

A study on minimizing discarded chemotherapy drugs and financial consequences for Medicare part B in USA healthcare system.

Dissertation submitted to



The IIHMR University, Jaipur

for the partial fulfilment for the award of the
degree of Master of Business Administration
MBA - Hospital Management

by

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Under the Supervision and Guidance of

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2023

DECLARATION BY STUDENT

I hereby declare that the dissertation titled “A study on minimizing discarded chemotherapy drugs and financial consequences for Medicare part B in USA healthcare system” is the bona fide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published work of others has been duly acknowledged in the text.

(Signature)

Dr. Anamitra Sarkar

31st May 2023

CERTIFICATE FROM FACULTY GUIDE AND SCHOOL DEAN

This is to certify that dissertation “A study on minimizing discarded chemotherapy drugs and financial consequences for Medicare part B in USA healthcare system” is a record of the research work undertaken by Anamitra Sarkar in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

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Date - 3rd June 2023

ABSTRACT

Objectives

- Analyzing the current spending trend of chemotherapy drugs in Medicare part B between 2017-2021.
- Determining the extent of discarded drugs in chemotherapy treatments for Medicare part B.

Methodology

Study Design: Analytical observational study design

Study Setting:

The study setting is based on USA healthcare system and the data comes from claims data which deals with claims involving outpatient care and doctor visits, which are part of Medicare part B. Additionally, it includes some home health care services and limited physical and occupational therapy services, both of which are not covered by any other part of programme.

1] Part B Discarded Drug Units dataset

The data comes from claims data for drugs that were administered in doctors' offices and other outpatient settings and paid through the Medicare part B program.

2] Medicare part B Spending by Drug dataset

This dataset is based on information gathered from CMS administrative claims data for Medicare beneficiaries enrolled in the Part B program.

Study population:

The study population is based in USA. The data deals in health insurance plan for:

- Individuals over the age of 65.
- people with specific disabilities under the age of 65.
- All ages of individuals with end-stage renal disease, which results in permanent kidney failure and calls for dialysis or a kidney transplant.

1] Part B Discarded Drug Units dataset

Inclusion criteria :

Medicare Billing Code (HCPCS Code), Brand Name, Generic Name, Total Medicare Allowed Amount, Total Allowed Amount for Units Administered, Total Allowed Amount for Units Discarded, Administered Units as % of Total Allowed Amount, Discarded Units as % of Total Allowed Amount from claims data.

Exclusion criteria:

Other indicators in the claims data were excluded.

2] Medicare part B Spending by Drug dataset

Inclusion criteria :

Medicare Billing Code (HCPCS Code), Brand Name, Generic Name, Year, Count, Total Spending, Total Dosage Units, Average Spending Per Dosage Unit from CMS administrative claims data

Exclusion criteria:

Other indicators in the CMS administrative claims data were excluded.

Study tools:

- Questionnaire
- Research articles
- CMS datasets

Duration of study:

3 months [1st March 2023 to 31st May 2023]

Sample size:

Part B Discarded Drug Units report for year 2021 – Latest updated year

Medicare part B Spending by Drug dataset [2017-21] – Latest updated data

Sampling technique:

Convenience sampling

Data collection procedure:

Primary Research:

Data collected through telephonic interview to understand the payer perspective on discarded chemotherapy drugs.

Secondary Research:

- The Drug dataset from source provided information on spending for medications given to Medicare part B enrollees in physician offices and outpatient settings by doctors and other healthcare providers.
- The dataset focused on avg spent per dosage unit and changes in avg spent per dosage unit over time.
- The other report from source provided spending information for Medicare part B drugs claims that were identified as drugs which were discarded.

Data Analysis Plan:

Primary research

- Through telephonic interview, insights and opinions based on experience and perspective of respondents from payer fraternity was taken to understand the challenges and potential solutions related to the reimbursement and waste issues associated with Medicare part B drugs.
- The survey respondents in primary research analysis represented national or regional health plans, including 51 commercial payers, 34 managed care organizations, 34 preferred provider organizations and 31 pharmacy benefit managers. (n=152).

Secondary research

- The data analysis plan had been divided into 2 essential parts.
- The first part dealt with analysis of Medicare part B by Drug dataset to investigate the trends of chemotherapy drug.
- The analysis was done on parameters like count, total spending, avg spent per dosage units and percentage change of the mentioned parameters.
- The above-mentioned parameters were isolated from the dataset by the identifier “J-codes” in “HCPCS codes” column for each year from 2017-2021 and compared for each of the “J-codes” using appropriate statistical techniques.
- The second part dealt with analysis of source report to gain insight into the percentage of discarded chemotherapy drugs and the total spending of discarded drugs which could be potentially saved.
- So, two types of analysis were performed in this.
- The first analysis was conducted to understand the number of chemotherapy drugs which had a discarded unit of a certain percentage and for this, we

divided total Medicare allowed amount for discarded units by total Medicare allowed amount. From this, discarded percentage was calculated for all the chemotherapy drugs which had a discarded dose amount.

- In the second analysis, all the “J-codes” relating to chemotherapy drugs were isolated and arranged according to total Medicare allowed amount of the discarded drugs from highest to lowest.
- Total of 100 chemotherapy drugs out of 125 had discarded units. Then, for each of 10 chemotherapy drugs, a category was assigned. Therefore, a total of 10 categories were established. For each category, total Medicare allowed amount for discarded units was calculated in decreasing order, cumulative calculated and cumulative percentage calculated.
- On the basis of the above-mentioned process, a pareto chart was prepared and analyzed.
- The report was examined with the aim to identify opportunities for optimizing drug utilization, reducing waste, and maximizing the potential value of discarded chemotherapy drug units.
- Through these analyses, appropriate statistical techniques were utilized, and software was used to examine the datasets, identify trends, and draw meaningful conclusions.

Ethical considerations:

- Protect privacy and confidentiality of all interviewed personnel.
- Protect privacy and confidentiality of beneficiaries in the data provided.
- Data file cleaned of all direct identifiers.

Key Results

Insights on trends of Medicare part B drugs presented that Chemotherapy drugs have seen significant deviations with respect to their count, change in count, total spending, change in total spending, average spending per dose, percentage change in average spending per dose for 5 years from 2017 to 2021.

Analysis was also done regarding the wastage and financial loss due to discarded units and the result achieved was that total spending (patient + payer) due to discarded units pertaining to 10% or more, was approximately \$ 328,709,379. Also the total spending (patient + payer) due to discarded units of all chemotherapy drugs was approximately \$ 486,188,485.

Conclusion

it can be concluded that Chemotherapy drugs belongs to the most significant category due to its increase in number, percentage change in total spending, average spending per dose, percentage change in average spending per dose and percentage change in average spending per beneficiary.

Due to this fact, it becomes noteworthy when chemotherapy doses are discarded because of more than required amount of dose in the drug packaging and which in turn leads to financial consequences among patient and payer fraternity.

Some of the recommendations to prevent wastage due to discarding of chemotherapy drugs on the basis of exploring various research articles are vial sharing, drug vial optimization, dose banding, dose rounding and dose capping but further deep research along with experimental results are required to consider them as safe and viable technique to prevent wastage due to discarding.

ACKNOWLEDGEMENT

The dissertation report titled “A study on minimizing discarded chemotherapy drugs and financial consequences for Medicare part B in USA healthcare system” is the result of lot of effort and sleepless nights. The topic was chosen in accordance with the current need of the organization and industry environment.

I would like to express my deepest gratitude to Shweta Vilatia Ma'am and the team for their support and encouragement in performing the tasks within the organization, providing me great insightful knowledge on data analysis, and providing clarity on the topic for my dissertation.

I extend my sincere appreciation and regards to my mentor Dr. Mamta Chauhan for her constant guidance and help with the dissertation. A special regard to Dr. Mahender Kumar and IIHMR University, Jaipur for providing me this opportunity. The placement team, IIHMR library as well as the IIHMR academics team was also very helpful during this process.

Last but not the least, I am really grateful for all the love and support I received from my family and friends, not just for the dissertation but for every aspect of my life.

Finally, I would like to thank God, for giving me the strength and encouragement throughout all the challenging moments of completing the dissertation.

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ABBREVIATIONS

CMS	Centres for Medicare and Medicaid Services
HHS	Health and Human Services
HCPCS	Healthcare common procedure coding system
GDP	Gross domestic product
DNA	Deoxy ribonucleic acid

Chapter 1: INTRODUCTION

The most recent statistics update from CMS shows that “American healthcare spending represented 18.3% of GDP in 2021. This is a decrease from 19.7% of GDP in 2020, primarily as a result of higher economic growth and lower federal financing for COVID-19. However, healthcare expenses in the US continue to be higher than they were prior to the pandemic, and they continue to be a major contributor to the unmanageable national debt. Spending on healthcare in the United States reached \$4.3 trillion in nominal terms in 2021, or roughly \$12,900 per person, a rise of almost 3.0 percent from the year before.” In 2021, spending on healthcare increased across the board for these key funding sources:

- The amount spent on private health insurance increased by 5.8%, accounting for \$1.2 trillion of total healthcare spending in 2021. The growth was mostly fueled by increases in the cost of medical supplies and services as private health insurance use and enrolment increased.
- Medicare Advantage and the standard fee-for-service program also saw rises in 2021, bringing the overall cost of the program to \$901 billion, an 8.4% increase.
- Medicaid spending increased by 9.2 percent to \$734 billion, partly as a result of a 22.3 percent increase in enrolment that can be attributed to the COVID-19 public health emergency clause, which is only temporary and was set to expire on May 11, 2023.
- Following a decline in use due to the COVID-19 pandemic's effects in 2020, out-of-pocket spending increased by 10.4 percent as more people used medical services and products.

Centers for Medicare & Medicaid Services

CMS is part of HHS (Health and Human services) and provides health coverage to more than 100 million people through various health insurance programmes.

Medicare part B

According to CMS, “Medicare part B is a health insurance plan for:

- Individuals over the age of 65.
- people with specific disabilities under the age of 65.
- All ages of individuals with end-stage renal disease, which results in permanent kidney failure and calls for dialysis or a kidney transplant.”

Outpatient care and doctor visits are part of Medicare part B. Additionally, it includes some home health care services and limited physical and occupational therapy services, both of which are not covered by any other part of programme.

Chemotherapy drugs

Chemotherapy involves getting rid of aberrant cells that divide quickly. In order to eradicate all of the unhealthy cells, chemicals and lasers are used. An oncologist is a doctor who specialises in this area of medicine. Chemotherapy is the term used to describe the process of eliminating cancer cells in a patient. Chemotherapy may be used with other therapies like radiation therapy or surgery to eradicate the cancerous tissue or cells,

depending on the stage of the disease and the affected body area. Chemotherapy as a whole is damaging to human health and weakens the body's defences against future ailments.

Chemotherapy drugs are those taken during chemotherapy, sometimes known as "chemo." One of the most popular and efficient cancer therapies is chemotherapy. It eliminates rapidly proliferating cells, such as cancer cells, and stops their growth.

The cell cycle is the process by which all types of cells, including healthy and cancerous cells, reproduce. A cell divides to create new cells and copies its genetic material (DNA) during the cycle. When necessary, healthy cells divide, and when no longer required, they die (apoptosis). On the other hand, cancer cells do not perish. Instead, they grow uncontrollably and develop tumours that can harm healthy tissue.

Chemotherapy drugs disrupt the cell cycle, killing cancer cells and stopping them from proliferating. Different chemotherapy medications work against cancer by altering the cell cycle in various ways.

Discarded units of chemotherapy drugs

- There is a significant waste of costly cancer medications, which has an impact on patients' finances.
- Even though reducing waste in healthcare sector is crucial, no one has considered the waste that can result from discarding of expensive chemotherapy drugs being packaged in quantity more than required.
- This is especially true for medications that come in single dose containers and whose dosage is determined by the weight of patient or size of body.
- Since individuals have different sized body and are not likely to fit the amount of drug in vial, there is roughly constantly some remaining over once these drugs are opened.
- Now, since the remaining drug still needs to be paid for even if it is thrown away, drug manufacturers can artificially raise the amount of dosage they sell per treated patient relative to typically required dosage.

HCPCS code

“Collection of standardized codes that represent medical procedures, supplies, products, and services. The codes are used to facilitate the processing of health insurance claims by Medicare and Medicaid.”

J-codes

“HCPCS code issued by CMS, which consist of a letter and four numbers and represent the medication and total dosage.”

Chapter 2: LITERATURE REVIEW

Authors name and Year	Title	Methodology	Results
“Caleb Scheckel, Aakash Desai, Chelsea Jensen, Jacob Orme, Joshua Pritchett, Amit Mahipal, Nandita Khera, Ronald S. Go(2022) ¹ ”	“Medicare expenditures for discarded oncology therapies”	Retrospective sampling technique was used on database to extract the samples with discarded units and therapies with high percentage of waste was identified.	• Medicare costs would have decreased by a median amount of \$153 million annually if the particular legislation had been applied early. • Strategies to reduce discarded units could result in significant cost savings and promote health equity in regions having trouble accessing these medications.
“Trovato A, Tyler LS, Nickman NA, Findlay R. (2022) ² ”	“Interventions to reduce waste and improve billing compliance with medications in single-dose vials”	Mapping of process was done from order entry to claims process and to identify drug waste, process map was used for three drugs of elevated risk of redundant waste.	• The study was done to incorporate elements in the electronic health records that would help in lowering unjustified drug waste for outpatient patients using vials of single amount. • The institute decreased drug waste and made financial savings by using a grouper and dose rounding.
“Shah V, Spence A, Bartels T, Betcher J, Soefje S. (2022) ³ ”	“Decreasing drug waste, reducing drug costs, improving workflow efficiency through the implementation of automated chemotherapy dose rounding rules in the	Systemic literature review was done to develop a technique to bring the dose to the nearest vial size.	• This study was conducted to integrate new techniques in the electronic health record, to mitigate drug discard and cost. • The results were positive, and the clinic was able to save large number of vials and thus reduce expenses based on the dose

	electronic health record system.”		rounding process.
“Ya-Chen T. Shih, Ying Xu, Hui Zhao, James C. Yao(2020) ⁴ ”	“Financial burden of discarded weight-based antineoplastic drugs to payers and patients in the private insurance market.”	From their claims data base, identification of patients was done on weight-based antineoplastic drugs. Using it, recommended dose and discarded percentage was calculated, and beta-regression technique applied to investigate factors associated with discarded percentages.	• The findings of the study show that payers were heavily burdened financially as a result of cancer drugs disposal. • The study also showed that private insured patients had a modest out of pocket expenditure, where only approximately five percent paid more than \$400 for wasted drugs.
“Lien K, Cheung MC, Chan KK. (2016) ⁵ ”	“Overspending driven by oversized single dose vials of cancer drugs.”	Typical doses calculated based on patient weights and skin area and amount of costs related to discarded units examined.	• This study looked at how often financial assessments of current parenteral therapy for hematologic malignancies utilized drug wastage modelling. • One of the vital findings of the study was examination of discrepancy between available vial sizes and frequently recommended dose of a particular cancer drug.

Chapter 3: METHODOLOGY

3.1 Research Questions

What is the extent of discarded chemotherapy drugs in Medicare part B?

3.2 Objectives

- Analyzing the current spending trend of chemotherapy drugs in Medicare part B between 2017-2021
- Determining the extent of discarded drugs in chemotherapy treatments for Medicare part B

3.3 Hypothesis

- H0 (Null hypothesis) – The extent of discarded drugs in chemotherapy treatments for Medicare part B is negligible or within an acceptable range.
- H1 (Alternative hypothesis) – The extent of discarded drugs in chemotherapy treatments for Medicare part B is significant and exceeds an acceptable range.

3.4 Materials & Methods

3.4.1 Study Design : Analytical observational study design

3.4.2 Study Setting :

The study setting is based on USA healthcare system and the data comes from claims data which deals with claims involving outpatient care and doctor visits, which are part of Medicare part B. Additionally, it includes some home health care services and limited physical and occupational therapy services, both of which are not covered by any other part of programme.

1] Part B Discarded Drug Units dataset

The data comes from claims data for drugs that were administered in doctors' offices and other outpatient settings and paid through the Medicare part B program.

2] Medicare part B Spending by Drug dataset

This dataset is based on information gathered from CMS administrative claims data for Medicare beneficiaries enrolled in the Part B program.

3.4.3 Study population :

The study population is based in USA. The data deals in health insurance plan for:

- Individuals over the age of 65.
- people with specific disabilities under the age of 65.
- All ages of individuals with end-stage renal disease, which results in permanent kidney failure and calls for dialysis or a kidney transplant.

1] Part B Discarded Drug Units dataset

Inclusion criteria :

Medicare Billing Code (HCPCS Code), Brand Name, Generic Name, Total Medicare Allowed Amount, Total Allowed Amount for Units Administered, Total Allowed Amount for Units Discarded, Administered Units as % of Total Allowed Amount, Discarded Units as % of Total Allowed Amount from claims data.

Exclusion criteria:

Other indicators in the claims data were excluded.

2] Medicare part B Spending by Drug dataset

Inclusion criteria :

Medicare Billing Code (HCPCS Code), Brand Name, Generic Name, Year, Total Spending, Total Dosage Units, Total Claims, Total Beneficiaries, Average Spending Per Dosage Unit, Average Spending Per Claim, Average Spending Per Beneficiary from CMS administrative claims data

Exclusion criteria:

Other indicators in the CMS administrative claims data were excluded.

3.4.4 Study tools:

- Questionnaire
- Research articles
- CMS datasets

3.4.5 Duration of study:

3 months [1st March 2023 to 31st May 2023]

3.4.6 Sample size:

Part B Discarded Drug Units report for year 2021 – Latest updated year

Medicare part B Spending by Drug dataset [2017-21] – Latest updated data

3.4.7 Sampling technique:

Convenience sampling

3.4.8 Data collection procedure:

Primary Research:

Data collected through telephonic interview to understand the payer perspective on discarded chemotherapy drugs.

Secondary Research:

- The Drug dataset from source provided information on spending for medications given to Medicare part B enrollees in physician offices and outpatient settings by doctors and other healthcare providers.
- The dataset focused on avg spent per dosage unit and changes in avg spent per dosage unit over time.
- The other report from source provided spending information for Medicare part B drugs claims that were identified as drugs which were discarded.

3.4.9 Data Analysis Plan:

Primary research

- Through telephonic interview, insights and opinions based on experience and perspective of respondents from payer fraternity was taken to understand the challenges and potential solutions related to the reimbursement and waste issues associated with Medicare part B drugs.
- The survey respondents in primary research analysis represented national or regional health plans, including 51 commercial payers, 34 managed care organizations, 34 preferred provider organizations and 31 pharmacy benefit managers. (n=152).

Secondary research

- The data analysis plan had been divided into 2 essential parts.
- The first part dealt with analysis of Medicare part B by Drug dataset to investigate the trends of usage of chemotherapy drug.
- The analysis was done on parameters like count, total spending, avg spent per dosage units and percentage change of the mentioned parameters.

- The above-mentioned parameters were isolated from the dataset by the identifier “J-codes” in “HCPCS codes” column for each year from 2017-2021 and compared for each of the “J-codes” using appropriate statistical techniques.
- The second part dealt with analysis of source report to gain insight into the percentage of discarded chemotherapy drugs and the total spending of discarded drugs which could be potentially saved.
- So, two types of analysis were performed in this.
- The first analysis was conducted to understand the number of chemotherapy drugs which had a discarded unit of a certain percentage and for this, we divided total Medicare allowed amount for discarded units by total Medicare allowed amount. From this, discarded percentage was calculated for all the chemotherapy drugs which had a discarded dose amount.
- In the second analysis, all the “J-codes” relating to chemotherapy drugs were isolated and arranged according to total Medicare allowed amount of the discarded drugs from highest to lowest.
- Total of 100 chemotherapy drugs out of 125 had discarded units. Then, for each of 10 chemotherapy drugs, a category was assigned. Therefore, a total of 10 category were established. For each category, total Medicare allowed amount for discarded units was calculated in decreasing order, cumulative calculated and cumulative percentage calculated.
- On the basis of the above-mentioned process, a pareto chart was prepared and analyzed.
- The report was examined with the aim to identify opportunities for optimizing drug utilization, reducing waste, and maximizing the potential value of discarded chemotherapy drug units.
- Through these analyses, appropriate statistical techniques were utilized, and software was used to examine the datasets, identify trends, and draw meaningful conclusions.

3.4.10 Ethical considerations:

- Protect privacy and confidentiality of all interviewed personnel.
- Protect privacy and confidentiality of beneficiaries in the data provided.
- Data file cleaned of all direct identifiers.

Chapter 4 : FINDINGS

Primary research findings

1] The number of respondents on the basis of 3 categories who are familiar with drugs administered by physician in Medicare part B and the percentage of categories are as follows -

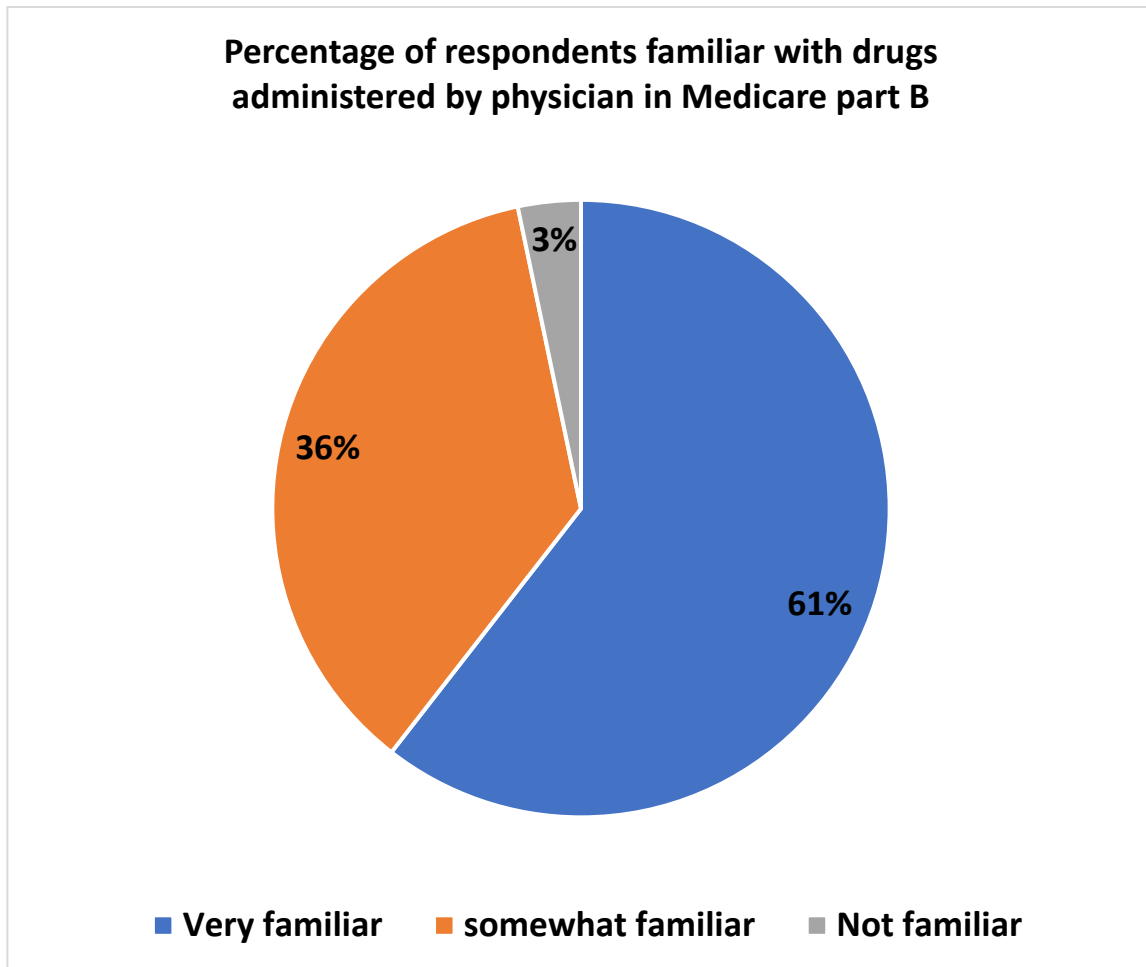


Figure 8.1 Percentage of respondents familiar with drugs administered by physician in Medicare part B

- 92 respondents out of 152 interviewed respondents were very familiar with Medicare part B drugs which formed 61% of total interviewed respondents.
- 55 respondents out of 152 interviewed respondents were somewhat familiar with Medicare part B drugs which formed 36% of total interviewed respondents.
- 5 respondents out of 152 interviewed respondents were very familiar with Medicare part B drugs which formed 3% of total interviewed respondents.

2] The number of respondents on the basis of 3 categories who are familiar with drugs administered by physician in Medicare part B indicating the category which leads to more Medicare part B spending are as follows –

Table 8.1 Category leading to more Medicare part B spending according to respondents

Familiarity with physician-administered drugs in Medicare part B	Category leading to more Medicare part B spending	Respondents
Very familiar [n = 92]	Drugs administered by injection	45
	Chemotherapy drugs	47
	Clotting factor drugs	0
	Miscellaneous drugs	0
	Inhalational solutions	0
	Immunosuppressive drugs	0
Somewhat familiar [n = 55]	Drugs administered by injection	27
	Chemotherapy drugs	24
	Clotting factor drugs	2
	Miscellaneous drugs	0
	Inhalational solutions	1
	Immunosuppressive drugs	1
Not familiar [n = 5]	Drugs administered by injection	1
	Chemotherapy drugs	1
	Clotting factor drugs	0
	Miscellaneous drugs	1
	Inhalational solutions	0
	Immunosuppressive drugs	2

3] The table below shows the number of respondents on the basis of 3 categories who are familiar with drugs administered by physician in Medicare part B indicating the category which leads to more spending on Medicare part B for each dose are as follows –

Table 8.2 Category leading to more spending on Medicare part B for each dose according to respondents

Familiarity with physician-administered drugs in Medicare part B	Category leading to more spending on Medicare part B for each dose	Respondents
Very familiar [n = 92]	Drugs administered by injection	35
	Chemotherapy drugs	57
	Clotting factor drugs	0
	Miscellaneous drugs	0
	Inhalational solutions	0
	Immunosuppressive drugs	0
Somewhat familiar [n = 55]	Drugs administered by injection	19
	Chemotherapy drugs	33
	Clotting factor drugs	1
	Miscellaneous drugs	0
	Inhalational solutions	1
	Immunosuppressive drugs	1
Not familiar [n = 5]	Drugs administered by injection	1
	Chemotherapy drugs	1
	Clotting factor drugs	0
	Miscellaneous drugs	1
	Inhalational solutions	1
	Immunosuppressive drugs	1

4] The following figure depicts awareness of respondents about the financial consequences of discarding Medicare part B drugs –

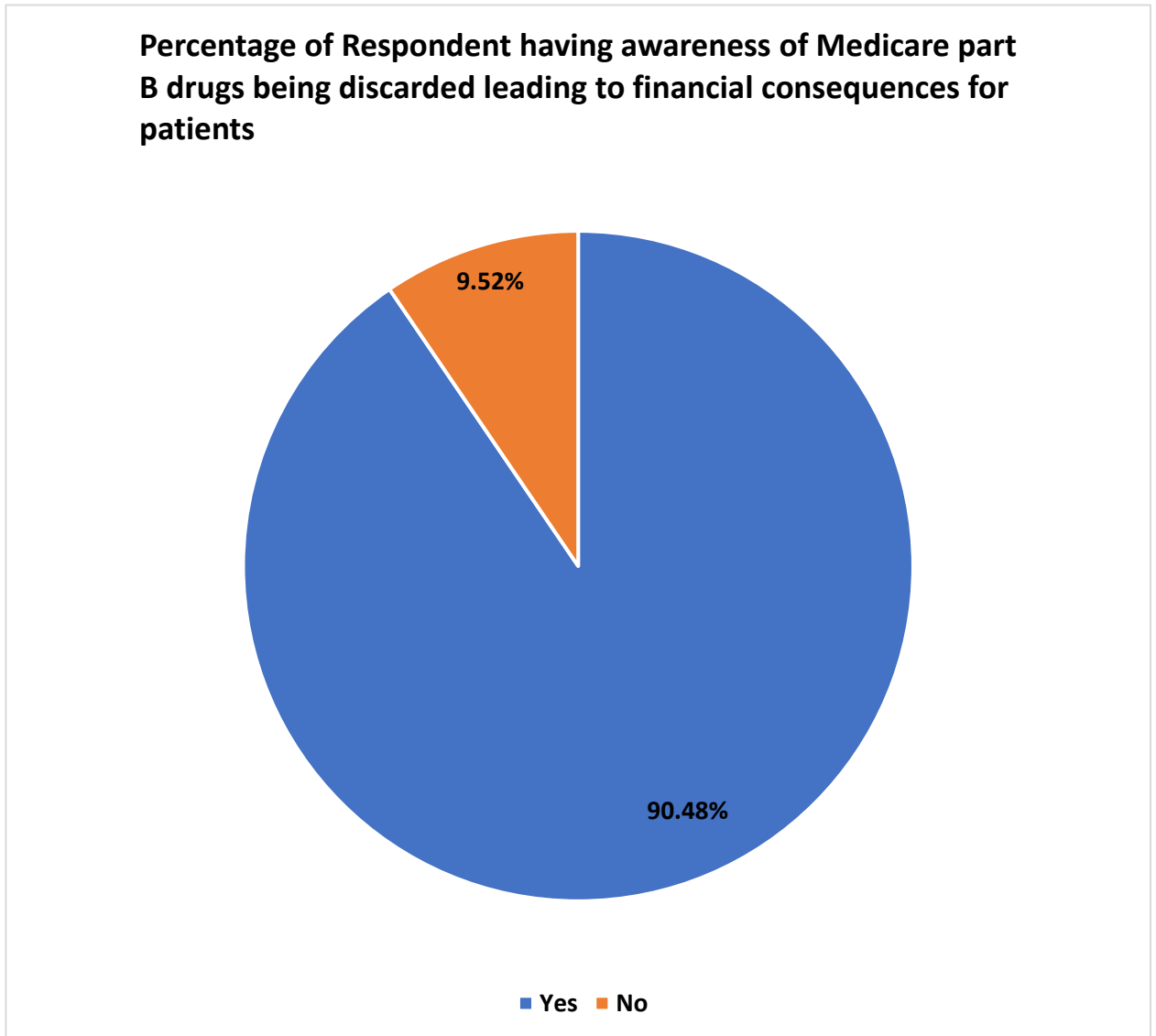


Figure 8.2 Percentage of respondents having awareness of Medicare part B drugs being discarded leading to financial consequences for patients

- The respondents under “Not familiar” category were removed from further analysis since they would not be able to contribute significantly to the study.
- 133 respondents out of 147 interviewed respondents, forming 90.48% were aware of financial consequences to patients due to discarding of Medicare part B drugs.
- 14 respondents out of 147 interviewed respondents, forming 9.52% were aware of financial consequences to patients due to discarding of Medicare part B drugs.

5] This figure addresses about the drug category leading to highest discarded units' wastage in Medicare part B according to respondents –

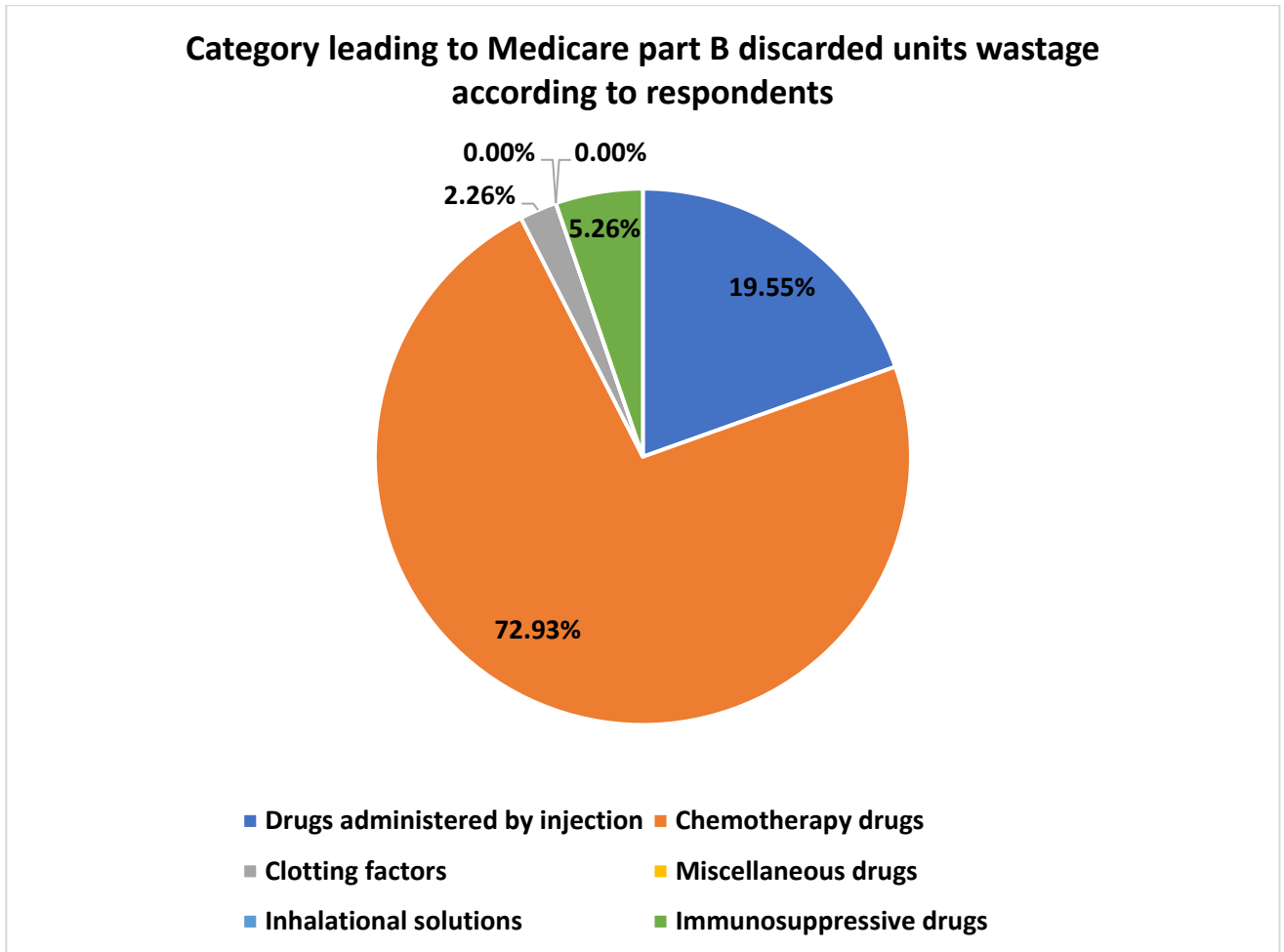


Figure 8.3 Percentage of respondents indicating drug category leading to highest Medicare part B discarded units wastage

- The respondents under “Not familiar” category were removed from further analysis since they would not be able to contribute significantly to the study.
- 97 respondents out of 147 interviewed respondents, forming 72.93% responded that chemotherapy drugs” category led to highest discarded units’ wastage of Medicare part B drugs, while 26 respondents out of 147 interviewed respondents, forming 19.55% responded that “Drugs administered by injection” category led to highest discarded units’ wastage of Medicare part B drugs.
- Lastly, 10 respondents of 147 interviewed respondents, forming 7.52% responded that “Immunosuppressive drugs” and “Clotting factor drugs” category led to highest discarded units’ wastage of Medicare part B drugs.

6] This figure talks about respondents' response to need for regulations required by drug manufacturers for appropriate packaging –

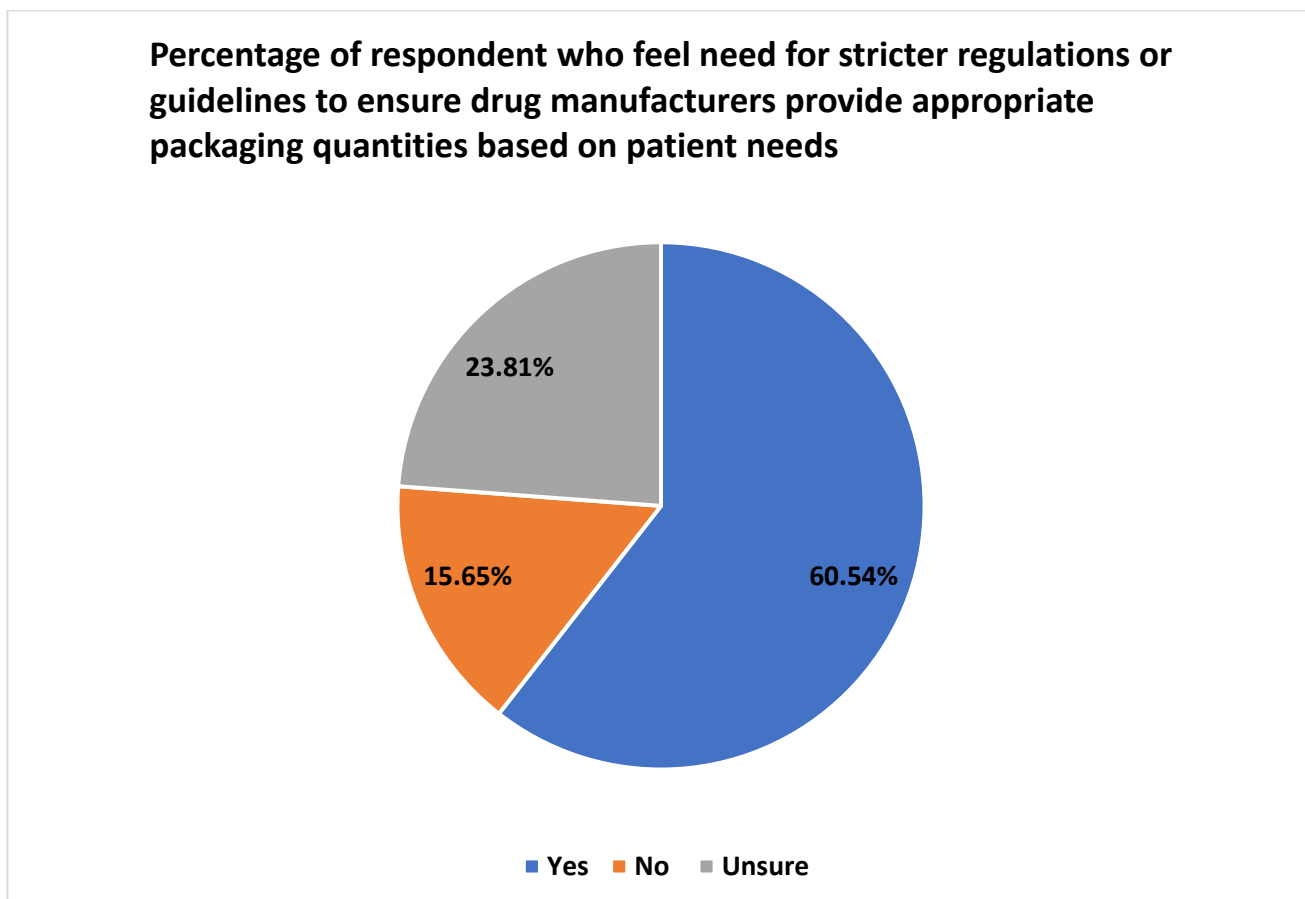


Figure 8.4 Percentage of respondents who feel need for stricter regulations or guidelines to ensure drug manufacturers provide appropriate packaging quantities based on patient needs

- The respondents under “Not familiar” category were removed from further analysis since they would not be able to contribute significantly to the study.
- 89 respondents out of 147 interviewed respondents, forming 60.54% felt that stricter regulations or guidelines should be followed to ensure drug manufacturers provided appropriate packaging quantities according to needs of patient, while 23 respondents out of 147 interviewed respondents, forming 15.65% felt that stricter regulations or guidelines should be followed to ensure drug manufacturers provided appropriate packaging quantities according to needs of patient
- Lastly, 35 respondents of 147 interviewed respondents were unsure about the same.

7] The following table depicts the response of respondents to potential solutions of waste due to discarded units of drugs –

Table 8.3 Payer perspective on potential solutions.

Payer perspective on potential solutions	Answer	Respondent
Should reimbursement mechanisms or payment structures be revised to incentivize appropriate packaging quantities and reduce waste?	Yes	101
	No	3
	Unsure	43
Is there a need for increased collaboration between stakeholders to address the problem of discarded units of chemotherapy drugs?	Yes	119
	No	1
	Unsure	27

- When it came to reimbursement mechanisms or payment structures to be revised to incentivize appropriate packaging quantities and reduce waste, approximately 69% of respondents answered in positive, while 2% replied in negative and rest 39% were unsure.
- As for an increased need for collaboration between stakeholders to address the problem of discarded units of chemotherapy drugs, approximately 81% of respondents answered in positive, while 1% replied in negative and rest 18% were unsure.

Secondary research results

Medicare part B Spending by Drug dataset

1] The following table and figure helps in determining the trend of number of Medicare part B drugs from 2017 to 2021 –

Table 8.4 Trend analysis of count of Medicare part B drugs from 2017-2021

Drug category	Number [2017]	Number [2018]	Number [2019]	Number [2020]	Number [2021]
Drugs administered by injection	271	277	297	306	319
Chemotherapy drugs	92	95	107	113	125
Clotting factors	19	19	26	27	30
Immunosuppressive drugs	16	16	16	16	16
Inhalational solutions	15	15	15	16	16
Miscellaneous drugs	9	9	11	13	15
Grand Total	422	431	472	491	521

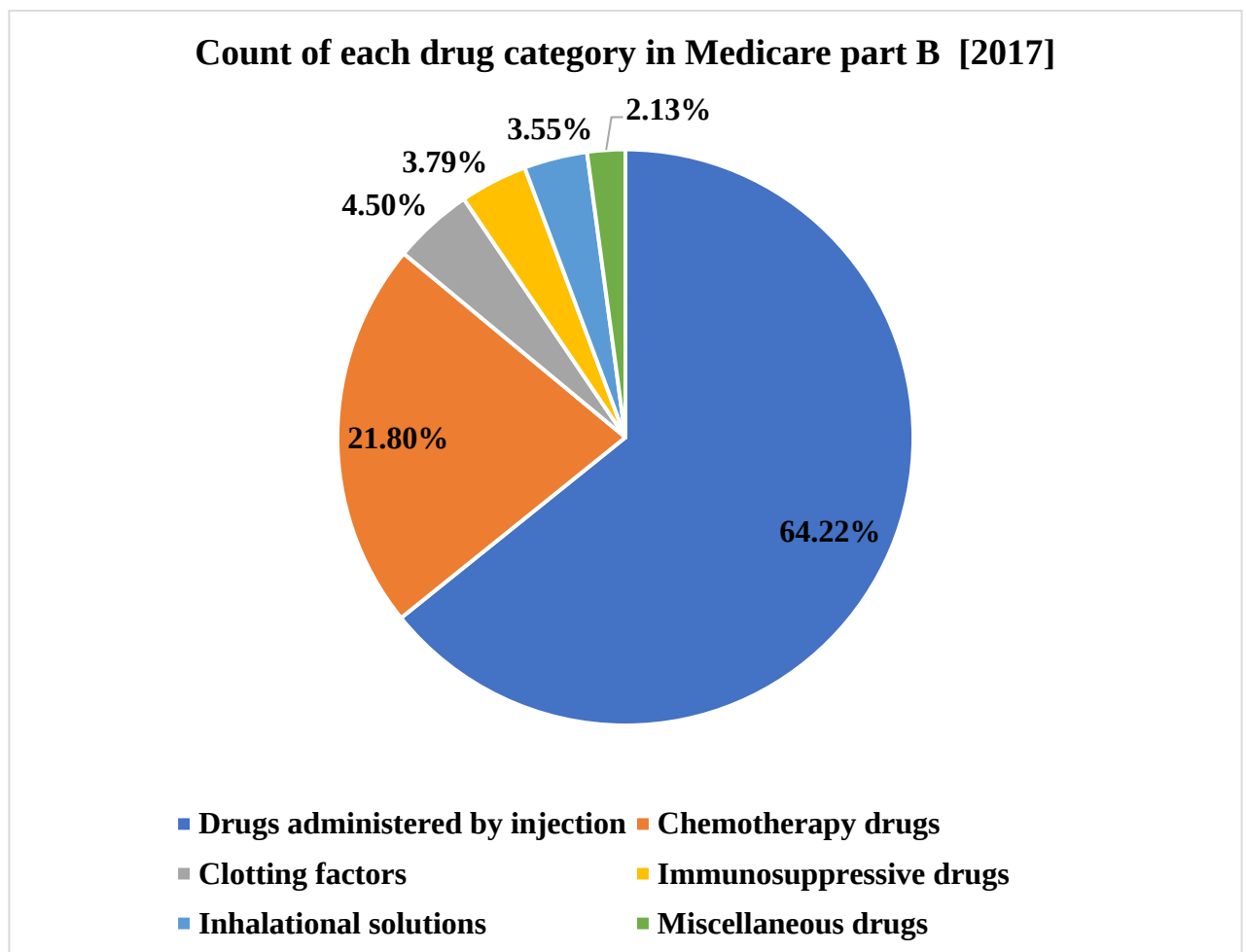


Figure 8.5 Count of each drug category in Medicare part B [2017]

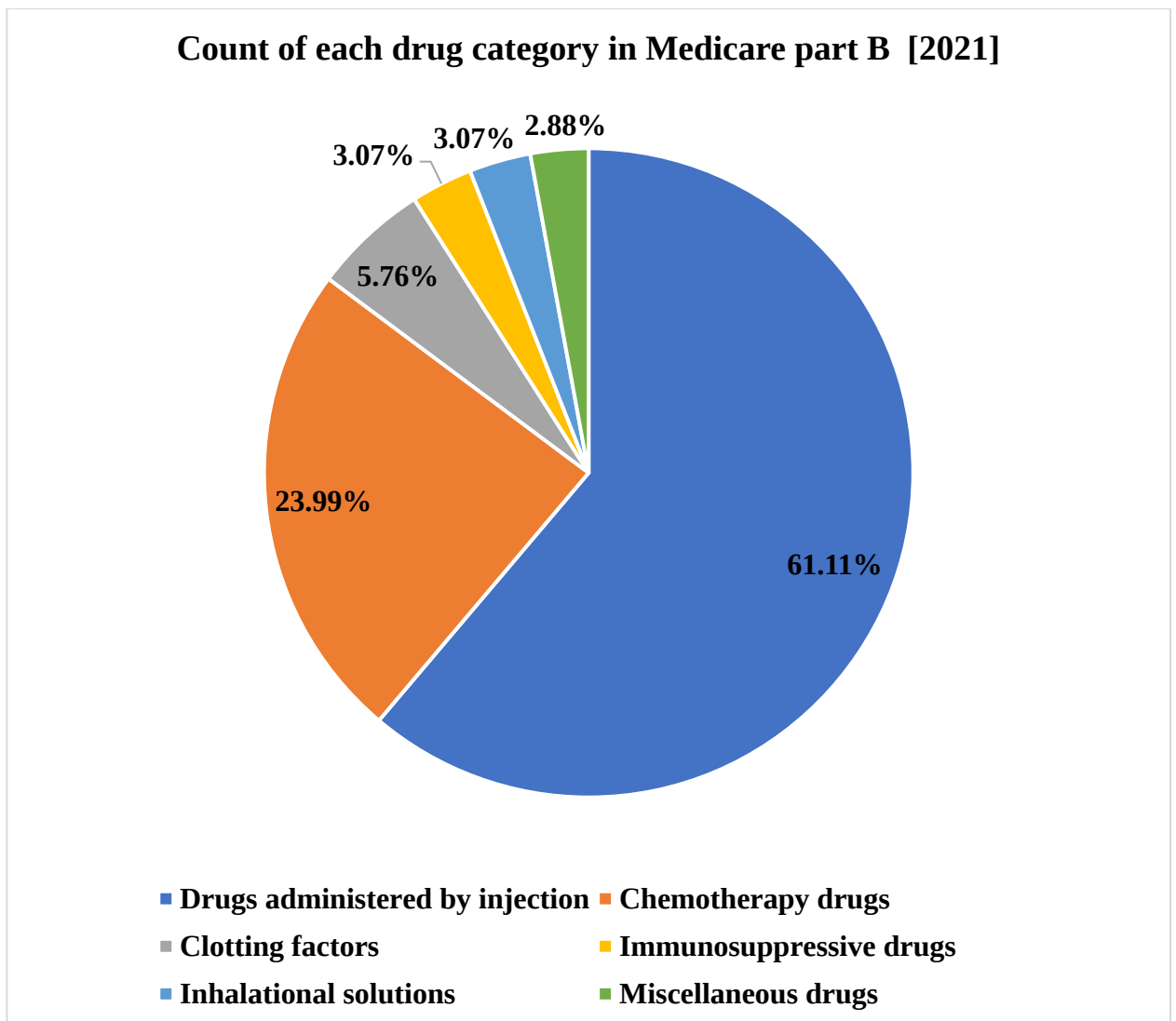


Figure 8.6 Count of each drug category in Medicare part B [2021]

- The first investigation into changes in the number of drugs in drug categories covered by Medicare part B shows that, from 2017 to 2021, the number of chemotherapy drugs has increased only little (percentage-wise) compared to other drug categories, likely as a result of the addition of new medications to the list each year.
- It can be observed that among all the Medicare part B drugs, “Chemotherapy drugs” category has increased marginally the most as compared to other drugs in part B from 2017 to 2021
- As of 2017, there were 92 chemotherapy drugs in Medicare part B and formed approximately 22% of Medicare part B drugs but till 2021, 33 more chemotherapy drugs were added, and it now occupied approximately 24% of drugs in Medicare part B.
- As of 2017, there were 271 drugs under “Drugs administered by injection”

category in Medicare part B and formed approximately 64% of Medicare part B drugs but till 2021, 48 more drugs were added in “Drugs administered by injection” category and now occupied approximately 61% of drugs in Medicare part B.

- Like this, we see number of drugs increasing across all the categories except Immunosuppressive drugs, but only chemotherapy drugs have increased marginally percentage wise the most as compared to other drugs in part B from 2017 to 2021

2] The following table and figure helps in determining the trend of number of drugs in Medicare part B from 2017 to 2021 –

Table 8.5 Trend analysis of total spent of drugs in Medicare part B from 2017-2021

Drug category	Total spending in dollars [2017 - 2021]				
	2017	2018	2019	2020	2021
Drugs administered by injection	15502910874.98	16766144939.81	18139777347.04	18615266592.05	19709313365.94
Chemotherapy drugs	9024638891.59	10439372388.39	14353825484.31	14359114071.79	14731513203.19
Inhalational solutions	727816740.18	726839941.27	714628739.73	851869595.63	830747015.08
Clotting factors	681215189.42	630805792.06	604197726.22	584969187.81	573911834.10
Miscellaneous drugs	509104060.56	471854767.74	623284322.84	393710218.08	422426684.49
Immunosuppressive drugs	341768441.42	385452465.96	378602237.65	377270535.47	322510883.10
Grand Total	26787454198	29420470295	34814315858	35182200201	36590422986

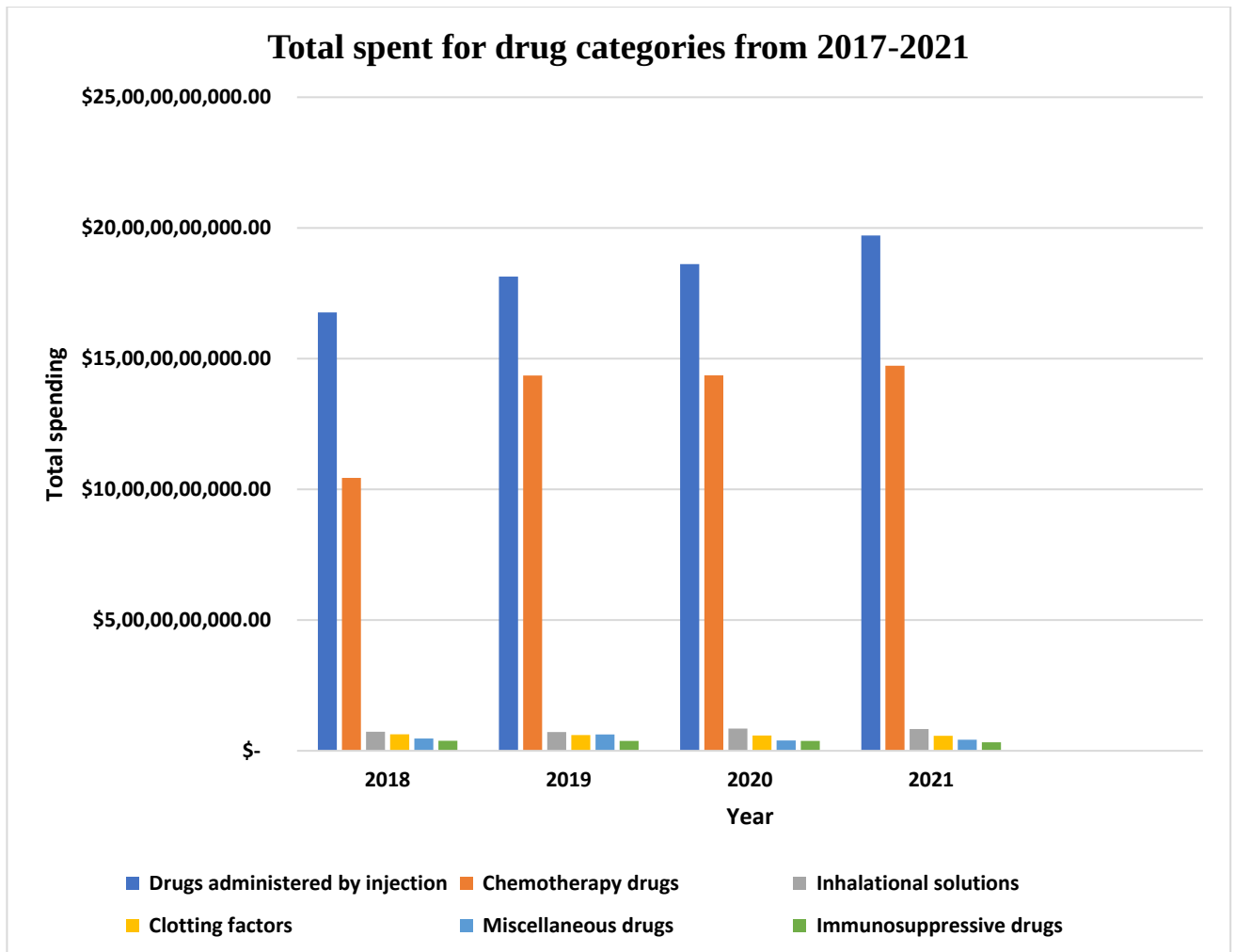


Figure 8.7 Total spending for drug categories in Medicare part B [2017-2021]

- It can be observed that among all the Medicare part B drugs, “Drugs administered by injection” category has the highest total spending among all the drugs from 2017 to 2021 and that is because of the maximum number of drugs in that category which we observed in the previous table and figures, where in 2017, there were 271 drugs under “Drugs administered by injection” category in Medicare part B and formed approximately 64% of Medicare part B drugs but till 2021, 48 more drugs were added in “Drugs administered by injection” category and now occupied approximately 61% of drugs in Medicare part B.
- So, the maximum total spending of “Drugs administered by injection” is because of more drugs in its category and thus more usage by patients but on further analysis of percentage wise change in spending on a yearly basis, another result has been investigated which has been shown below.

3] The following table and figure helps in determining the trend of percentage change in the number of Medicare part B drugs from 2017 to 2021 –

Table 8.6 *Trend analysis of percentage change in total spending of Medicare part B drugs from 2017-2021*

Drug category	Percentage change in total spending from 2017 to 2021			
	% change (2017 to 2018)	% change (2017 to 2019)	% change (2017 to 2020)	% change (2017 to 2021)
Drugs administered by injection	8%	17%	20%	27%
Chemotherapy drugs	16%	59%	59%	63%
Inhalational solutions	0%	-2%	17%	14%
Clotting factor drugs	-7%	-11%	-14%	-16%
Miscellaneous drugs	-7%	22%	-23%	-17%
Immunosuppressive drugs	13%	11%	10%	-6%
Grand Total	10%	30%	31%	37%

- It can be observed that among all the Medicare part B drugs, Chemotherapy drugs have increased percentagewise on a year-to-year basis the most, as compared to other drugs in part B.
- From 2017 to 2021, Chemotherapy drugs increase 63% with a constant growth rate and this can be correlated with increase in number of drugs for the “chemotherapy drug” category.
- This percentage change can be correlated with two major aspects in USA healthcare system –
 - a) Increase in prevalence rate of cancer among elderly people (above 65 years) from the same time period.
 - b) Increase in average annual cost of new cancer drugs by 53% from \$185,000 to more than \$ 283,000.
- “Drugs administered by injection” category and “Inhalational solutions” solution are the other category that have grown constantly on a year-to-year basis but less than “Chemotherapy drugs” category.
- The rest of the other categories have shown negative deviation from 2017 to 2021.

Following figure shows the above-mentioned table in detail –

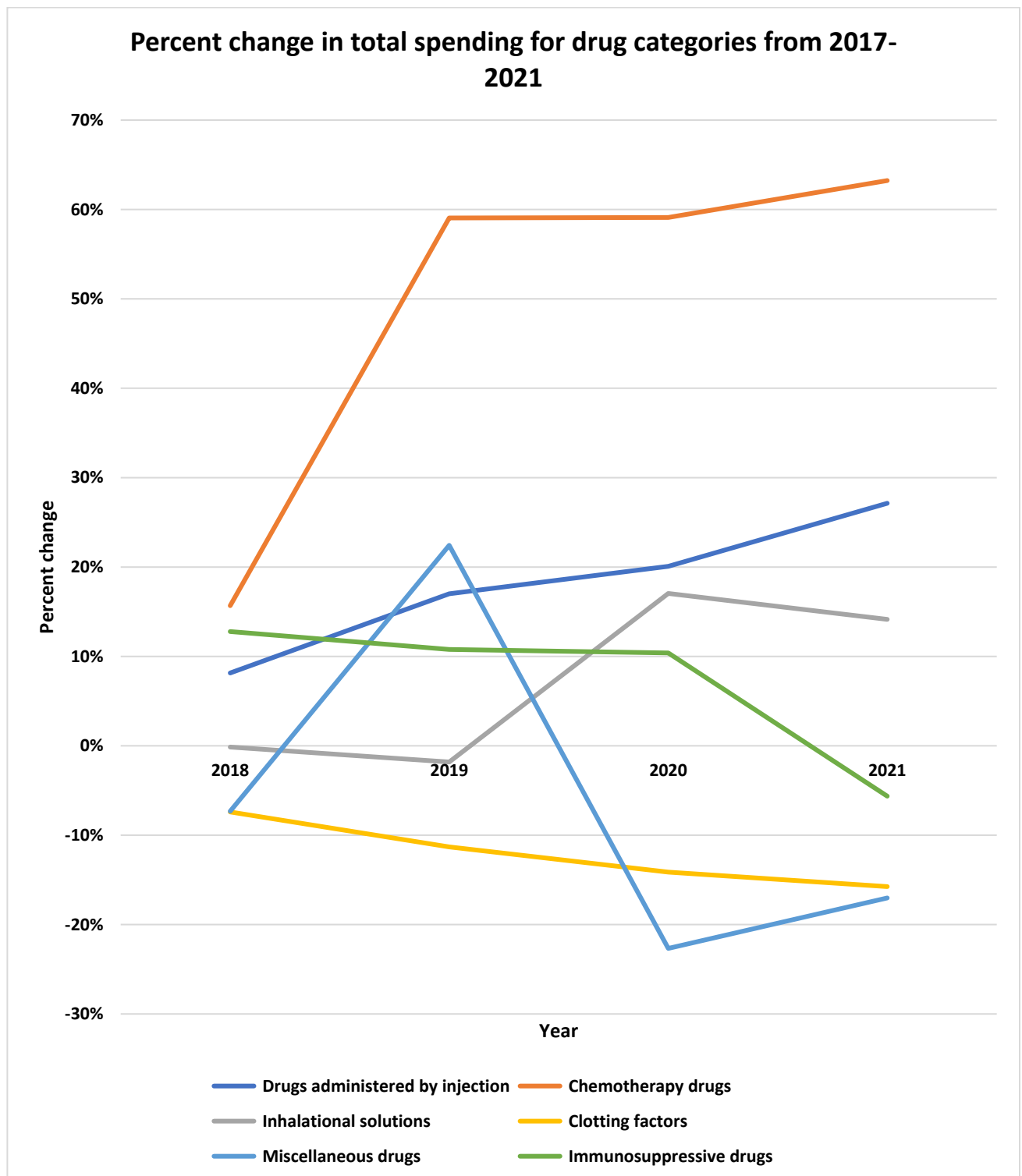


Figure 8.8 Percentage change in total spending for drug categories in Medicare part B [2017-2021]

4] The following table and figure helps in determining the trend of average spending per dosage unit of Medicare part B drugs from 2017 to 2021 –

Table 8.7 Trend analysis of average spending per dose of Medicare part B drugs from 2017-2021

Drug category	Average spending per dosage unit in dollars [2017-2021]				
	2017	2018	2019	2020	2021
Drugs administered by injection	32868.53	31853.57	36588.84	38650.04	38800.80
Chemotherapy drugs	29665.49	31469.16	35161.62	37926.44	40793.64
Immunosuppressive drugs	2467.75	2378.91	2652.89	2552.87	2581.70
Miscellaneous drugs	2292.72	2238.37	2893.62	2882.04	3123.15
Inhalational solutions	641.97	682.44	708.72	741.38	788.36
Clotting factor drugs	150.46	83.80	81.27	81.07	89.18

- Average spending per dosage unit was obtained by dividing total spending of each drug category by total dosage unit for each drug category.
- It can be observed that “Drugs administered by injection” category have the highest average spending per dosage unit of drugs from 2017 till 2020 but in 2021, “Chemotherapy drugs” category have the highest average spending per dosage of drugs.
- Rest other categories have very less average spending per dosage of drugs as compared to “chemotherapy drugs” category and “Drugs administered by injection” category.

Following figure describes the content given in above table -

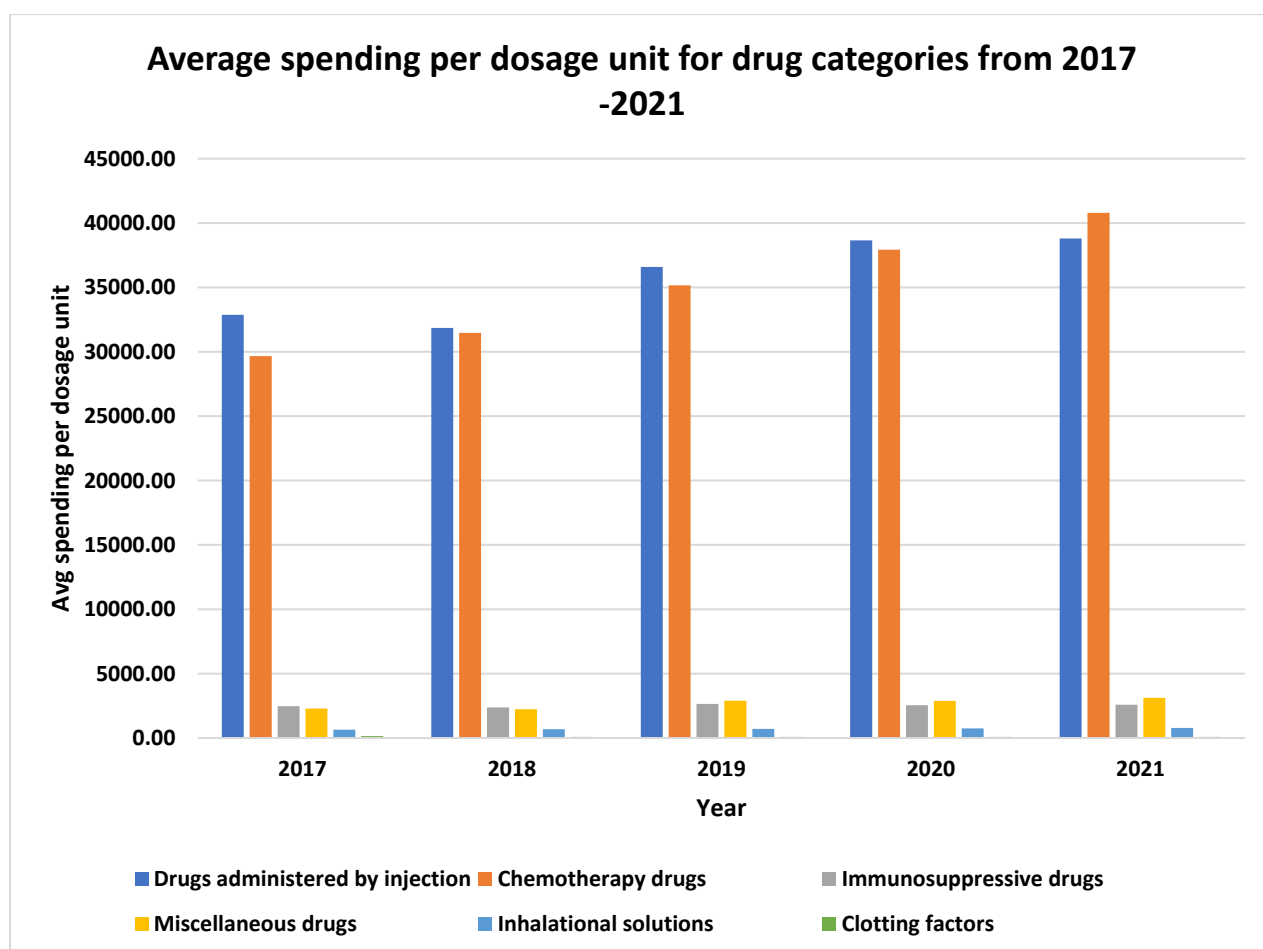


Figure 8.9 Average spending per dosage unit for drug categories in Medicare part B [2017-2021]

5] The following table and figure helps in determining the trend of percentage change in avg spent per dosage unit from 2017 to 2021 –

Table 8.8 Trend analysis of percentage change in average spending per dose of Medicare part B drugs from 2017-2021

Drug category	Percent change in Avg spent per dosage unit [2017-2021]			
	2018	2019	2020	2021
Drugs administered by injection	-3%	11%	18%	18%
Chemotherapy drugs	6%	19%	28%	38%
Immunosuppressive drugs	-4%	8%	3%	5%
Miscellaneous drugs	-2%	26%	26%	36%
Inhalational solutions	6%	10%	15%	23%
Clotting factor drugs	-44%	-46%	-46%	-41%

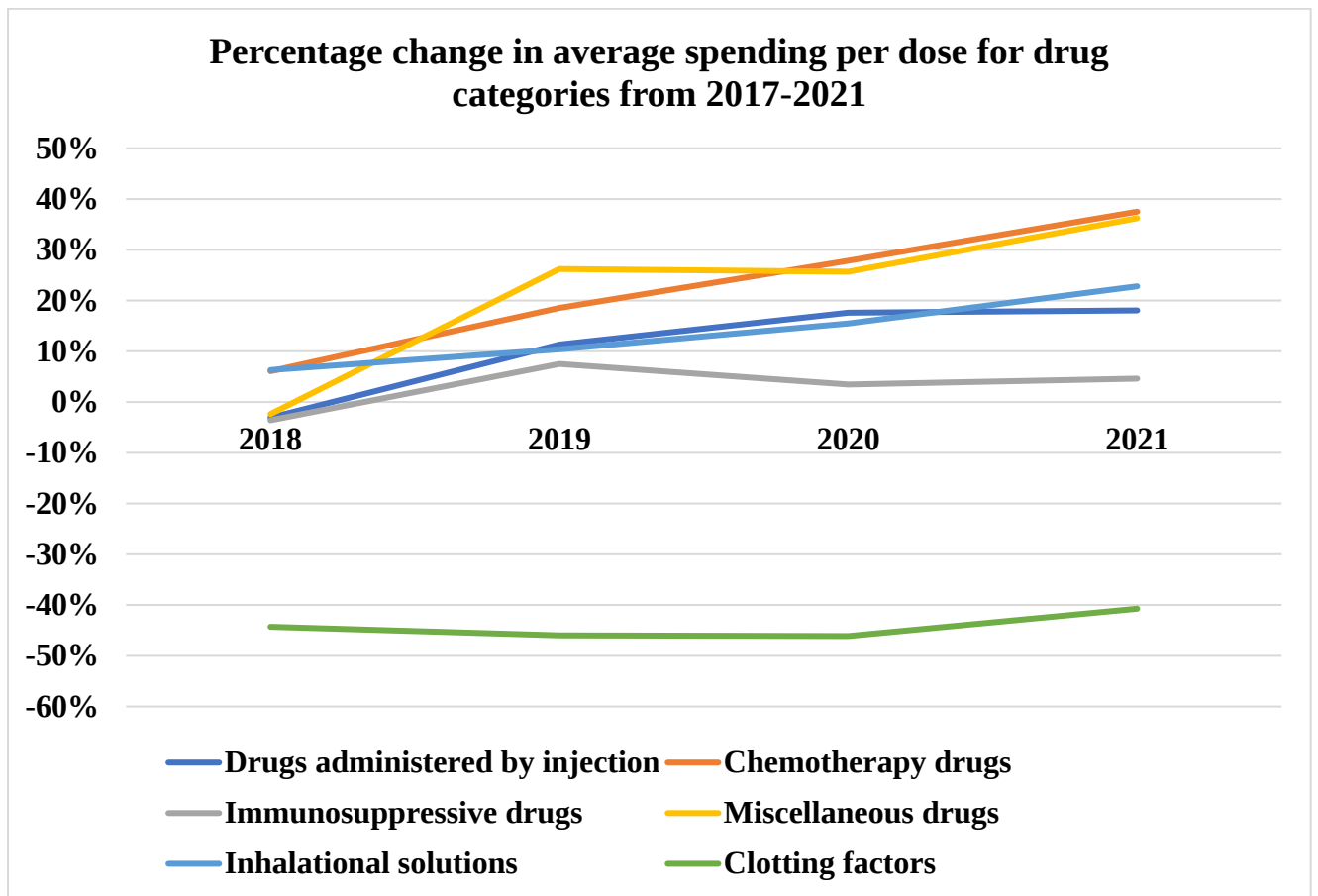


Figure 8.10 Percentage change in Avg spent per dosage unit for drug categories in Medicare part B [2017-2021]

- It can be observed that “Chemotherapy drugs” category have the highest average percentage change in spending per dosage unit of drugs from 2017 till 2021.
- Rest other categories have less percentage change in average spending per dosage of drugs as compared to “chemotherapy drugs” category, while clotting factor drugs have negative deviation for the same.

Part B Discarded Drug Units dataset
First Analysis

1] The following table depicts the chemotherapy drugs which have equal to or greater than 20 % discarded units as a percentage of total Medicare allowed amount.

Table 8.9 chemotherapy drugs which have equal to or greater than 20 % discarded units

Chemotherapy drugs equal to or greater than 20% discarded units		
HCPCS code	Description	Discarded units %
J9281	Mitomycin instillation	38%
J9262	Inj, omacetaxine mep, 0.01mg	31%
J9043	Cabazitaxel injection	29%
J9041	Inj., velcade 0.1 mg	27%
J9351	Topotecan injection	26%
J9044	Inj, bortezomib, 0.1 mg	22%
J9025	Azacitidine injection	22%
J9017	Arsenic trioxide injection	21%
J9065	Inj cladribine per 1 mg	20%
J9223	Inj. lurbinectedin, 0.1 mg	20%

- The discarded units percentage is obtained by dividing total Medicare allowed amount for discarded drugs by total Medicare allowed amount.
- Total number of chemotherapy drugs for discarded drugs greater than or equal to 20% is 10.

2] The following table depicts the chemotherapy drugs which have equal to or greater than 10 % discarded units as a percentage of total Medicare allowed amount.

Table 8.10 Total Medicare allowed amount for discarded units of chemotherapy drugs which have equal to or greater than 20 % discarded units

HCPCS code	Discarded units as % of total allowed amount	Total Medicare allowed amount for discarded units [in dollars]
J9281	38%	\$ 10039643.24
J9262	31%	\$ 68454.45
J9043	29%	\$ 42721955.58
J9041	27%	\$ 102718188.43
J9351	26%	\$ 125455.90
J9044	22%	\$ 1011456.65
J9025	22%	\$ 8293968.79
J9017	21%	\$ 368250.06
J9065	20%	\$ 91449.10
J9223	20%	\$ 18386451.37
Grand Total		\$ 183825273.57

Total Medicare allowed amount for discarded drugs was calculated which was \$ 183825273.57 approximately for discarded drugs amount greater than or equal to 20%

3] The following table depicts the chemotherapy drugs which have equal to or greater than 10 % and less than 20% discarded units as a percentage of total Medicare allowed amount.

Table 8.11 chemotherapy drugs which have equal to or greater than 10 % and less than 20% discarded units

Chemotherapy drugs [≥ 10 % and $< 20\%$] discarded units		
HCPCS code	Description	Discarded units %
J9178	Inj, epirubicin hcl, 2 mg	19%
J9229	Inj inotuzumab ozogam 0.1 mg	18%
J9153	Inj daunorubicin, cytarabine	15%
J9027	Clofarabine injection	14%
J9264	Paclitaxel protein bound	14%
J9179	Eribulin mesylate injection	13%
J9307	Pralatrexate injection	13%
J9037	Inj belantamab mafodot blmf	12%
J9042	Brentuximab vedotin inj	12%
J9319	Inj romidepsin lyophil 0.1mg	12%
J9205	Inj irinotecan liposome 1 mg	12%
J9228	Ipilimumab injection	11%
J9269	Inj. tagraxofusp-erzs 10 mcg	10%
J9352	Injection trabectedin 0.1mg	10%
J9203	Gemtuzumab ozogamicin 0.1 mg	10%
J9263	Oxaliplatin	10%

- The discarded units percentage is obtained by dividing total Medicare allowed amount for discarded drugs by total Medicare allowed amount.
- Total number of chemotherapy drugs for discarded drugs greater than or equal to 10% but less than 20% is 16.

4] The following table depicts the chemotherapy drugs which have equal to or greater than 10 % and less than 20% discarded units as a percentage of total Medicare allowed amount.

Table 8.12 Total Medicare allowed amount for discarded units of chemotherapy drugs which have equal to or greater than 10 % and less than 20% discarded units

HCPSC code	Discarded units %	Total Medicare allowed amount for discarded units [in dollars]
J9178	19%	\$ 1880.20
J9229	18%	\$ 3262099.34
J9153	15%	\$ 828995.40
J9027	14%	\$ 8749.34
J9264	14%	\$ 48142886.28
J9179	13%	\$ 5539110.90
J9307	13%	\$ 2884364.03
J9037	12%	\$ 4002833.94
J9042	12%	\$ 20144555.44
J9319	12%	\$ 773975.93
J9205	12%	\$ 6863427.15
J9228	11%	\$ 47638125.90
J9315	10%	\$ 2392123.98
J9269	10%	\$ 786969.96
J9352	10%	\$ 931677.80
J9203	10%	\$ 294046.67
J9263	10%	\$ 388283.62
Grand Total		\$ 144884105.88

Total Medicare allowed amount for discarded drugs was calculated which was \$ 144884105.88 approximately for discarded drugs greater than or equal to 10% but less than 20%

Second Analysis

1] The following table depicts the chemotherapy drugs segregated on basis of highest total Medicare allowed amount for Pareto chart analysis.

Table 8.13 Category wise segregation of chemotherapy drugs on basis of highest total Medicare allowed amount.

Category 1	Category 2	Category 3	Category 4	Category 5	Category 6	Category 7	Category 8	Category 9	Category 10
J9041	J9312	J9303	J9307	J9044	J9263	J9214	J9190	J9261	J9130
J9264	J9047	J9179	J9315	J9352	J9032	J9395	J9328	J9390	J9293
J9228	J9173	J9271	J9301	J9306	J9017	J9030	J9247	J9027	J9178
J9043	J9035	J9177	J9204	J9034	J9207	J9171	J9206	J9000	J9060
J9042	J9025	J9055	J9070	J9153	J9203	J9311	J9267	J9155	J9250
J9355	J9299	J9308	J9349	J9144	J9119	J9065	J9202	J9045	J9100
J9223	J9358	J9037	J9039	J9269	J9400	J9316	J9217	J9181	J9040
J9305	J9205	J9309	J9022	J9319	J9330	J9036	J9201	J9360	J9209
J9354	J9317	J9229	J9033	J9227	J9353	J9262	J9313	J9208	J9260
J9281	J9145	J9176	J9325	J9023	J9351	J9371	J9280	J9370	J8540

2] The following table depicts the cumulative and cumulative% done of chemotherapy drugs segregated on basis of highest total Medicare allowed amount for Pareto chart analysis.

Table 8.14 Cumulative and cumulative% of chemotherapy drugs on basis of highest total Medicare allowed amount.

S.no.	Category	Total Medicare allowed amount for discarded units [in dollars]	Cumulative	Cumulative %
1	Category 1	\$ 332372882.95	332372883	68.36%
2	Category 2	\$ 81485442.11	413858325	85.12%
3	Category 3	\$ 42455671.85	456313997	93.86%
4	Category 4	\$ 17956150.23	474270147	97.55%
5	Category 5	\$ 8070371.64	482340519	99.21%
6	Category 6	\$ 2443935.25	484784454	99.71%
7	Category 7	\$ 931521.37	485715975	99.90%
8	Category 8	\$ 394357.12	486110333	99.98%
9	Category 9	\$ 65671.72	486176004	100.00%
10	Category 10	\$ 12480.37	486188485	100.00%

3] Analysis of 100 chemotherapy drugs which have discarded units greater than 0% -

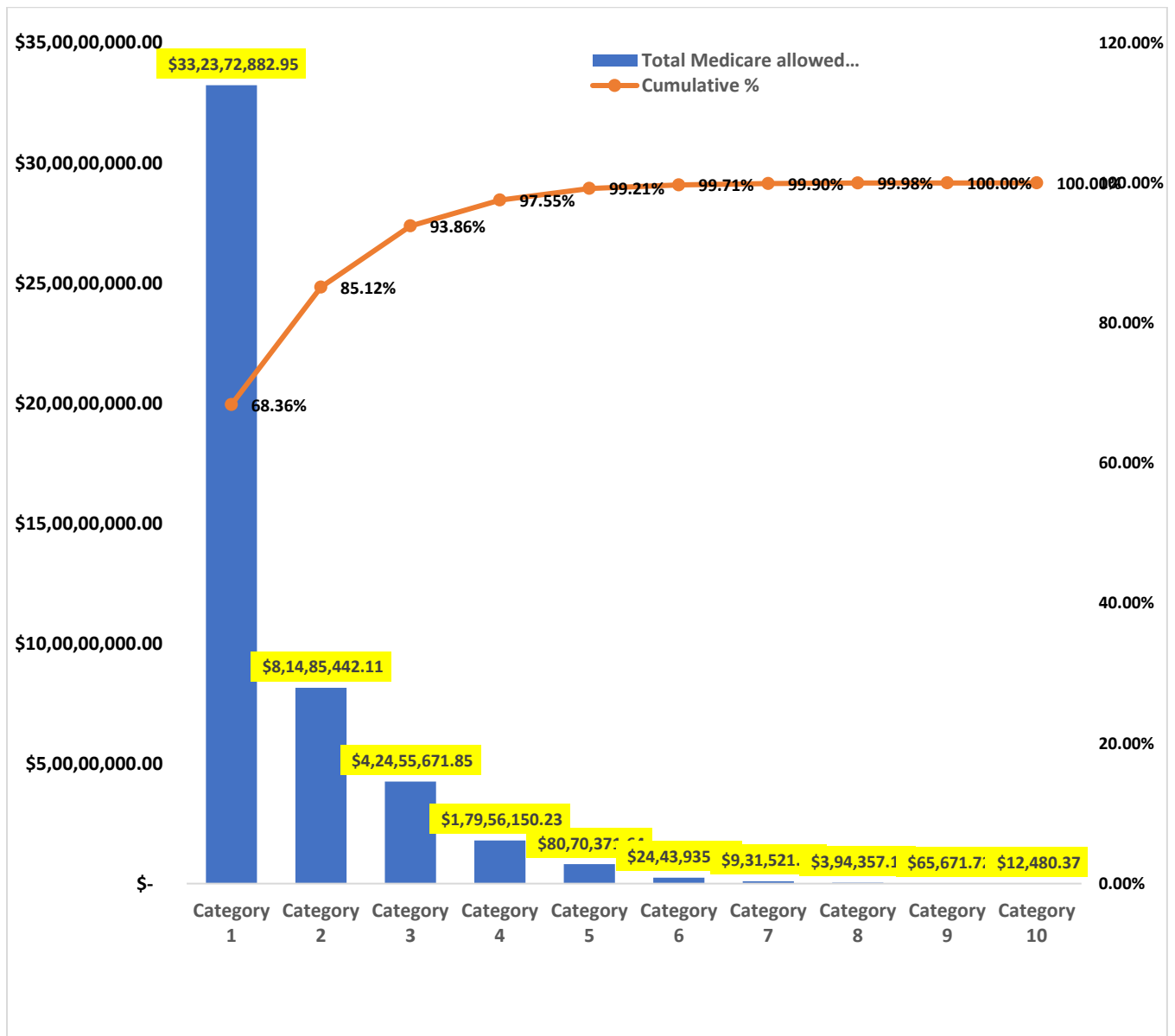


Figure 8.11 Pareto chart analysis

On analysing the pareto chart, it is found that category 1 and category 2 chemotherapy drugs formed 20% of the discarded chemotherapy drugs which resulted in 85% of the total Medicare allowed amount.

Chapter 5 : RESULT & DISCUSSION

Through telephonic interview, insights and opinions based on experience and perspective of respondents from payer fraternity was taken to understand the challenges and potential solutions related to the reimbursement and waste issues associated with Medicare part B drugs.

The survey respondents in primary research analysis represented national or regional health plans, including 51 commercial payers, 34 managed care organizations, 34 preferred provider organizations and 31 pharmacy benefit managers. (n=152)

The first section of the primary research analysis examines respondents' general awareness of Medicare part B. According to the results, 61% of the respondents who were interviewed said they were "very familiar" with physician-administered medications covered by Medicare part B, 36% said they were "somewhat familiar," and 5% said they were "not familiar." Additionally, according to the primary study analysis, 51.08% of respondents who indicated they were "very familiar" with the topic said that "Chemotherapy drugs" were the drug category that resulted in higher Medicare part B cost. In the 'somewhat familiar' category, 43.4% of respondents said that 'Chemotherapy drugs' were the drug category leading to greater Medicare part B spending, while 20% of respondents in the 'not familiar' category said the same.

Further investigation indicated that 61.96% of respondents who identified themselves as "very familiar" with the topic identified "Chemotherapy drugs" as the drug category that contributed to greater Medicare part B spending per dose. 60% of respondents in "somewhat familiar" category expressed the same sentiment While no inference could be made from the "not familiar category".

The second section of the primary research analysis examines respondent awareness of discarding and financial consequences of Medicare part B drugs. For this, and subsequent sections, "not familiar" category of respondents was removed. (n=147)

The insight derived was that 90.48% of respondents were aware of discarding and financial consequences of Medicare part B drugs and out of them 72.93% felt that "Chemotherapy drugs" were the category leading to maximum discarded units' wastage.

The third section of primary research analysis represents the need for drug manufacturing regulations in which 60.54% of respondents felt the need for stricter regulations or guidelines to ensure drug manufacturers provide appropriate packaging quantities in accordance with patient demands.

The fourth section addresses potential fixes from the payer's standpoint. There is a need for increased stakeholder collaboration to address the issue of discarded units of chemotherapy drugs, according to 80.95% of respondents and 68.71% of those who think payment or

reimbursement structures should be changed to encourage appropriate packaging quantities and lessen discarded waste.

The secondary research analysis consisted of analysing two datasets from same source. The first data set - Medicare part B Spending by Drug dataset, from CMS provided us with insights on trends of Medicare part B drugs with respect to their count, change in count, total spending, change in total spending, Avg spent per dose and percent change in Avg spent per dose for 5 years from 2017 to 2021 [latest updated year].

The first investigation into changes in the number of drugs in drug categories covered by Medicare part B shows that, from 2017 to 2021, the number of chemotherapy drugs has increased only little (percentage-wise) compared to other drug categories, likely as a result of the addition of new medications to the list each year.

Next, total spending for each drug category in Medicare part B was investigated and it was found that year on year, “Drugs administered by injection” category occupied the top position among all the categories with respect to total spending from 2017-2021 but on analysing percentage change of total spending, “Chemotherapy drugs” category showed greater positive deviation, year on year as compared to other category.

The next analysis looked at average spending per dosage unit from 2017 to 2021 and found that "Drugs administered by injection" held the top spot among all categories in terms of total spending from 2017 to 2020. "Chemotherapy drugs" held the top spot among all categories in terms of average spending per dosage unit from 2017 to 2021. Further analysis revealed that the "Chemotherapy drugs" category showed a bigger positive deviation year over year when compared to other categories in terms of the percentage change of total spending per dose unit.

Coming to second data set - Part B Discarded Drug Units report for year 2021, from CMS, two different types of analyses were performed.

The first analysis was conducted to understand the number of chemotherapy drugs which had a discarded unit percentage of 10% and above and was tabulated in two categories which were a) equal to or greater than 20% and b) equal to or greater than 10% but less than 20%.

After this, for the same set of drugs, total Medicare allowed amount was calculated which was \$ 328,709,379 approximately for discarded drugs greater than or equal to 10% This indicates that this much cost could be saved for patients and payers if chemotherapy drugs are not discarded, and alternate strategies are developed.

The second analysis was done by extracting all the chemotherapy drugs which have discarded units greater than 0% and arranged on basis of greatest total Medicare allowed amount. Total of 100 chemotherapy drugs out of 125 had greater than 0% discarded units. Then, for each of 10 chemotherapy drugs, a category was assigned. Therefore, a total of 10 category were established. For each category, total Medicare allowed amount was calculated in decreasing order, cumulative calculated and cumulative percentage calculated.

On the basis of above-mentioned process, it was found that category 1 and category 2 formed 20% of the discarded chemotherapy drugs which resulted in 85% of the total Medicare allowed amount which was being wasted due to discarding of chemotherapy drugs and this

amount could be saved if alternate strategies are developed to combat discard of chemotherapy drugs.

Recently, CMS has passed a ruling that drug manufacturers will need to refund amounts to CMS for discarded amounts at least 10% of total charges for drug in a given calendar year.

So, on the basis of that ruling, following HCPCS codes should be tracked and analysed for the year 2023 –

Chemotherapy drugs equal to or greater than 20% discarded units

J9281, J9262, J9043, J9041, J9351, J9044, J9025, J9017, J9065 and J9223

Chemotherapy drugs [$\geq 10\%$ and $< 20\%$] discarded units

J9178, J9229, J9153, J9027, J9264, J9179, J9307, J9037, J9042, J9319, J9205, J9228, J9269, J9352, J9203, J9263

Limitations of the study

- ❖ The study has been done only for Chemotherapy drugs category in Medicare part B.
- ❖ The study is for the year 2021 [latest updated year of CMS].

Chapter 6: CONCLUSION

From the study mentioned above, it can be concluded that Chemotherapy drugs belongs to the most significant category in Medicare part B due to its increase in number, percentage change in total spending, avg spent per dose and percentage change in avg spent per dose

Hence, it becomes noteworthy when chemotherapy doses are discarded because of more than required amount of dose in the drug packaging and which in turn leads to financial consequences among patient and payer fraternity.

So, analysis was done regarding the wastage and financial loss due to discarded units and it was concluded that total spending (patient + payer) due to discarded units pertaining to 10% or more, was approximately \$ 328,709,379.

Also the total spending (patient + payer) due to discarded units of all chemotherapy drugs was approximately \$ 486,188,485.

From the result obtained, there is a serious need for increased collaboration between stakeholders to address the problem of discarded units of chemotherapy drugs and also a reimbursement mechanism or payment structures should be revised to incentivize appropriate packaging quantities and reduce waste due to discarded Medicare part B drugs with a special focus on “chemotherapy drugs” category.

Some of the recommendations to prevent wastage due to discarding of chemotherapy drugs on the basis of exploring various research articles are vial sharing, drug vial optimization, dose banding, dose rounding and dose capping but further deep research along with experimental results are required to consider them as safe and viable technique to prevent wastage due to discarding.

Chapter 7 : REFERENCES

- 1) Scheckel C, Desai A, Jensen C, Orme J, Pritchett J, Mahipal A, Khera N, Go RS. Medicare expenditures for discarded oncology therapies.
- 2) Trovato A, Tyler LS, Nickman NA, Findlay R. Interventions to reduce waste and improve billing compliance with medications in single-dose vials. *American Journal of Health-System Pharmacy*. 2023 Feb 15;80(4):222-6.
- 3) Shah V, Spence A, Bartels T, Betcher J, Soefje S. Decreasing drug waste, reducing drug costs, and improving workflow efficiency through the implementation of automated chemotherapy dose rounding rules in the electronic health record system. *American Journal of Health-System Pharmacy*. 2022 Apr 1;79(8):676-82.
- 4) Shih YC, Xu Y, Zhao H, Schrag D, Yao J. Financial burden of discarded weight-based antineoplastic drugs to payers and patients in the private insurance market. *JNCI Cancer Spectrum*. 2021 Aug;5(4):pkab045.
- 5) Bach PB, Conti RM, Muller RJ, Schnorr GC, Saltz LB. Overspending driven by oversized single dose vials of cancer drugs. *Bmj*. 2016 Mar 1;352.

Chapter 9 : ANNEXURE

Drugs Dictionary

Part B Discarded Drug Units report –

Medicare Billing Code (HCPCS Code)

Variable name - HCPCS_Cd

Definition - Healthcare Common Procedure Coding System (HCPCS) code used to identify the drug furnished by the provider.

Brand Name

Variable name - Brnd_Name

Definition - Name of the drug furnished by the provider. This includes both brand names (drugs that have a trademarked name) and generic names (drugs that do not have a trademarked name).

Generic Name

Variable name - Gnrc_Name

Definition - A term referring to the chemical ingredient of a drug rather than the trademarked brand name under which the drug is sold.

Total Medicare Allowed Amount

Variable name - Tot_Mdcr_Alowd_Amt

Definition - Total Medicare allowed amount for Part B Drug. Medicare allowed amounts includes the amount Medicare pays, the deductible and coinsurance amounts that the beneficiary is responsible for paying, and any amounts that a third party is responsible for paying.

Total Allowed Amount for Units Administered

Variable name - Tot_Mdcr_Alowd_Admnrd_Amt

Definition - Total Medicare allowed amount paid for the portion of the drug administered to the beneficiary.

Total Allowed Amount for Units Discarded

Variable name - Tot_Mdcr_Alowd_Dscrd_Amt

Definition - Total Medicare allowed amount paid for portion of the drug NOT administered to the beneficiary.

Administered Units as % of Total Allowed Amount

Variable name - PCT_Admnrd_Units

Definition - Percentage of total Medicare allowed amount that for the portion of the drug that was administered to a beneficiary.

Discarded Units as % of Total Allowed Amount

Variable name - PCT_Dscrd_Units

Definition - Percentage of total Medicare allowed amount for a given drug that discarded and NOT administered.

Medicare part B Spending by Drug dataset –

Medicare Billing Code (HCPCS Code)

Variable name - HCPCS_Cd

Definition - Healthcare Common Procedure Coding System (HCPCS) code used to identify the drug furnished by the provider.

Drug Description

Variable name - HCPCS_Desc

Definition - Description of the HCPCS code for the drug furnished by the provider.

Brand Name

Variable name - Brnd_Name

Definition - Name of the drug furnished by the provider. This includes both brand names (drugs that have a trademarked name) and generic names (drugs that do not have a trademarked name)

Generic Name

Variable name - Gnrc_Name

Definition - A term referring to the chemical ingredient of a drug rather than the trademarked brand name under which the drug is sold

2017 Total Spending

Variable name - Tot_Spndng_2017

Definition - Aggregate drug spending for the Part B program during 2017.

2017 Total Dosage Units

Variable name - Tot_Dsg_Units_2017

Definition - The sum of the dosage units of medication dispensed in 2017 (e.g. number of tablets, grams, millilitres, or other units). For Part B, the quantity of a drug in a dosage unit is the same as the quantity of the drug in a HCPCS billing unit.

2017 Total Claims

Variable name - Tot_Clms_2017

Definition - Number of claims for each drug in 2017.

2017 Total Beneficiaries

Variable name - Tot_Benes_2017

Definition - Number of Medicare part B fee-for-service beneficiaries utilizing the drug during 2017.

2017 Average Spending Per Dosage Unit

Variable name - Avg_Spndng_Per_Dsg_Unt_2017

Definition - Part B drug spending in 2017 divided by the number of dosage units in 2017.

2017 Average Spending Per Claim

Variable name - Avg_Spndng_Per_Clm_2017

Definition - Part B drug spending in 2017 divided by the number of claims in 2017.

2017 Average Spending Per Beneficiary

Variable name - Avg_Spndng_Per_Bene_2017

Definition - Total Part B drug costs in 2017 divided by the number of unique beneficiaries utilizing the drug during 2017.

2018 Total Spending

Variable name - Tot_Spndng_2018

Definition - Aggregate drug spending for the Part B program during 2018.

2018 Total Dosage Units

Variable name - Tot_Dsg_Unts_2018

Definition - The sum of the dosage units of medication dispensed in 2018 (e.g. number of tablets, grams, millilitres, or other units). For Part B, the quantity of a drug in a dosage unit is the same as the quantity of the drug in a HCPCS billing unit.

2018 Total Claims

Variable name - Tot_Clms_2018

Definition - Number of claims for each drug in 2018.

2018 Total Beneficiaries

Variable name - Tot_Benes_2018

Definition - Number of Medicare part B fee-for-service beneficiaries utilizing the drug during 2018.

2018 Average Spending Per Dosage Unit

Variable name - Avg_Spndng_Per_Dsg_Unt_2018

Definition - Part B drug spending in 2018 divided by the number of dosage units in 2018.

2018 Average Spending Per Claim

Variable name - Avg_Spndng_Per_Clm_2018

Definition - Part B drug spending in 2018 divided by the number of claims in 2018.

2018 Average Spending Per Beneficiary

Variable name - Avg_Spndng_Per_Bene_2018

Definition - Total Part B drug costs in 2018 divided by the number of unique beneficiaries utilizing the drug during 2018.

2019 Total Spending

Variable name - Tot_Spndng_2019

Definition - Aggregate drug spending for the Part B program during 2019.

2019 Total Dosage Units

Variable name - Tot_Dsg_Units_2019

Definition - The sum of the dosage units of medication dispensed in 2019 (e.g. number of tablets, grams, millilitres, or other units). For Part B, the quantity of a drug in a dosage unit is the same as the quantity of the drug in a HCPCS billing unit.

2019 Total Claims

Variable name - Tot_Clms_2019

Definition - Number of claims for each drug in 2019.

2019 Total Beneficiaries

Variable name - Tot_Benes_2019

Definition - Number of Medicare part B fee-for-service beneficiaries utilizing the drug during 2019.

2019 Average Spending Per Dosage Unit

Variable name - Avg_Spndng_Per_Dsg_Unt_2019

Definition - Part B drug spending in 2019 divided by the number of dosage units in 2019.

2019 Average Spending Per Claim

Variable name - Avg_Spndng_Per_Clm_2019

Definition - Part B drug spending in 2019 divided by the number of claims in 2019.

2019 Average Spending Per Beneficiary

Variable name - Avg_Spndng_Per_Bene_2019

Definition - Total Part B drug costs in 2019 divided by the number of unique beneficiaries utilizing the drug during 2019.

2020 Total Spending

Variable name - Tot_Spndng_2020

Definition - Aggregate drug spending for the Part B program during 2020.

2020 Total Dosage Units

Variable name - Tot_Dsg_Units_2020

Definition - The sum of the dosage units of medication dispensed in 2020 (e.g. number of tablets, millilitres, or other units). For Part B, the quantity of a drug in a dosage unit is the same as the quantity of the drug in a HCPCS billing unit.

2020 Total Claims

Variable name - Tot_Clms_2020

Definition - Number of claims for each drug in 2020.

2020 Total Beneficiaries

Variable name - Tot_Benes_2020

Definition - Number of Medicare part B fee-for-service beneficiaries utilizing the drug during 2020.

2020 Average Spending Per Dosage Unit

Variable name - Avg_Spndng_Per_Dsg_Unit_2020

Definition - Part B drug spending in 2020 divided by the number of dosage units in 2020.

2020 Average Spending Per Claim

Variable name - Avg_Spndng_Per_Clm_2020

Definition - Part B drug spending in 2020 divided by the number of claims in 2020.

2020 Average Spending Per Beneficiary

Variable name - Avg_Spndng_Per_Bene_2020

Definition - Total Part B drug costs in 2020 divided by the number of unique beneficiaries utilizing the drug during 2020.

2021 Total Spending

Variable name - Tot_Spndng_2021

Definition - Aggregate drug spending for the Part B program during 2021.

2021 Total Dosage Units

Variable name - Tot_Dsg_Unts_2021

Definition - The sum of the dosage units of medication dispensed in 2021 (e.g. number of tablets, millilitres or other units). For Part B, the quantity of a drug in a dosage unit is the same as the quantity of the drug in a HCPCS billing unit.

2021 Total Claims

Variable name - Tot_Clms_2021

Definition - Number of claims for each drug in 2021.

2021 Total Beneficiaries

Variable name - Tot_Benes_2021

Definition - Number of Medicare part B fee-for-service beneficiaries utilizing the drug during 2021.

2021 Average Spending Per Dosage Unit

Variable name - Avg_Spndng_Per_Dsg_Unt_2021

Definition - Part B drug spending in 2021 divided by the number of dosage units in 2021.

2021 Average Spending Per Claim

Variable name - Avg_Spndng_Per_Clm_2021

Definition - Part B drug spending in 2021 divided by the number of claims in 2021.

2021 Average Spending Per Beneficiary

Variable name - Avg_Spndng_Per_Bene_2021

Definition - Total Part B drug costs in 2021 divided by the number of unique beneficiaries utilizing the drug during 2021.

Questionnaire

Title:

Payer Perspective: Addressing discarded and Financial Consequences of Medicare part B Drugs

Introduction:

Thank you for taking the time to participate in this questionnaire. Your input as a member of the payer fraternity is valuable in understanding the challenges and potential solutions related to the reimbursement and waste issues associated with physician-administered drugs under Medicare part B. Please provide your insights and opinions based on your experience and perspective. Your responses will remain confidential.

Section 1: General Understanding

[1] How familiar are you with the physician-administered drugs in Medicare part B?

- a) Very familiar
- b) Somewhat familiar
- c) Not familiar

[2] Which category in your experience leads to more Medicare part B spending?

- a) Drugs administered by injection.
- b) Clotting factor drugs
- c) Miscellaneous drugs
- d) Immunosuppressive drugs
- e) Inhalational solutions
- f) Chemotherapy drugs

[3] Which category in your experience serves more Medicare part B spending per beneficiary?

- a) Drugs administered by injection.
- b) Clotting factor drugs
- c) Miscellaneous drugs
- d) Immunosuppressive drugs
- e) Inhalational solutions
- f) Chemotherapy drugs

[4] Which category in your experience lead to more Medicare part B spending per dose?

- a) Drugs administered by injection.
- b) Clotting factor drugs
- c) Miscellaneous drugs
- d) Immunosuppressive drugs
- e) Inhalational solutions
- f) Chemotherapy drugs

Section 2: Waste and Financial Consequences

[1] Are you aware of the significant amounts of expensive Medicare part B drugs being discarded, leading to waste and financial consequences for patients?

a) Yes

b) No

If Yes, Which category in your experience lead to more Medicare part B discarded units wastage?

a) Drugs administered by injection.

b) Clotting factor drugs

c) Miscellaneous drugs

d) Immunosuppressive drugs

e) Inhalational solutions

f) Chemotherapy drugs

Section 3: Drug manufacturing regulations

Should there be stricter regulations or guidelines to ensure drug manufacturers provide appropriate packaging quantities based on patient needs?

a) Yes

b) No

c) Unsure

Section 4: Potential Solutions

[1] Should reimbursement mechanisms or payment structures be revised to incentivize appropriate packaging quantities and reduce waste?

a) Yes

b) No

c) Not sure

[3] Do you think there is a need for increased collaboration between stakeholders to address the payer aspect of discarded chemotherapy drugs

a) Yes

b) No

c) Not sure

Thank you for your participation in this questionnaire. Your insights are greatly appreciated.