Overall, about one in 10 doses were not administered as originally planned. The doses that did not match the original dose indicated a change from planned treatment: either no dose was given, or the dose was increased or decreased. Colon cancer treatments were the most likely to be changed (16.5 percent), followed by breast (8 percent), prostate (7.4 percent) and lung cancers (5.9 percent). (Exhibit 3), (Exhibit 4)

**Limitations related to Study:** The database

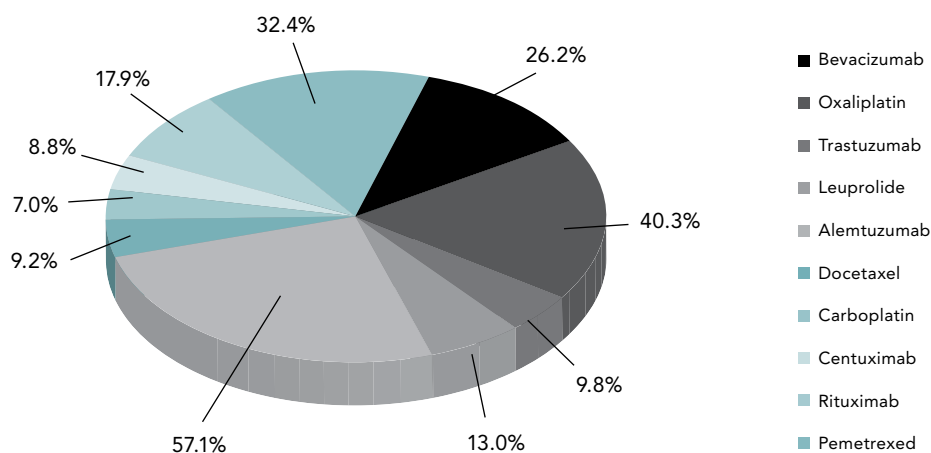
source offers one of the most detailed national records currently available across multiple practices related to the actual utilization of cancer treatment planning versus actual delivery. Health plans only receive claims information from practices related to drugs actually used in treatment. Many physician practice EMRs might track treatments dosed, but not necessarily the original treatment plan if it differed. As detailed as this database was, other variations in treatment were unable to be pulled although they do occur often in actual practice. Such variations uncounted in this study could include:

- Complete changes in regimen based upon a re-assessment of the patient from one treatment to another, especially when related to a change in disease progression.

**Exhibit 7: Top 10 Chemo Drugs "Waste" – doses valued at AWP-17% Dataset 4/1/11 - 3/31/12**



**Exhibit 8: Top 10 Chemo Drugs "Waste" % not matching original dose Dataset 4/1/11 - 3/31/12**



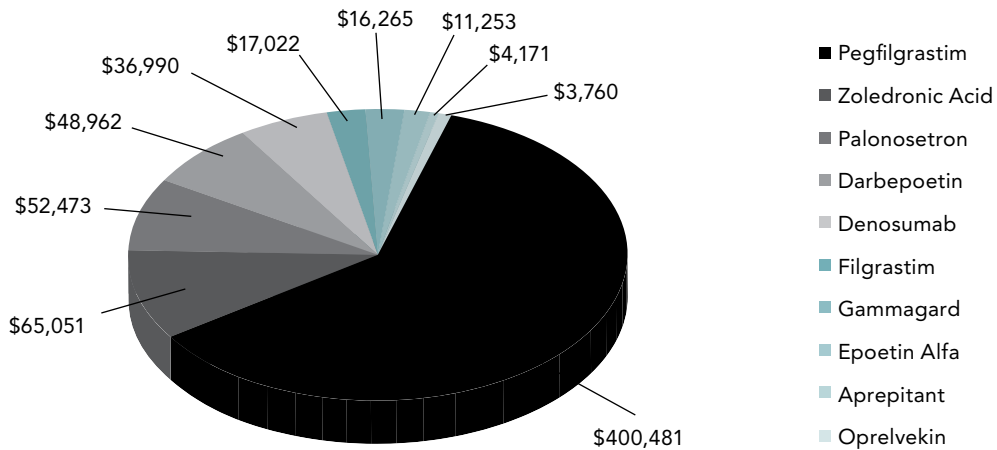
- Undercounting of chemotherapy dosing changes (other reports have suggested higher variation rates – we chose to track only what was documented in this limited data set for these four cancers). Another recent study from ICORE Healthcare found a 20 percent rate of change for shipped cancer drugs – *“Moreover, approximately 20 percent of drugs shipped to a provider’s office fail to be used due to, for example, changes in dose, therapy, duration of therapy, benefit, and higher costs, since partial vial use is not possible when billing NDC-11 codes to the pharmacy benefit.”*
- Under-tracking of actual experience due to escalating volume of documentable cases each month from April 1, 2011 to March 31, 2012. Actual total drug administrations in database for all of 2011 were 13,651. In contrast, the actual total drug administrations in the database for just the first four

months of 2012 (as more practices came online with the EMR and entered data) were 18,495, which if annualized could total 55,485 for 2012. Since the database is in a phase of constant growth, a conservative decision was made to analyze only those administrations that were actually documented for the twelve months of the study period (April 1, 2011 to March 31, 2012 – an actual total of 25, 202.<sup>4</sup>

### Discussion

Oncology patients receiving treatment are evaluated by the treating physician to determine appropriate treatment for the state and stage of the disease. Many, if not most, planned treatments can be a combination of different chemotherapy agents, as well as some combination of ancillary drugs in-

Exhibit 9: Top 10 Ancillary Drugs "Waste" – doses valued at AWP-17% Dataset 4/1/11 - 3/31/12



tended to mitigate toxicities and side effects of the chemotherapy agents. Advances in cancer treatment now allow for more aggressive use of chemotherapy agents when accompanied by the ancillary drugs to help manage the side effects of these toxic chemotherapy drugs, but patients continue to fight on a daily basis the impact of the disease and the treatment on their bodies and minds. Cancer patients are thus evaluated at the beginning of each day of treatment to determine the appropriateness of the planned treatment given their daily medical, physical and psychological condition. While there may be a few times when drugs could be retained to be used later for that same patient, the majority of these cases in practice seem to require that substitution/correction/change/cancellation of drug choice and dosage must occur.

**Estimated Impact of Cancer Treatment Variation from Original Prescription under the two different drug delivery models:** If the planned drug was shipped to the MD office under an "External Delivered Model", and then not given, or more or less drug was actually administered, the unused drug is paid for by the payer upon shipment and cannot be used for another patient or sent back to the shipping facility. It must be discarded and thus becomes "waste". This waste does not exist under the physician Direct Acquisition Model (sometimes also referred to as "Buy and Bill"), because only drug actually administered is billed to the payer by the provider. If planned treatment changes occur under the Direct Acquisition Model, the original drug may be left on the shelf or in the refrigerator for the next patient because it is not "issued" to an individual patient until the moment it is actually

used, and thus remains available for use for the next patient if not needed for the current one.

**Calculation of Impact:** "Potential Waste" – This study looked at chemotherapy treatments ordered and administered by hundreds of oncologists over a one-year period, and where sufficient documentation existed, tracked the frequency, volume and value of when a difference occurred between the specific drugs *initially ordered* and the specific drugs *actually administered* to the patient in the oncology office on the day of treatment.

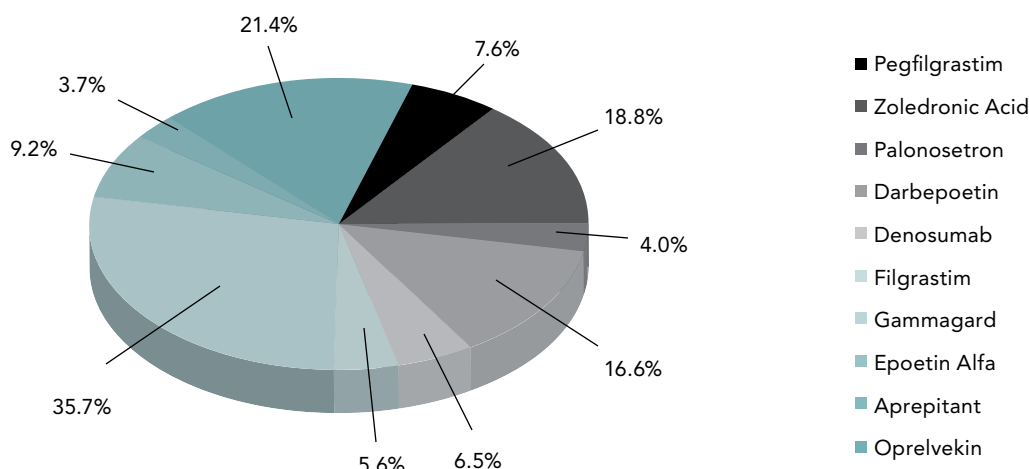
Managed care organizations pay for drugs in two different ways: 1) upon shipment out of a specialty pharmacy before delivery and actual use for a specific patient (usually at a rate of AWP minus 17 percent), or 2) directly to the physician upon submission of a claim for the exact drugs that were administered to the patient in the course of treatment (at a variable rate but ASP + 10 percent is fairly common). If drugs are shipped out of a specialty pharmacy for treatment, but not actually used in the treatment for the patient, the health plan would incur costs for drugs twice for that patient – both the drugs *initially ordered*, as well as *those ultimately administered*.

This study quantified those times where differences occurred between the drugs originally ordered and those administered. It then valued those differences at the most common rate at which health plans pay specialty pharmacies for drugs billed out when shipped (AWP minus 17 percent), to create a reasonable estimate of costs that health plans could incur if oncology drugs were provided under an External Delivered Model rather than a Direct Acquisition Model.

This data drawn from the emerging resource of



Figure 10: Top 10 Ancillary Drugs "Waste" % not matching original dose Dataset 4/1/11 - 3/31/12



electronic medical records in the treating provider office demonstrated that for the documented breast, lung, colon and prostate cancers (if the planned drugs had been shipped before treatment and billed at a usual specialty pharmacy payment rate of AWP minus 17 percent) a potential drug "waste" of over \$1.1 million paid by health plans could have resulted BEFORE payment for the drugs actually used in an individual patient. On a per physician basis, this could amount to close to \$5,000 per treating MD. (Exhibit 5) (Exhibit 6)

With over 6,000 currently practicing oncologists in the United States, a wholesale conversion of all cancer drugs from the Direct Acquisition Model to the External Delivered Model could potentially result, on a conservative basis, in almost \$30 million of shipped and paid for drug becoming "waste" because the patient in whose name those drugs were delivered for some reason was not able to receive the planned treatment on the day of treatment.

**Study projects Potential "Waste", if delivery model were to change, not actual current magnitude of "waste":** Since the majority of cancer drugs are not now delivered by specialty pharmacy to cancer practices but are currently acquired under the Direct Acquisition Model, this "waste" does not yet occur in large quantities. In some areas of the country oncology practices do receive delivered drugs from external sources, and do also anecdotally report high rates of unused drug that has been paid for by the payer but cannot be used by the patient, nor returned. In these circumstances, the drug accumulates in the storage areas of the practices until it can be discarded. It was the existence of these needless situations of "waste" that prompted

the implementation of this study to ascertain the frequency and potential implications of a shift in drug delivery models on a more widespread basis.

It may be useful in another study to assess the degree of current "waste" generated by the few areas where the External Delivered Model does result in shipped drug in advance of the day of treatment. Most of those situations do now involve drugs for Medicaid patients, which are not found in high volumes in private community offices, so the volume and incidence is still fairly low. Variation in treatment for oral chemotherapy drugs and ancillary drugs does also happen and there are a few areas of the country where either state pharmacy policy or private payer oncology policy lead to External Delivered Models for these drugs. Again, this study doesn't quantify the extent of potential "waste" from those situations, but does recognize that there are several reports of similar unusable "waste" accumulating in those practices, for which health plans have already paid.<sup>5</sup>

**Slight Variations can lead to High "Waste":** Even doses not matching rates of less than 10 percent per drug in a given disease can lead to very high "waste" rates at the drug reimbursement rate for specialty pharmacy of about AWP - 17 percent.

While about one in 10 cancer treatments in this 12-month database did show variations in treatment, the majority of those variations (over 90 percent) led to the planned dose not being given at all on the day of treatment. The rest of the variations were from resultant dose increases or decreases. The database was not able to provide the detail of the reason for the variation in treatment for each patient, but oncology practice physicians and nurses have verbal-

ized that patient health status changes are the most common reason that led to an inability to tolerate the treatment, or the need for postponement or cancellation of treatment. These health status changes can occur rapidly in a fragile cancer patient, so assessment of the patient's ability to accept the planned treatment needs to occur on the day of treatment, rather than a day or more in advance.

### **Management of costs in cancer is critical to health plans**

Pharmaceutical spend in cancer, on a per member per year (PMPY) basis, is higher for cancer than for any other therapy class.<sup>6</sup> In the "Distribution of Pharmacy and Medical Specialty Spending, Ranked by Relative Change in Medical Spend, Thomson Reuters MarketScan<sup>®</sup> Commercial Database, 2006-2010", the 2011 Express Scripts Drug Trend Report ranked the top ten therapy classes by per member per year costs for both the medical and pharmacy benefits. Cancer totaled \$68.88 per member per year. Even just 10 percent (\$6.88 PMPY) of the cancer costs amounted to more than the individual per member per year spend for pulmonary hypertension (\$4.03 PMPY), respiratory conditions (\$5.95 PMPY), transplant (\$6.11 PMPY) or hepatitis C (\$2.17 PMPY). All growth deficiency pharmaceutical spend totaled just a little more on a PMPY basis (\$7.92) than 10 percent of the cancer spend. A health plan strategic decision regarding selection of an External Delivered Model that could affect additional health plan expenses for up to one in 10 cancer treatments could have financial implications far greater than all monies spent on any one of those therapy classes.

### **Examples of Specific Percentages of Potential "Waste" Doses and Potential Financial Cost of such "Waste"**

The top 10 chemotherapy and ancillary drugs, as measured by the potential financial cost of possible "waste" are illustrated in Exhibits 7 and 9. Exhibits 8 and 10 also show the percentage of time the original planned dose did not match the actual dose used on the day of treatment. These analyses illustrate that even small rates of treatment doses not matching planned doses can lead to high potential "waste", which would be magnified if applied to every cancer patient in the country. (Exhibits 7,8,9 and 10)

Ancillary drugs are often considered as manageable (and deliverable) separate from chemotherapy drugs by external vendors and oncology drug managers. These ancillary drugs are often considered as primary candidates for External Delivered Models even when chemotherapy drugs may not be by some

health plans. However, the ancillary drugs play a critical role in the success of chemotherapy, and for most cancers other than breast, showed greater variation and potential "waste" impact than the chemotherapy treatments. In breast cancer, the potential financial impact of both chemotherapy and ancillary "waste" was fairly close. The ancillary drugs manage the symptoms and side effects of the toxic chemotherapy treatments (both oral and infused/injectable), and as such are sensitive to variations in the patient's health status on the day of treatment.

- Alemtuzumab in over half of the doses in the database (57.1 percent), did not match the original dose, showing variations that could have resulted in over \$31,000 in total "waste".
- Leuprolide had a rate of just 13 percent not matching but also demonstrated a total "waste" of over \$31,000.
- Bevacizumab reflected a better than one in four dose likelihood of not matching prescribed doses (26 percent), leading to the highest total "waste" of over \$155,000.
- 40.3 percent of oxaliplatin doses didn't match the original plan (about a two in five likelihood per dose), for the second highest total "waste" of over \$79,000.
- The ancillary drug Pegfilgrastim showed a rate of just under one in 10 (less than 8 percent) for not matching the original planned dose, but posted the highest ancillary "waste" total of over \$400,000.

**Summary Observations and Next Steps:** It is clear that there are variations on the day of actual treatment that can become significant to health plans and providers (even if the percentage is below 10 percent) between an original prescribed oncology treatment plan and dosing and the final actual given oncology treatment and doses. These variations and changes have now been quantified because of new documentation and tracking options that were not previously available to the oncology community. As electronic medical records are increasingly utilized in oncology practices, and more complete information is entered, additional information should become available not only about the frequency and volume of such variations, but eventually the reasons.

If the current dominant Direct Acquisition Model were to be eliminated in favor of the External Delivered Model, the timing of both the pre-treatment drug order and fulfillment as well as the payment by the health plan to the billing entity would change dramatically. This study has illustrated the magnitude of how actual drug utilization can vary from the original drug prescription on the day of treatment. Because the payment under the External Delivered Model goes directly from the health plan to

the specialty pharmacy upon shipment of the drug, health plans would end up paying for drug that is not actually used in treatment of the patient. Additionally, the drugs shipped to the oncology practice for an individual patient, that are not actually used must be discarded at a management cost to the oncology practice. They cannot be returned nor used for another patient under pharmacy regulations. Specialty pharmacies are usually paid by health plans at a rate of about AWP minus 17 percent, so it was possible for this study to value the potential “waste” that could occur from unused but shipped drug under an External Delivered Model.

The study revealed significant potential financial costs that could be incurred by health plans under a shift to a External Delivered Model (on a conservative basis almost \$5,000 per treating oncology provider) before the costs of the drugs actually used in treatment for the patients. The study also showed that conservatively, at least one in 10 cancer treatments for the top four cancers are likely to result in the treatment not matching the original plan. Additional notable findings were as follows:

- There is potential for a high dollar impact to health plans even if there are fairly low (under 10 percent) variations in drug use resulting from same day patient health status changes.
- Many chemotherapy drugs observed in this study do have notable rates of variation from planned doses – most between 10 and 20 percent and some even as high as 100 percent.
- In lung, prostate and colon cancers, there is even a higher potential dollar impact on health plans from variations in ancillary drugs used to support high density chemotherapy administration than there is in the chemotherapy drugs used for those cancers. Ancillary and chemotherapy impact is fairly equal for breast cancer treatments; yet, ancillary drugs are more likely to be considered as candidates for movement to Delivered Drug Models through a specialty pharmacy.

**Implications for the future for health plans and providers:** This study has demonstrated and quantified a reality of the complexity of cancer treatment for fragile cancer patients that has previously gone unmeasured or quantified in a formal manner. Health plans, specialty pharmacies and oncology providers are likely to examine the potential logistical and financial implications of a shift from a Direct Acquisition Model to an External Delivered Model carefully in light of these findings.

It appears to be essential that if drugs were to be delivered to an oncology practice, it would need to happen in a timely fashion after the patient assessment has occurred, and any subsequent treatment

changes have been made. Logistically, this would be extremely difficult to manage for each cancer treatment site on the same day of treatment, and yet it would not be medically practical to assess the patient on other than the day of treatment. Health plans will not want to pay for drugs that are shipped but not used, and we cannot afford as a society to create a situation that will lead to huge numbers of cancer drugs having to be discarded.

There are some External Delivered Models in practice that have demonstrated that timing and assessment hurdles can be surmounted. This study was presented so that the entire community that cares for and pays for cancer treatments can better understand some of the variables that the different models bring, not to suggest that one model is inherently better than the other. As health plans, treating providers and specialty pharmacies continue to address changes in oncology management, an understanding of the complexity of the delivery of cancer treatment to fragile oncology patients will help all entities to make informed decisions.

The U.S. Drug Enforcement Administration’s (DEA’s) fifth semiannual National Takeback Day program was held on September 29, 2012. At the previous event, in April 2012, 276 tons of unused, expired, or excess medication was collected, bringing the total for the four previous events held to over 1.5 million pounds (774 tons).<sup>7</sup> This medication waste resulted mostly from medications that the general public had taken home but were unable to take as planned. It is not likely that the pharmacy regulations governing the management of medications that have been prescribed for an individual will be significantly changed, but it is possible to consider the implications of oncology drug management policy in light of these new findings on the complexity of cancer patients during treatment.

### Obtaining the Report

The full report on this Impact on Cancer Drug Costs from Different Delivery Models is available from the National Association of Managed Care Physicians, by contacting Katie Eads at [keads@namcp.org](mailto:keads@namcp.org) or 804-527-1905. In the full report, further details are provided on the analyses and specific variations for each of the four major cancers: breast, lung, colon and prostate.

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