



September 18, 2020

The Honorable Frank Pallone Jr.  
Chairman, Committee on Energy and  
Commerce  
U.S. House of Representatives  
2017 Rayburn House Office Building  
Washington, DC 20515

The Honorable Anna G. Eshoo  
Chairwoman, Subcommittee on Health  
Committee on Energy and Commerce  
U.S. House of Representatives  
202 Cannon House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
Chairwoman, Subcommittee on Oversight and Investigation  
Committee on Energy and Commerce  
U.S. House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

**RE: Request for Information and Data on United States Postal Service Operational Changes and Home Delivery Services (August 21, 2020)**

Dear Chairman Pallone, Chairwoman Eshoo, and Chairwoman DeGette:

On behalf of the Pharmaceutical Care Management Association (PCMA), I am writing in response to your letter of August 21, 2020 requesting information and data relating to reported delays in home delivery of prescription drugs (mail-service pharmacy) as a result of recent operational changes at the United States Postal Service (USPS).

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors, including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others. Our members work closely with employers, health plans, and other issuers to secure lower prescription drugs costs, increase access to affordable medication, and promote better individual health outcomes.

Our member companies also operate mail-service, retail, and specialty pharmacies, which many Americans rely on for convenience and value. Mail-service pharmacies ship hundreds of millions of prescriptions each year via the USPS and other national mail and shipping carriers, including to individuals living with chronic conditions, such as cardiovascular disease and depression;<sup>1</sup> and

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<sup>1</sup> Juliette Cubanski, Jeannie Fuglesten Biniek, Matthew Rae, Anthony Damico, Brittni Frederiksen, and Alina Salganicoff, "Mail Delays Could Affect Mail-Order Prescriptions for Millions of Medicare Part D Enrollees and Large Employer Plan Enrollees" Kaiser Family Foundation (August 20, 2020), <https://www.kff.org/coronavirus-COVID->



individuals and families residing in rural, remote, and other underserved communities. Mail-service pharmacies offer important benefits for patients, including higher rates of prescription adherence, fewer medication errors (such as drug-to-drug interactions), greater dispensing accuracy, and cost savings.<sup>2</sup>

Throughout the coronavirus (COVID-19) public health emergency, PBMs' mail-service pharmacies have continued to be a safe, convenient and reliable way for patients practicing physical distancing to get their maintenance medications and other essential prescription drugs. PBMs also continued to provide the vital clinical services and support to see individuals and families through this difficult time. That has not changed. In fact, data show an increase in prescription drugs dispensed through mail-service pharmacy during the pandemic.<sup>3,4</sup> In addition, PBMs and their retail pharmacy partners have worked together to develop industry best practices to allow for waiver of proof-of-delivery signature requirements to minimize patient (and carrier) exposure when patients receive a prescription through home delivery.

The USPS and other national mail and shipping carriers are vital to delivering needed medications to America's patients, and our PBM-member companies value the particular role of the USPS in assuring the reliability and affordability of mail-service pharmacy. PBMs carefully plan for, and nimbly adjust in response to, any potential disruptions, including reported issues with the USPS. PBMs use multiple national mail and shipping carriers and employ a suite of sophisticated processes that have mitigated the experience of significant delivery delays thus far. To be sure, the USPS is critical to affordable and timely mail-service pharmacy operations, and we believe America's post office should be adequately funded and well functioning.

PCMA appreciates the committee's interest in and support for the essential role of mail-service pharmacy. We believe our answers to your questions provide helpful context, information, and data as the committee continues its work. In addition to responding to the specific questions, we believe it helpful to provide background on mail-service pharmacy; the value and benefits mail-service pharmacies provide to patients, employers, health plans, and other issuers; how PBMs facilitate reliable and timely access to mail-delivered prescription drugs; and the important role of the USPS and other national shipping and mail providers in facilitating continued access to prescription drugs during the COVID-19 pandemic and beyond.

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[19/issue-brief/mail-delays-could-affect-mail-order-prescriptions-for-millions-of-medicare-part-d-and-large-employer-plan-enrollees/](#).

<sup>2</sup> Elena V. Fernandez, Jennifer A. McDaniel, Norman V. Carroll, "Examination of the Link Between Medication Adherence and Use of Mail-Order Pharmacies in Chronic Disease States," *Journal of Managed Care & Specialty Pharmacy* (November 2016) Vol. 22, No. 11: 1247-1259, <https://www.jmcp.org/doi/10.18553/jmcp.2016.22.11.1247>.

<sup>3</sup> Op. cit, IQVIA (August 17, 2020).

<sup>4</sup> Alliance of Community Health Plans, "COVID-19 Shifts Consumer Behavior, Attitudes Toward Health Care Services" (May 21, 2020), <https://achp.org/release-COVID-19-shifts-consumer-behavior-attitudes-toward-healthcare-services/>.

## Background

PBMs are projected to save employers, unions, government programs, and consumers more than \$1 trillion on prescription drug costs over the next decade.<sup>5</sup> PBMs are the only part of the pharmaceutical supply and payment chain working to reduce drug costs across the health care system, including by:

- Offering home delivery of medications and creating networks of high quality and more affordable pharmacies;
- Encouraging the use of generics and more affordable brand medications;
- Negotiating rebates from drug manufacturers and discounts from pharmacies;
- Providing personalized care coordination, case or disease management services, patient counseling and education services, and pharmacist review (to detect adverse drug reactions) to ensure better quality of health care for patients, including those prescribed high-cost and often complex specialty medications<sup>6</sup>; and
- Reducing prescription drug waste, helping prevent medication errors, and improving drug therapy and patient adherence.<sup>7</sup>

PBMs build networks of pharmacies to provide consumers convenient, high-quality, and more affordable access to their needed medications, through retail, mail-service, and specialty pharmacies. In building these pharmacy networks, PBMs make recommendations to employers, health plan sponsors, and other issuers on the diversity of available pharmacy channels (i.e., retail, mail, and specialty) to best meet consumer needs and preferences.

Across all network pharmacies, regardless of channel, PBMs monitor prescription safety, alerting pharmacists to potential drug interactions—even if a consumer uses multiple pharmacies. Network pharmacies compete on service, convenience, and quality to attract consumers within a particular health plan. This competition helps keep the rising costs of prescription drugs down.

For PBMs, our top priority remains enabling everyone to access, as safely, conveniently, and cost-effectively as possible, the quality health care they need. Retail pharmacies are an important avenue for accessing prescription drugs; so, too, is mail-service pharmacy. A significant number of consumers find that having their regularly needed medications – often referred to as

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<sup>5</sup> Visante, “Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers” (February 2020), <https://www.pcmnet.org/wp-content/uploads/2020/02/Pharmacy-Benefit-Managers-Generating-Savings-for-Plan-Sponsors-and-Consumers-2020-1.pdf>.

<sup>6</sup> Through specialty pharmacy services, PBMs will help extend and improve the quality of life for patients with multiple sclerosis and rheumatoid arthritis by approximately 1 million quality-adjusted life years (QALYs) over 10 years. See Visante, “The Return on Investment (ROI) on PBM Services” (February 2020), <https://www.pcmnet.org/wp-content/uploads/2020/02/ROI-on-PBM-Services-FINAL.pdf>.

<sup>7</sup> Over the next 10 years, PBMs will help prevent 1 billion medication errors (approximately 100 million per year). PBMs improve drug therapy and patient adherence in diabetes patients, helping to prevent some 400,000 heart attacks; 230,000 incidents of kidney disease; 250,000 strokes; and 8,000 amputations annually. Ibid.



maintenance medications – delivered to their homes by mail is more convenient and affordable, and surveys show patients are highly satisfied with mail-service pharmacies.

During the current public health emergency, mail-service pharmacies have continued to be a safe, convenient, and reliable way for patients to get their maintenance medications and other essential prescription drugs. In fact, through July 2020, the IQVIA Institute has found a 20% increase in prescription drugs filled through mail-service pharmacies during the pandemic, as compared to 2019.<sup>8</sup> Mail-service has helped Americans to access their prescriptions while sheltering at home or practicing physical distancing at this crucial time.

To use a mail-service pharmacy, a patient may first use their local retail pharmacy to fill a new prescription. If the prescription is for a chronic condition, a patient will often fill the first several prescriptions at the retail pharmacy. Once stabilized on the medication, the patient can choose to use mail-service delivery for their prescription moving forward. The patient, as well as their physician or other prescriber, can use the telephone, fax, mail, or internet to submit their prescription(s) and communicate with the mail-service pharmacy. Prescriptions are filled and shipped to the patient, usually within three-to-five business days. Mail-service pharmacies may offer delivery within 24 to 48 hours depending on a patient's needs and the type of medication.

Mail-service pharmacies are heavily regulated, including extensive federal requirements and regulations and state licensure requirements, and adhere to community standards of professionalism. For example, the Centers for Medicare & Medicaid Services (CMS) regulates the use of mail-service pharmacy within Medicare Part D, including conditions on the automatic mailing of medications; enrollee protections, such as initial consent, withdrawal of consent, and the ability to file grievances and complaints; cost-sharing refunds for unneeded or unwanted mailed medications; discontinuation of automatic deliveries; and printed and online enrollee materials.<sup>9</sup> Indeed, under current CMS policy, use of mail-service pharmacies or any automatic mailings of medications within Part D must be voluntary. Part D plan sponsors are permitted to offer voluntary opt-in to automatic mailing of refills of established prescription drug therapies, on a drug-by-drug basis, and *only* upon consent from the enrollee. In addition, mail-service pharmacies are required to comply with federal regulatory requirements for the storage and dispensing of controlled substances, as enforced by the U.S. Drug Enforcement Administration.

Many states require mail-service pharmacies to meet all federal standards.<sup>10</sup> In addition, many require they be licensed and in good standing with the state board of pharmacy in their home states. In states in which they do business other than their home states, most require mail-service

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<sup>8</sup> IQVIA, "Monitoring the Impact of COVID-19 on the Pharmaceutical Market" (August 17, 2020),

<https://www.iqvia.com/library/white-papers/monitoring-the-impact-of-COVID-19-on-the-pharmaceutical-market>.

<sup>9</sup> Centers for Medicare & Medicaid Services (CMS), *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, "CY 2020 Call Letter," Section III – Part D, Part D Mail Order Auto-Ship Modifications (April 1, 2019), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>.

<sup>10</sup> Examples include the States of New York and Washington, among others.



pharmacies to obtain a Nonresident Pharmacy License, Mail-Order Pharmacy License, Controlled Substance License, and/or Nonresident Pharmacist-in-Charge (PIC) License. Often as a condition for obtaining a Nonresident Pharmacy License, states also may require one or more PICs or other pharmacists on staff to be licensed in the nonresident state. Accreditation may also be required by employers, health plans, and other issuers.

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### **Value of Mail-Service Pharmacy**

On health care issues, poll after poll shows that cost is the greatest concern for both consumers and employers. At the same time, the growth of online retailers highlights greater consumer preference for convenience and home delivery. While patients with short-term, acute needs continue to use retail pharmacies, patients living with chronic conditions often use mail-service and specialty pharmacies for the convenience and cost savings.

While the combination of the ongoing COVID-19 pandemic and changes to USPS operational processes reflect new and evolving conditions, America's PBMs continue to mail medications safely, and patients continue to have reliable access to this pharmacy channel. Patients experience numerous benefits when using mail-service pharmacies, including use of more-affordable alternative drug options, including generics; greater safety through higher dispensing accuracy rates; convenient access to 24/7 confidential counseling and telepharmacy; and greater medication adherence.

There is more than 10 years of peer-reviewed evidence in the literature detailing the clinical, safety, and cost-savings benefits of receiving prescriptions by mail. Below we describe this well-established body of research and discuss its implications.

#### Clinical Outcomes

Mail-service pharmacies are vital and effective options for American consumers with prescription drug needs. Mail-service pharmacies are not only preferred by patients and help them to save money on prescription drugs, but peer-reviewed research has demonstrated the potential for improved clinical outcomes from the use of mail-service pharmacies. Specifically, a well-established body of research has demonstrated that filling prescriptions through mail-service pharmacies and in 90-day supplies, the typical quantity dispensed through mail, can increase adherence to drug regimens, including for individuals living with chronic conditions.

Peer-reviewed research shows:

- Patients receiving their medications through mail-service pharmacies have higher medication adherence rates (84.7%) as compared to patients obtaining medications through retail pharmacies (76.9%).<sup>11</sup>
- Patients who received their medications in 90-day supplies, the typical quantity dispensed through mail-service pharmacies, have higher adherence rates compared to those receiving 30-day supplies.<sup>12</sup>
- A 2016 review of research pertaining to retail and mail-service pharmacies and medication adherence found that a majority of studies – 14 out of the 15 reviewed – supported higher adherence through mail-service pharmacies.<sup>13</sup>
- “A prescription refill synchronization program for Medicare beneficiaries using a mail-order pharmacy was associated with improvements in adherence to antihypertensives, lipid-lowering agents, and antidiabetic agents.”<sup>14</sup>
- A 2014 presentation to the Academy of Managed Care Pharmacy described a study finding higher medication adherence in patients who continuously used mail-service pharmacies as compared to members who switched between mail-service and retail pharmacies. The study found a similar pattern across multiple therapeutic classes of maintenance medications and different enrollee populations.<sup>15</sup>
- A review of oral antidiabetic medication adherence among Medicare Part D beneficiaries concluded that beneficiaries using mail-service pharmacies had improved adherence compared to those who used retail pharmacies.<sup>16</sup>

Adherence to treatment is a major step in improving clinical outcomes for those living with chronic conditions. Medication adherence contributes significantly to reducing the chances of adverse

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<sup>11</sup> O. Kenrik Duru, Julie A. Schmittiel, Wendy T. Dyer, Melissa M. Parker, Connie S. Uratsu, James Chan, and Andrew J. Karter, “Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications” *American Journal of Managed Care* (January 2010) Vol. 16, No. 1: 33-40, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3015238/>.

<sup>12</sup> Matthew Hermes, Patrick P. Gleason, and Catherine I. Starner, “Adherence to Chronic Medication Therapy Associated with 90-Day Supplies Compared with 30-Day Supplies,” *Journal of Managed Care Pharmacy* (2010) Vol. 16: 141-142; Michael Taitel, Leonard Fensterheim, Heather Kirkham, Ryan Sekula, and Ian Duncan, “Medication Days’ Supply, Adherence, Wastage, and Cost Among Chronic Patients in Medicaid,” *Medicare & Medicaid Research Review* (2012) Vol. 2, No. 3, [https://www.cms.gov/mmr/Downloads/MMRR2012\\_002\\_03\\_A04.pdf](https://www.cms.gov/mmr/Downloads/MMRR2012_002_03_A04.pdf); and, Sarah King, Celine Miani, Josephine Exley, Jody Larkin, Anne Kirtley, and Rupert A. Payne, “Impact of issuing longer- versus shorter-duration prescriptions: a systemic review,” *British Journal of General Practice* (April 2018) Vol. 68, No. 669: e286-e292, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5863683/>.

<sup>13</sup> Op. cit, Elena V. Fernandez et al. (November 2016).

<sup>14</sup> Jalpa A. Doshi, Raymond Lim, Pengxiang Li, Peinix P. Young, Victor F. Lawnicki, Joseph J. State, Andrea B. Troxel, and Kevin G. Volpp, “A Synchronized Prescription Refill Program Improved Medication Adherence,” *Health Affairs* (2015), Vol. 35, No. 8, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1456>.

<sup>15</sup> Josephine Tran, C.M. Conrad, Toros Caglar, W. O’Byrant, Karen M. Stockl, Heidi C. Lew, and Brian K. Solow, “Adherence to Chronic Therapeutic Classes of Medications in Mail Service Users,” *Journal of Managed Care & Specialty Pharmacy* (April 2014) Vol. 20, No. 4-a, <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2014.20.4-a.S1>.

<sup>16</sup> Lihua Zhang, Armen Zakharyan, Karen M. Stockl, Ann S. M. Harada, Bradford S. Curtis, and Brian K. Solow, “Mail-order pharmacy use and medication adherence among Medicare Part D beneficiaries with diabetes,” *Journal of Medical Economics* (2011) Vol. 14, No. 5: 562-567, <https://pubmed.ncbi.nlm.nih.gov/21728913/>.

health outcomes and lowering overall health care costs through avoidance of acute episodes, including extra visits to the doctor and rehospitalizations. According to the Centers for Disease Control and Prevention, “nonadherence [to medication] is associated with higher rates of hospital admissions, suboptimal health outcomes, increased morbidity and mortality, and increased health care costs.”<sup>17</sup>

There is a well-established body of evidence demonstrating not only higher rates of prescription adherence among patients using mail-service pharmacies, but other improved clinical outcomes correlated to adherence. For example, patients with diabetes who received prescribed heart medications by mail were less likely to visit the emergency room than those patients who picked up their medications in person, according to a 2013 study.<sup>18</sup> A 2011 study found that “new statin users who primarily refilled by mail were more likely to be in control of their LDL-C levels within 3-15 months after medication initiation than patients who used” retail pharmacies. This positive association was consistent across patient gender, race, and ethnicity.<sup>19</sup>

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### Safety and Accuracy

The National Academy of Medicine’s (formerly the Institute of Medicine) seminal report, *To Err is Human: Building a Safer Health System*, found that thousands of patients are harmed by medication errors.<sup>20</sup> Citing studies of inpatient and outpatient settings of care, the National Academy of Medicine concluded a high frequency and cost of medication errors, including errors in prescribing medications, dispensing by pharmacists, and unintentional patient nonadherence, which may result in what are called adverse drug reactions (ADRs). According to a 2018 U.S. Food and Drug Administration report, ADRs may result in more than 106,000 deaths and 2 million injuries per year in the United States.<sup>21</sup> One estimate of the cost of prescription drug-related morbidity and mortality is \$135 billion annually.<sup>22</sup>

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<sup>17</sup> Andrea B. Neiman, Todd Ruppap, Michael Ho, Larry Garber, Paul J. Weidle, Yuling Hong, Mary G. George, and Phoebe G. Thorpe, CDC, “CDC Grand Rounds: Improving Medication Adherence for Chronic Disease,” *Morbidity and Mortality Weekly Report* (November 17, 2017), Vol. 66, No. 45, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm>.

<sup>18</sup> Julie A. Schmittiel, Andrew J. Karter, Wendy T. Dyer, James Chan, and O. Kenrik Duru, “Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes,” *American Journal of Managed Care* (November 2013), <https://www.ajmc.com/view/safety-and-effectiveness-of-mail-order-pharmacy-use-in-diabetes>.

<sup>19</sup> Julie A. Schmittiel, Andrew J. Karter, Wendy T. Dyer, Melissa Parker, Connie Uratsu, James Chan, and O. Kenrik Duru, “The Comparative Effectiveness of Mail Order Pharmacy Use vs. Local Pharmacy Use on LDL-C Control in New Statin Users,” *Journal of General Internal Medicine* (December 2011) Vol. 26, No. 12: 1396-1402, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3235607/>.

<sup>20</sup> Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Eds. *To Err is Human: Building a Safer Health System*. Committee on Quality of Health Care in America, Institute of Medicine (now, National Academy of Medicine). Washington, D.C.: National Academies Press (2000), <https://pubmed.ncbi.nlm.nih.gov/25077248/>.

<sup>21</sup> U.S. Food and Drug Administration, “Preventable Adverse Drug Reactions: A Focus on Drug Interactions” (March 6, 2018), <https://www.fda.gov/drugs/drug-interactions-labeling/preventable-adverse-drug-reactions-focus-drug-interactions>.

<sup>22</sup> J. Lyle Bootman, Donald L. Harrison, and Emily Cox, “The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities,” *Archive of Internal Medicine* (1997), Vol. 157, No. 18: 2089-2096, <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/623885>.

The safety and efficacy of mailed prescriptions is of utmost importance and is well reflected in the level of precision and planning undertaken by mail-service pharmacies in the mailing of prescription drugs, including those with special handling requirements. The precision also reflects the needs and preferences of consumers not only for safe, high-quality products, but also to know when their prescription will be shipped and received.<sup>23</sup>

Mail-service pharmacies offer enhanced safeguards for safety and accuracy. Before shipping a prescription to a patient's home, mail-service pharmacies' staff pharmacists electronically review the patient's medications to detect ADRs, especially any potentially harmful drug-to-drug interactions — even when the patient uses several pharmacies.<sup>24</sup> Pharmacists on staff also employ this information to conduct clinical case management, patient education, and counseling.

Pharmacist oversight is complemented by the use of highly automated systems (e.g., computer-controlled quality processes, robotic dispensing, and advanced workflow practices) allowing pharmacies to fill large quantities of prescriptions while simultaneously ensuring the accuracy of counting and dispensing medications and reducing potential medication errors. Peer-reviewed data found that highly automated mail-service pharmacies dispensed prescriptions with 23 times greater accuracy than retail pharmacies.<sup>25</sup> The error rate for mail-service pharmacies was zero in several of the most critical areas, including dispensing the correct drug, dosage, and dosage form. An analysis by the U.S. Department of Defense Office of Inspector General also found fewer clinical errors associated with prescriptions dispensed by mail-service pharmacies.<sup>26</sup>

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### Cost Savings

Along with improved clinical outcomes and increased safety, accuracy, and adherence, mail-service pharmacies will save consumers an estimated \$5.1 billion in a single year, or \$59.6 billion over 10 years.<sup>27</sup> Mail-service pharmacies also have been found to be more cost-effective than retail pharmacies by the Federal Trade Commission, U.S. Department of Defense, CMS,

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<sup>23</sup> For example, as required by CMS, Medicare Part D plan sponsors require their network mail-service pharmacies to provide enrollees an approximate shipping date range, of within two-to-three days, prior to delivery. See CMS, "Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions" (December 12, 2013).

<sup>24</sup> In such cases, mail-service pharmacies operated by PBMs do not have purview into competitively sensitive information of their competitors (e.g., pharmacy pricing, reimbursement data, etc.).

<sup>25</sup> In contrast, retail pharmacies had an average error rate of one in 50 prescriptions. See J. Russell Teagarden et al., "Dispensing Error Rate in a Highly Automated Mail-Service Pharmacy Practice," *Pharmacotherapy: Official Journal of the American College of Clinical Pharmacy* (2005) Vol. 25, No. 11: 1629-1635, <https://pubmed.ncbi.nlm.nih.gov/16232024/>.

<sup>26</sup> Office of Inspector General, U.S. Department of Defense, "The TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place" (July 2013), <https://www.dodig.mil/reports.html/Article/1118953/the-tricare-mail-order-program-was-cost-efficient-and-adequate-dispensing-contr/>.

<sup>27</sup> Visante, "Mail-Service and Specialty Pharmacies Will Save More than \$300 Billion for Consumers, Employers, and Other Payers Over the Next 10 Years" (September 2014), <http://www.pcmnet.org/images/stories/uploads/2014/visantepcma%20mail%20and%20specialty%20savings.pdf>.

and U.S. Government Accountability Office (GAO).<sup>28,29,30,31</sup> Studies by the U.S. Department of Defense and CMS both found maintenance medications dispensed through mail-service pharmacies cost less overall than when dispensed by retail pharmacies: 16.7% savings in the TRICARE program, and 16% savings in Medicare Part D. As further evidence of their cost effectiveness, the U.S. Department of Health and Human Services listed mail-service pharmacy as a way states could “purchase drugs more efficiently” for their Medicaid programs.<sup>32</sup>

Based on a national survey of employer plan sponsors, the median mail-service pharmacy discount on brand drugs is 3-5 percentage points better than the discount achieved by retail drugstores.<sup>33</sup> In addition, the survey found that 55% of plan sponsors pay no dispensing fees to mail-service pharmacies, which represents approximately 1 additional percentage point of savings for brand drugs and 4% of savings for generic drugs. Based on this evidence, Visante estimates savings from mail-service pharmacies of up to 1.2% of total expenditures for plans with full use of mail-service pharmacies and an average mail-service savings of 0.5% on overall drug costs relative to expenditures without mail-service pharmacies.

In addition to lower drug acquisition costs, mail-service pharmacies can dispense prescription drugs at lower costs in part because they have lower overhead and fulfillment costs.<sup>34</sup> For example, a mail-service pharmacy may buy in bulk, which presents efficiencies easily translated into lower costs and greater affordability for health plan sponsors and patients. According to a study by the GAO on the Federal Employees Health Benefits Program, “the average price paid at mail order for the brand and generic drugs was about 27% and 53% below the average cash-paying customer price, respectively” at a retail pharmacy.<sup>35</sup> Cost savings achieved by mail-service pharmacies are essential in the ongoing struggle to keep health insurance affordable and available to consumers in the face of ever-rising drug prices.

Prescriptions obtained through mail-service pharmacies are associated with less waste, which can result in cost savings for the overall health care system. Waste occurs when patients stop taking their medication before using the entire supply of a prescription. This can be due to the

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<sup>28</sup> Federal Trade Commission, “Pharmacy benefit manager: Ownership of mail-order pharmacies” (August 2005), <http://ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

<sup>29</sup> Op. cit, Office of Inspector General, U.S. Department of Defense (July 2013).

<sup>30</sup> CMS, “Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies” (December 2013).

<sup>31</sup> U.S. Government Accountability Office (GAO), “Federal Employees’ Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies,” Figure 2 (January 2003), <https://www.gao.gov/assets/240/236828.pdf>.

<sup>32</sup> U.S. Department of Health and Human Services, Secretary of Health and Human Services, “Letter to Governors of February 3, 2011” (February 3, 2011), <https://medicaidirectors.org/wp-content/uploads/2015/08/hhslettertogovernors.pdf>.

<sup>33</sup> Pharmacy Benefit Management Institute (PBMI), “2018 Trends in Drug Benefit Design” (February 2019), [https://www.pbmi.com/ItemDetail?iProductCode=BDR\\_2018&Category=BDR](https://www.pbmi.com/ItemDetail?iProductCode=BDR_2018&Category=BDR).

<sup>34</sup> Jonathan Orszag and Kevin Green, “The Economic Benefits of Pharmacy Benefit Managers” (December 5, 2011), [http://compass-lexecon.s3.amazonaws.com/prod/cms-documents/3ba1d5cf75e5e5f4/The\\_Economic\\_Benefits\\_of\\_Pharmacy\\_Benefit\\_Managers\\_Orszag\\_Green.pdf](http://compass-lexecon.s3.amazonaws.com/prod/cms-documents/3ba1d5cf75e5e5f4/The_Economic_Benefits_of_Pharmacy_Benefit_Managers_Orszag_Green.pdf).

<sup>35</sup> Op. cit, GAO (January 2003).

need to discontinue therapy, switch to a different drug, or change dosage strengths. To minimize waste, mail-service pharmacies are typically used only once a patient is established on a particular prescription drug regimen; for example, after having finished several 30-day prescriptions from their retail pharmacy. A 2011 study of patients taking statin medications found that, on a yearly basis, four 90-day prescriptions dispensed through retail pharmacies were associated with 4.04 days of waste, while four 90-day prescriptions dispensed through mail-service pharmacies were associated with 3.08 days of waste.<sup>36</sup>

When patients' circumstances change, whether unexpectedly or due to a change in prescription therapy or personal preference, mail-service pharmacies have well-established processes to respond to patient requests. Discontinuing auto-ship arrangements and other adjustments are essential not only to patient health and safety, but also to decreasing the potential for waste. For example, as required by CMS, Medicare Part D plan sponsors require network mail-service pharmacies to permit enrollees to opt-out of auto-ship refills at any time and for any reason.<sup>37</sup> In addition, Part D plan sponsors require mail-service pharmacies to discontinue auto-ship arrangements, including when an enrollee has entered a skilled nursing facility or elected hospice coverage. Part D plan sponsors also provide a minimum of two shipping reminders *before* each auto-ship of a refill, an approximate shipping date range, and the option to return – with refund – unwanted or unneeded medications.<sup>38</sup>

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## PCMA Response to Committee Questions

Across the months of August and September 2020, PCMA surveyed 13 of its PBM-member companies on the six questions specified in the committee's August 21, 2020 letter.<sup>39</sup> Of these, eight member companies (or 60% of those surveyed) responded, representing 182 million non-specialty prescriptions delivered to consumers from mail-service pharmacies in 2019. We note, however, that not all eight respondents completed the survey in full. As a result, several responses to the committee's questions reflect a smaller sample size than this total non-specialty prescription fill figure, which are noted in each of the specific responses.

To ensure company-specific information remained confidential, the survey was conducted confidentially through a third-party organization. The aggregate data reflects total volume for all

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<sup>36</sup> T. Vuong et al., "Statin Waste Associated with 90-day Supplies Compared to 30-day Supplies," presented to the Academy of Managed Care Pharmacy (2011), [http://cdn2.content.compendiumblog.com/uploads/user/e7c690e8-6ff9-102a-ac6d-e4aebca50425/accf0d87-0d14-4aa7-bbf3-193b90c8d68c/File/93a2f313bba7cfd7db19da5a9e3be3b1/statin\\_waste\\_amcposter6.pdf](http://cdn2.content.compendiumblog.com/uploads/user/e7c690e8-6ff9-102a-ac6d-e4aebca50425/accf0d87-0d14-4aa7-bbf3-193b90c8d68c/File/93a2f313bba7cfd7db19da5a9e3be3b1/statin_waste_amcposter6.pdf).

<sup>37</sup> Op. cit, CMS (April 1, 2019).

<sup>38</sup> Op. cit, CMS (December 12, 2013).

<sup>39</sup> As of September 20, 2020, the following companies were members of PCMA: Abarca, CerpaxRx, CVS Health, Envolve Pharmacy Solutions, Express Scripts, Humana Pharmacy Solutions, IngenioRx, Integrated Prescription Management, MagellanRx Management, MaxorPlus, MedImpact, OptumRx, PerformRx, Prime Therapeutics, Serve You Rx, and WellDyne. For a listing of PCMA's member companies, see <http://www.pcmnet.org/about/members/>.



of 2019, unless otherwise noted, and includes only mail-service prescriptions and no prescription deliveries originating from a retail pharmacy. Because surveys were completed under a strict confidentiality agreement to shield competitive information from becoming apparent to member companies, PCMA's members do not know which of the surveyed member companies responded.

Within the time permitted and based on the data provided through this anonymous PBM industry survey, we respond below to each of the committee's questions as comprehensively as possible given the inherent and identified limitations in the available data.<sup>40</sup> We believe our answers provide helpful context as the committee seeks to investigate reported delays and disruptions in the delivery of mail, including prescription drugs, by the USPS.

**1. Please provide a description of the mail-order delivery services offered by PCMA's members, including the breakdown of supply duration for prescription refills (i.e., the percentage of 30-day and 90-day supplies filled).**

Nearly all PCMA survey respondents specified the following components of mail-service pharmacy services: providing 90-day supplies of maintenance medications for chronic conditions; conducting medication safety reviews; making available call centers staffed by licensed clinicians; making available online patient portals; establishing safety procedures to reduce medication filling error rates; and providing disease-management programs for patients.

A minority of respondents also noted that they offer refill synchronization and programs that encourage medication adherence. For the non-specialty prescriptions filled through mail-service pharmacies in 2019, survey respondents noted approximately nine in 10 mail-service fills were for 90-day supplies (88%), with 30-day and other number-of-day supplies representing a minority of fills (4% and 8%, respectively).

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<sup>40</sup> The results of this survey are impacted by selection effects in multiple ways, including that the survey was voluntary and PBM-member companies self-selected to participate. This sample selection does not permit proper randomization to be achieved. Further, as the survey reflects a portion of not only the PBM market and mail pharmacy channel, but also a portion of the overall prescription drug market, the findings are not wholly representative of the experiences of the U.S. population. For example, the survey does not and cannot account for the experiences of individuals served by the U.S. Department of Veterans Affairs, which is not served by private-sector mail-service pharmacies. In addition to sample selection, the survey is impacted by attrition, whereas not all self-selected respondents completed the survey in full. To provide the most comprehensive data possible, we have included all received data; we did not remove respondents' responses to questions in cases where the respondent did not respond to other questions (i.e., nonresponse).

**2. Please provide any known demographic data for the enrollees utilizing PCMA’s membership’s mail-order delivery services for prescription medications, including by known medical condition, age, race and ethnicity, income level, and geographic status, where possible).**

Reflecting the committee’s question, the survey asked respondents to provide available demographic data along the following parameters for patients filling at least one non-specialty prescription through mail-service pharmacy in 2019: drug class (as a proxy for known medical condition), age, gender, race and/or ethnicity, household income level, and U.S. census region (as a proxy for geographic status). For the more than 10 million unique patients that filled at least one non-specialty prescription through mail-service pharmacy in 2019, our survey findings suggest an equitable and expected distribution across the following demographic categories: drug class (Figure 2.1), age (Figure 2.2), gender (Figure 2.3), and geography (Figure 2.4).<sup>41</sup>

With regard to the committee’s request for data regarding race and ethnicity and income level, respondents to our survey noted that they do not request race/ethnicity or household income level data from the consumers they serve, and thus we do not have the requisite data to be responsive to this particular portion of the question.

With regard to the committee’s request for data regarding patients’ known medical conditions, the survey employed “drug class” as a proxy (Figure 2.1). This was done because medical claims data is typically unavailable to PBMs and mail-service pharmacies. Specifically, we would note with respect to the Medicare Prescription Drug Program (Part D), stand-alone Prescription Drug Plans (PDPs) *cannot* use, except for limited purposes, medical claims data collected under the Medicare fee-for-service program. Broader authority to use such data could provide more comprehensive information about an enrollee’s specific medical conditions and current health care treatments and enable Part D plans to improve integration and coordination of care.<sup>42</sup>

We appreciate that Congress addressed this concern in 2018, although to coordinate care and make the best coverage decisions for beneficiaries, Part D plans need to be able to use medical as well as prescription data. Legislative changes allowing use of these data for this purpose would promote coordination of care, allow indication-based formularies, advance value-based payment, and reduce prescriber burden

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<sup>41</sup> Importantly, to place the provided demographic data in context: not all of the member company respondents answered this question in full or at all, which may result in a differential between the total unique patients figure and the demographic category-specific figures. Not all figures add to 100 percent due to rounding.

<sup>42</sup> Under the Bipartisan Budget Act (BBA) of 2018, Congress required the U.S. Department of Health and Human Services to establish a process under which a Part D plan could request Medicare Parts A and B medical claims data for enrollees in their drug plan. The BBA specified limitations on the use of the Parts A and B claims data, including prohibiting use of the data to inform Part D coverage determinations. This session, the Senate Finance Committee reported out a bill that would allow Part D plans to use Medicare claims data for Part D coverage determinations, such as to improve therapeutic outcomes.

Figure 2.1. Percentage of Unique Consumers with At Least One Non-Specialty Prescription Drug through Mail-service Pharmacy from Each Select Drug Class, 2019

<b>Drug Class</b>	<b>% Consumers</b>
Statins	39%
Antidiabetics	18%
Antidepressants and Anti-Anxiety	24%
Blood Pressure	53%
Anti-Inflammatory <sup>43</sup>	0.2%

Figure 2.2. Percentage of Unique Consumers with At Least One Non-Specialty Prescription Drug through Mail-service Pharmacy by Age Group, 2019

<b>Age Group<sup>44</sup></b>	<b>% Consumers</b>
0-18	3%
19-64	45%
65 and older	52%

Figure 2.3. Percentage of Unique Consumers with At Least One Non-Specialty Prescription Drug through Mail-service Pharmacy by Gender, 2019

<b>Gender</b>	<b>% Consumers</b>
Male	57%
Female	43%
Other or Not Identified	0.03%

With regard to geographic distribution (Figure 2.4), we note that the distribution better reflects the member company respondents' service areas, versus the geographic distribution of all mail-service pharmacy consumers. The data suggests, however, that mail-service pharmacy consumers served by our survey's respondents are not highly concentrated in any one particular region or regions. In addition, the geographic data does not reflect unique consumers, as some consumers have multiple addresses on file with their PBM or mail-service pharmacy.

<sup>43</sup> This category does not include nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids.

<sup>44</sup> If a patient changed age groups during the year (2019), the patient was counted in the older age group.

Figure 2.4. Percentage of Consumers with At Least One Non-Specialty Prescription Drug through Mail-service Pharmacy by Region as Defined by U.S. Census Bureau State, 2019

<b>U.S. Census Region</b>	<b>% Consumers</b>
<b>Midwest</b> (Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, North Dakota, Nebraska, Ohio, South Dakota, and Wisconsin)	24%
<b>Northeast</b> (Connecticut, Delaware, Maine, Maryland, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Washington, D.C.)	26%
<b>South</b> (Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia)	34%
<b>West</b> (Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington, and Wyoming)	16%
<b>Other</b> (e.g., Guam, Puerto Rico, Virgin Islands, etc.)	0.1%

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**3. To the fullest extent that the following is known and available, please provide:**

- a. The total, percentage, and breakdown by enrollee type of prescriptions filled via mail-order delivery services among PCMA’s membership each month for the period of March 2019 through August 2019 and March 2020 through August 2020.**

Figures 3.1 and 3.2, below, summarize total non-specialty prescriptions filled through survey respondents’ mail-service pharmacies. These figures reflect a narrower scope of respondents (five) than that for the total of non-specialty prescription fills in 2019 provided in response to Question 1 (eight).

The majority of prescriptions filled through mail-service pharmacies are 90-day versus 30-day fills (e.g., 88% in 2019), the 90-day prescriptions have a cyclical nature: a hill-and-valley trend. In 2019, for example, the 90-day “hill” appears to occur in April, whereas the “hill” in 2020 is in March (Figure 3.1). This year-over-year difference is echoed in data made available by the IQVIA Institute, which has speculated that the March 2020 “hill” may reflect preparedness and possible stockpiling behavior at the onset of the COVID-19 pandemic.<sup>45</sup>

This hill-and-valley trend appears in the March through August periods of both 2019 and 2020, but the hills appear in different months. Therefore, a longitudinal assessment (i.e., six months) of total percent change in non-specialty prescriptions filled through mail-service pharmacy is a better metric for evaluating pandemic-affected trends than a single month or month-to-month comparison. For the six-month period of March through August, our survey suggests a 3% (3.0

<sup>45</sup> Op. cit, IQVIA Institute (August 17, 2020).

million) increase in non-specialty prescriptions filled through mail-service pharmacy in 2020 as compared to 2019 (Figure 3.2).<sup>46</sup>

**Figure 3.1. Total and Percentage of Non-Specialty Prescriptions Filled through Mail-service Pharmacy, by Enrollee Type, March through August 2019 and March through August 2020**

	Medicare	Medicaid	Commercial	Other	Total
March 2019	7,272,809 (50%)	2,994 (0.02%)	2,934,444 (20%)	4,448,117 (30%)	14,658,364
March 2020	8,752,043 (52%)	3,002 (0.02%)	3,125,190 (18%)	5,067,170 (30%)	16,947,405
April 2019	7,915,649 (50%)	3,245 (0.02%)	3,248,993 (21%)	4,642,475 (29%)	15,810,362
April 2020	8,257,690 (52%)	3,765 (0.02%)	2,870,440 (18%)	4,667,468 (30%)	15,799,363
May 2019	7,817,241 (50%)	2,896 (0.02%)	3,151,414 (20%)	4,661,946 (30%)	15,633,497
May 2020	7,284,552 (51%)	3,019 (0.02%)	2,609,164 (18%)	4,488,908 (31%)	14,385,643
June 2019	7,298,490 (50%)	2,298 (0.02%)	2,896,834 (20%)	4,367,293 (30%)	14,564,915
June 2020	8,723,842 (54%)	3,486 (0.02%)	2,834,790 (17%)	4,742,757 (29%)	16,304,875
July 2019	8,035,172 (50%)	2,583 (0.02%)	3,007,414 (19%)	4,890,234 (31%)	15,935,403
July 2020	8,156,137 (52%)	3,462 (0.02%)	2,865,691 (18%)	4,680,081 (30%)	15,705,371
August 2019	7,689,263 (51%)	2,328 (0.02%)	2,740,322 (18%)	4,762,627 (31%)	15,194,540
August 2020	8,212,110 (53%)	3,259 (0.02%)	2,807,099 (18%)	4,612,669 (30%)	15,635,137

**Figure 3.2. Total Year-over-Year Change by Enrollee Type and Total Change and Total Percent Change in Non-Specialty Prescriptions Filled through Mail-service Pharmacy, by Select Months, March 2019 through August 2020**

	Medicare	Medicaid	Commercial	Other	Total and Total %Change
March	1,479,234	8	190,746	619,053	2,289,041 (16%)
April	342,041	520	-378,553	24,993	-10,999 (-0.1%)
May	-532,689	123	-542,250	-173,038	-1,247,854 (-8%)
June	1,425,352	1,188	-62,044	375,464	1,739,960 (12%)
July	120,965	879	-141,723	-210,153	-230,032 (-1%)
August	522,847	931	66,777	-149,958	440,597 (3%)
<b>Total Change</b>	<b>3,357,750</b>	<b>3,649</b>	<b>-867,047</b>	<b>486,631</b>	<b>2,980,713 (3%)</b>

<sup>46</sup> In interpreting the data, it should be noted that some survey respondents grouped their commercial data into the “other” category, making it appear larger than it otherwise would.

**b. The total percentage and breakdown by enrollee type of prescriptions filled via mail-order services delivered by USPS among PCMA’s membership each month for the period of March 2019 through August 2019 and March 2020 through August 2020.**

PCMA survey respondents reported a range of 93% to 94% of non-specialty mail-service prescriptions were delivered by the USPS for the March through August 2020 period, which is materially unchanged for the same period in the prior year (2019) despite the co-occurrence of the COVID-19 pandemic and operational changes at the USPS.

When PCMA surveyed in May 2020, survey respondents (i.e., five of the eight surveyed) reported an average of more than 85% of mail-service prescriptions delivered by the USPS, with several respondents reporting (again, anonymously to PCMA) numbers in excess of 90%. The difference in findings between our May 2020 and August-September 2020 surveys reflects the underlying difference in the collected samples based on those PBMs that were surveyed and responded, as well as the different markets (types of enrollees) served by the respondent PBMs. For example, as Figure 3.3 demonstrates, below, differences are evident between enrollee type (e.g., Medicare versus Medicaid), and such differences can be observed at the PBM-company level.

**Figure 3.3. Total Percentage of Non-Specialty Prescriptions Filled through Mail-service Pharmacy and Delivered by USPS, by Enrollee Type, by Select Months, March 2019 through August 2020**

	Medicare	Medicaid	Commercial	Other	Total
March 2019	93%	86%	90%	92%	92%
March 2020	96%	87%	93%	91%	94%
April 2019	96%	94%	93%	93%	94%
April 2020	96%	87%	93%	91%	94%
May 2019	95%	90%	93%	93%	94%
May 2020	96%	88%	93%	91%	94%
June 2019	94%	84%	91%	93%	93%
June 2020	95%	88%	92%	91%	94%
July 2019	93%	83%	91%	92%	92%
July 2020	95%	86%	92%	91%	93%
August 2019	94%	83%	91%	92%	93%
August 2020	95%	87%	92%	91%	93%

**c. The range and average length of delivery time for mail-order delivery services among PCMA’s membership each month for the period of March 2019 through August 2019 and March 2020 through August 2020.**

PCMA survey respondents were asked about the range and average length of delivery time for mail-service prescriptions for the identified periods. Three companies responded to this question, of which only one provided complete and valid data that also was consistent with the terms of the Committee’s question. In addition to the overly limited sample (i.e., one response), meaningful conclusions cannot be drawn as it is unclear how representative this single response is of the broader PBM market.

Overall, however, the three responses suggest the average number shipping time through the USPS increased slightly for the March through August 2020 period. Individually, the respondents’ varied data points each suggest a small increase in delivery time over the entire six-month period in 2020, rather than a cliff effect in a specific month. This gradual increase in average delivery time is not such that it would affect continuity of care. Our members are able to maintain this continuity by building in any potential delays when providing refills of 90-day prescriptions. Shipping refills with the goal of having them in the patients’ hands up to seven days prior to the end of the previous fill creates a “buffer” to accommodate potential mail delays. This reinforces that companies are closely monitoring delivery times and proactively taking action to maintain continuity of pharmacy care and facilitate patients’ timely access to needed medications.

Throughout the current pandemic and period of operational changes at the USPS, the safety, efficacy, and timeliness of mailed prescriptions remain of the utmost importance. Mail-service pharmacies continue to monitor dynamics surrounding the USPS closely and tailor their precision processes to ensure reliable and timely receipt of mailed prescriptions.

The level of precision and planning undertaken by mail-service pharmacies in the mailing of prescription drugs extends to a range of approaches to mitigate the potential for, and response to, delivery delays or disruptions. Companies employ sophisticated automation, geographically dispersed mail-service pharmacies, and proprietary route determination and sorting processes that help make it an extremely accurate, timely, and convenient way to obtain prescription drugs. For example, mail-service pharmacies may presort their shipments so that mailed prescriptions can be placed further downstream into the USPS mail process, thereby skipping sorting facilities and saving on shipping time. Geographically dispersed mail-service pharmacy sites also can reduce delivery times by shipping from facilities closer to patients.

In addition, mail-service pharmacies’ staff pharmacists and supporting clinicians can ship refills earlier to ensure there is not disruption and may remind consumers to request a refill of a prescription with sufficient time for delivery. In cases where a patient may be impacted by an extended shipping time frame, mail-service pharmacies may send a filled prescription overnight utilizing a different courier or help patients obtain a short-term supply from their local retail pharmacy to ensure continuity of pharmacy care.

- d. The percentage of prescriptions filled via mail-order delivery services by PCMA’s membership for the period of March 2019 through August 2019 and March 2020 through August 2020 broken down by type of enrollee, as well as medication class and type, including specialty drugs. For each medication type, please indicate and describe any time-sensitive factors.**

Reflecting the committee’s question, the survey asked respondents to provide the percentage of mail-service prescriptions by enrollee type across American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classifications, for the March through August 2019 and March through August 2020 periods.<sup>47</sup> Due to limitations in available data, Figures 3.4 to 3.8 do not include specialty prescription drugs that are home delivered and which are more likely to require special handling.

The committee also has requested a description of any time-sensitive factors, including storage temperature considerations, that may necessitate expedited delivery or special handling (Figure 3.9). Mail-service pharmacies leverage proprietary software to map out the ideal packaging journey for those prescriptions that must stay within a specific temperature range. Such software accounts for the acceptable temperature range for each prescription, forecasted weather conditions, and destination temperatures; based on this information, the appropriate shipping *time frame* and *packaging* are determined specific to that prescription and its destination.

The vast majority of prescriptions do not require special handling or packaging. Mail-service pharmacies use U.S. Pharmacopeia guidelines to determine if a prescription has specific handling needs, including temperature requirements. For prescription drugs that require it (Figure 3.9), a mail-service pharmacy may package them in temperature-protective coolers with gel packs to ensure that the prescriptions stay within a safe temperature range — even if the package is sitting outside for hours after delivery. Specialty prescription drugs, including injectable drugs with special handling requirements, are usually shipped through commercial mail and shipping carriers, such as UPS and Federal Express. Specialty drugs requiring refrigeration are typically shipped for overnight delivery, often through common carriers other than the USPS.

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<sup>47</sup> The AHS classification allows the grouping of prescription drugs with similar pharmacologic, therapeutic, and/or chemical characteristics. It is used by state Medicaid programs and by CMS as an alternative to the U.S. Pharmacopeia Model Guidelines for Medicare PDPs. It also is included in the International Classification of Diseases.



Figure 3.4. Percentage of Prescriptions Filled through Mail-service Pharmacy for All Insurance Types, By AHFS Drug Class, By Select Months, March 2019 through August 2020

	Cardiovascular Agents	Central Nervous System	Hormones and Synthetics	Gastrointestinal	All Other Classes
March 2019	37%	15%	16%	6%	25%
March 2020	37%	15%	16%	5%	25%
April 2019	37%	15%	17%	6%	25%
April 2020	37%	15%	16%	6%	25%
May 2019	37%	15%	17%	6%	25%
May 2020	37%	15%	16%	5%	25%
June 2019	37%	15%	17%	6%	25%
June 2020	37%	15%	17%	5%	25%
July 2019	37%	15%	16%	6%	25%
July 2020	37%	15%	16%	6%	25%
August 2019	37%	15%	16%	6%	25%
August 2020	37%	15%	16%	5%	25%

Figure 3.5. Percentage of Prescriptions Filled through Mail-service Pharmacy for Medicare, By AHFS Drug Class, By Select Months, March 2019 through August 2020

	Cardiovascular Agents	Central Nervous System	Hormones and Synthetics	Gastrointestinal	All Other Classes
March 2019	41%	13%	14%	6%	25%
March 2020	41%	13%	14%	6%	26%
April 2019	41%	13%	14%	6%	25%
April 2020	40%	14%	14%	6%	26%
May 2019	41%	13%	14%	6%	25%
May 2020	41%	14%	14%	6%	25%
June 2019	41%	14%	14%	6%	25%
June 2020	41%	14%	14%	6%	26%
July 2019	41%	14%	14%	6%	25%
July 2020	41%	14%	14%	6%	26%
August 2019	40%	14%	14%	6%	26%
August 2020	41%	14%	14%	6%	26%

**Figure 3.6. Percentage of Prescriptions Filled through Mail-service Pharmacy for Medicaid, By AHFS Drug Class, By Select Months, March 2019 through August 2020**

	<b>Cardiovascular Agents</b>	<b>Central Nervous System</b>	<b>Hormones and Synthetics</b>	<b>Gastrointestinal</b>	<b>All Other Classes</b>
March 2019	24%	21%	16%	5%	34%
March 2020	24%	20%	16%	5%	34%
April 2019	25%	22%	16%	5%	32%
April 2020	24%	20%	16%	6%	33%
May 2019	25%	21%	16%	5%	34%
May 2020	24%	22%	16%	5%	32%
June 2019	26%	20%	16%	6%	33%
June 2020	25%	22%	16%	5%	32%
July 2019	25%	21%	16%	5%	33%
July 2020	23%	22%	17%	5%	33%
August 2019	25%	21%	16%	5%	34%
August 2020	24%	22%	17%	5%	32%

**Figure 3.7. Percentage of Prescriptions Filled through Mail-service Pharmacy for Commercial, By AHFS Drug Class, By Select Months, March 2019 through August 2020**

	<b>Cardiovascular Agents</b>	<b>Central Nervous System</b>	<b>Hormones and Synthetics</b>	<b>Gastrointestinal</b>	<b>All Other Classes</b>
March 2019	35%	17%	21%	5%	22%
March 2020	34%	18%	20%	5%	23%
April 2019	35%	17%	21%	5%	22%
April 2020	34%	18%	20%	5%	23%
May 2019	35%	17%	21%	5%	22%
May 2020	34%	18%	20%	5%	22%
June 2019	35%	17%	21%	5%	22%
June 2020	34%	18%	21%	5%	23%
July 2019	35%	17%	21%	5%	22%
July 2020	34%	18%	20%	5%	22%
August 2019	35%	18%	20%	5%	23%
August 2020	34%	18%	20%	5%	23%

**Figure 3.8. Percentage of Prescriptions Filled through Mail-service Pharmacy for Other Insurance Types, By AHFS Drug Class, By Select Months, March 2019 through August 2020**

	<b>Cardiovascular Agents</b>	<b>Central Nervous System</b>	<b>Hormones and Synthetics</b>	<b>Gastrointestinal</b>	<b>All Other Classes</b>
March 2019	33%	15%	14%	7%	32%
March 2020	33%	15%	14%	6%	32%
April 2019	33%	15%	14%	7%	31%
April 2020	32%	15%	14%	6%	32%
May 2019	33%	15%	14%	7%	31%
May 2020	32%	16%	14%	6%	33%
June 2019	33%	15%	14%	7%	31%
June 2020	32%	15%	15%	5%	32%
July 2019	33%	15%	14%	7%	31%
July 2020	33%	15%	14%	6%	32%
August 2019	33%	15%	14%	7%	31%
August 2020	33%	15%	14%	5%	32%

**Figure 3.9. Sampling of Special Handling Requirements for Specialty Prescription Drugs**

<b>Therapeutic Class</b>	<b>Special Handling Requirement(s)</b>
Hemophilia	Some must be kept cold and shipped overnight/next day with cold packs.
HIV	<ul style="list-style-type: none"> <li>Some must be kept cold and shipped overnight/next day with cold packs.</li> <li>Some (e.g., Kaletra solution) are considered hazardous/consumer commodity material and must be shipped ground.</li> </ul>
Hepatitis C	Some must be kept cold and shipped overnight/next day with cold packs, but most are normal storage.
Cystic Fibrosis	Some must be kept cold and shipped overnight/next day with cold packs (e.g., inhaled medications) but most are normal storage.
Oncology	Some must be kept cold and shipped overnight/next day with cold packs (e.g., Xeloda, Jakafi), and others are hazardous and can only be shipped ground, but most are normal storage.
Multiple Sclerosis	<ul style="list-style-type: none"> <li>A few of these must be kept cold and shipped overnight/next day with cold packs (e.g., Tecfidera, Gilenya).</li> <li>Some require normal refrigerated shipping.</li> </ul>
Anti-Inflammatories	Most TNF-inhibitor injectable medications are set as refrigerated storage condition and follow normal refrigerated shipping.

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**4. Has any official from the Postal Service or the Trump Administration consulted with PCMA or PCMA's membership regarding the changes to the Postal Service or inquired about the potential impact on mail-order prescription delivery services? If so, please provide further information regarding this interaction, including the first date of the related interaction.**

No official from the USPS or the Trump administration has contacted with PCMA regarding the operational changes to the USPS, nor has a Postal Service or Administration official inquired about the potential impact on prescriptions filled through mail-service pharmacies and delivered by the USPS.

In response to questions relating to contact by the USPS of PBM-member companies, a minority of survey respondents (i.e., two of five) shared that the company had been contacted in the ordinary course of business. One respondent noted the USPS communicated leadership structure changes and affirmed Postal Service capacity; another respondent proactively outreached to the USPS regarding shipping or delivery times and delays. Relating to contact by the Administration, a single respondent (of four) indicated they had been contacted regarding changes in Postal Services, shipping or delivery times, postal rate increases, and potential delivery delays. No further details of these contacts were provided by respondents.

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**5. Has PCMA or any of PCMA's membership received complaints from health plans or employers, or their beneficiaries or employees, regarding delays or lost mail-order delivery prescriptions since March 2020?**

In our survey, PCMA survey respondents were asked about calls received from employers, health plans, and other issuers, as well as patients, regarding delays or disruptions to the delivery of their mail-service prescriptions for March through August 2020 period. Four companies responded to this question. The differences in the data reported by each of the four respondents to this question do not lend to data aggregation or broad interpretation.

In an effort to identify top-line trends from these differing data types, it is clear that respondent companies have had varied experiences, including one respondent observing no increases in call volume, to others observing a doubling of calls related to delivery time from an incredibly low proportion of both overall prescriptions filled and calls received. Specifically, one indicated that they had not seen an increase in the number of such calls and reported 0.17 calls per million mail-service prescriptions. The other respondents reported increases in the number of calls they received about mail-service prescriptions that were either delayed, lost during shipping, or required reshipment. Each of these three respondents reported that such calls more than doubled between March and July 2020, although this translated to a low absolute number of calls. The companies reported fewer than three calls of this nature per 1,000 consumer calls as the March 2020 baseline, compared to a high of fewer than six per 1,000 consumer calls in August 2020.

**6. Should Postmaster General DeJoy’s operational changes within the Postal Service, such as restricting delivery transportation schedules and bundling mail services, not be fully reversed or be implemented further after November 3, 2020, what potential impacts on prescription drug delivery and American’s health could occur? What actions, if any, is PCMA intending to take to mitigate any adverse impacts?**

The USPS and national commercial mail and shipping carriers are vital to delivering needed medications to America’s patients, and PBMs value the particular role of the USPS in assuring the convenience, reliability, and affordability of mail-service deliveries. While the USPS implements, pauses, and considers further administrative changes to its services and processes, we caution that changes resulting in the delay of mail may cause a potential gap in care when, for example, a refill has not arrived in time, or pose a barrier to adherence. As noted previously, PBMs have proactively taken steps to prevent adherence issues and will continue to use all of their capabilities to similarly prevent issues in the future.

The health and safety of the more than 266 million Americans served by PCMA’s member companies remain our collective top priority. This extends to taking every precaution to continue to provide patients with the convenient, reliable mail-service delivery of their needed prescription drugs. As discussed previously, and while information on particular business practices are proprietary to our individual member companies, survey respondents indicated they are adjusting their shipping methods and approaches to maintain continuity of care for patients and minimize disruption no matter the condition or challenge, including utilization of alternate carriers, adjusting when refilled prescriptions are shipped, allowing emergency refills at any network pharmacy, allowing overrides for early refills, and allowing for transition fills at retail pharmacies.

Akin to mitigating prescription drug access concerns arising in response to a global health care event, natural disaster, or supply chain disruption, our member-PBM companies employ sophisticated, automated technology; geographically dispersed mail-service pharmacies; proprietary route determination and sorting processes; and contracts with multiple national delivery carriers to ensure mail-service pharmacy remains a safe, reliable, and affordable way to access prescription drugs. PBMs also remind patients to refill their prescriptions, educate patients on the digital and voice channels to check the real-time status of their pending prescription order, and often make available 24/7-access to a pharmacist or supporting clinician for any reason, including delivery and supply concerns.

As Congress considers broader Postal reform issues, maintaining access to affordable, reliable, and timely USPS delivery service is critical to the ability to meet the affordability and access needs of mail-service pharmacy customers.

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While the combination of the ongoing COVID-19 pandemic and changes to USPS services and processes reflect new and evolving conditions, PBMs and their mail-service pharmacies continue to take every step to facilitate the safe and timely arrival of mailed prescription drugs. Our top priority remains facilitating access, as safely, conveniently, and cost-effectively as possible, to quality health care. PCMA is committed to ongoing dialogue with the committee regarding opportunities to continue to promote reliable and timely access to prescription drugs.

If you or your staff should have need for additional information on our industry's efforts, or further questions on which we can be helpful, please contact Jonathan Heafitz, Vice President of Federal Affairs, at (202) 756-5735 or by email ([jheafitz@pcmanet.org](mailto:jheafitz@pcmanet.org)).

Sincerely,

A handwritten signature in black ink, appearing to read "JC Scott", written in a cursive style.

JC Scott  
President and Chief Executive Officer

cc: Kristin Bass, Chief Policy and External Affairs Officer, PCMA  
Jonathan Heafitz, Vice President, Federal Affairs, PCMA