Dear <<Insurance Company>>:

We have been informed that <<Insurance Company>> has instituted a policy requiring that certain intravenous (IV) medications procured, quality controlled, and appropriately stored on-site by our practice, and administered to <<Insurance Company’s>> patients in our clinic(s) must now be provided by <<Insurance Company’s>> affiliated specialty pharmacy. <<Insurance Company’s>> policy mandates that our practice accept medications that are not controlled by our practice’s and wholesaler’s drug supply chain security procedures and our quality-control procedures that guarantee safety for administration of all medications to our patients. It is further unclear whether <<Insurance Company’s>> policy will permit not only the practice of “white bagging” – where the specialty medication is filled by the pharmacy and delivered directly to the practice – but also the more alarming- practice of “brown bagging” – where the pharmacy dispenses the specialty medication to the patient, who in turn, brings the medication to our practice for in-office administration. Additionally, some payers may contract with home care services for a clinician to administer a drug in the patient’s home. Home infusion may be considered a subset of brown bagging and associated supplies for home infusion are typically shipped directly to the patient’s home.[[1]](#footnote-1)

We have ***serious*** concerns with this new mandate, starting with the potential for serious adverse impacts on patient safety and care. Not having control over the sourcing, storage, preparation, and handling of specialty rheumatology medications exposes our patients to potentially serious harm, while increasing the administrative burdens on our practice and the liability to our practice and providers. Your mandate compromises and is detrimental to patient care on so many levels, ranging from optimization of therapy, patient access and missed doses, interruptions to critical treatment, worsening disease states, increasing risks of medication errors, adverse events, interference with the patient physician relationship, and failure to ensure and monitor FDA-mandated REMS. As with all types of care, our practice needs reasonable assurances as to the quality and integrity of treatments our providers are recommending and administering to patients. As such, our practice cannot possibly even consider accepting white-bagged medications for in-office administration until <<Insurance Company>> satisfactorily responds to each question raised below.

Further, while our practice has requested reasonable information needed for basic assurances before even considering accepting white-bagged prescriptions for administration, it is the strict policy of our practice not to accept for in-office administration any prescription that has been physically dispensed to and in the possession of the patient or delivered to the patient’s home.(i.e., brown bagging).

Based on the foregoing, we request that <<Insurance Company>> provide prompt and thorough responses to the following questions posed below. Included in Appendix A is a form containing these questions that must be completed and returned to the practice. In addition, before even considering accepting white-bagged medications for our patients, we require that <<Insurance Company>> and its affiliated specialty pharmacy execute the Assumption of Liability and Indemnification Agreement contained in Appendix B.

*Optional:* We want to underscore that our first and most important concern is the safety of our patients. As such, we feel these are extraordinarily reasonable requests, especially considering the authority we hold under existing state “Any Willing Provider” laws, and therefore it can only be viewed as an extraordinarily unreasonable mandate that we accept white-bagged rheumatology medications – all for the sake of your company’s financial interests and having nothing at all to do with patient safety and wellbeing.

1. **Violation of State White Bagging Laws**

We begin with a concern with overall compliance with law in even accepting white-bagged medications. A review of state laws and regulations reveals several states that have banned or curtailed these practices. For example, Massachusetts identifies white bagging as “redispensing” which is prohibited.[[2]](#footnote-2) Other states, like California, have laws that require health plans to demonstrate that their medical decisions are “unhindered by fiscal and administrative management.”[[3]](#footnote-3)

**Question: How does our practice’s acceptance of white-bagged medications comply with applicable state laws?**

1. **Delays in Treatment, Drug Waste and Impact on Value Based Care (VBC) Arrangements**

Because the practice would be required to obtain the drug product from <<Insurance Company’s>> affiliated specialty pharmacy, patients are going to face delays in treatment and unnecessary hardships, as compared to the practice sourcing products from its own inventory for in-office administration. This will also create waste, which will ultimately cost patients and their payers (i.e., employers) more.

When a physician utilizes drugs, the practice has on hand in its inventory, the physician is able to quickly and efficiently address patient care real time, and avoid waste. Rheumatology regimens are complex and may require dosing adjustments at the time of administration or therapy cancellation depending on the patient’s laboratory results, imaging, and other clinical considerations, such as shifts in the patient’s weight.[[4]](#footnote-4) When utilizing medications from the onsite inventory, physicians are able to make these changes at the time of administration without any delays or risk of waste (they can simply select a different medication or dose off the shelf). However, the same cannot be said if the medications are supplied by <<Insurance Company’s>> affiliated specialty pharmacy. Under the white bagging mandate, the physician is required to write a “prescription” and send it to <<Insurance Company’s>> affiliated specialty pharmacy to be filled. Circumstances requiring dosing adjustments or therapy cancellation could occur in the time between when an “order” is written by the physician, and when the medication is received from a specialty pharmacy. Moreover, once the prescription has a patient-specific label, it cannot be returned to stock (unlike products kept within the practice’s inventory for in-office administration).  As a result, this entire medication would essentially go to waste (costing the plan sponsor and patient potentially tens of thousands of dollars).

In addition, because the drug product would be coming from <<Insurance Company’s>> affiliated specialty pharmacy (and not off the practice’s shelf), patients are susceptible to delays in the receipt of the medication. Delays in receiving the medication past an anticipated date are commonly caused by a variety of factors, including failed delivery, incorrect medications being delivered, medications shipped to the wrong address, prior authorization issues, out of stock medications, etc. In addition, patients may have to pay for drugs before they are shipped by <<Insurance Company’s>> affiliated specialty pharmacy, which can interrupt critical treatment if patients cannot afford to pay for the therapies. Many patients receiving medication from our practice are placed on monthly payment plans, allowing them to immediately receive the treatment even when they have not yet met their financial responsibility up front (the same cannot be said for prescriptions dispensed by specialty pharmacies who often require payment in full before the specialty pharmacy will dispense the medication). Ultimately this can cause confusion and the potential for missed treatment doses or not receiving the medication at all.

These delays and hardships are exacerbated by the fact that the physician is often ordering a “cocktail” of different drugs and therapies that must be taken in concert. To the extent one or more of the drugs in this cocktail needs to be supplied by <<Insurance Company’s>> affiliated specialty pharmacy through white bagging, there is great risk that the process, timing and coordination of these therapies could be jeopardized.

And even when the medication is timely provided by <<Insurance Company’s>> affiliated specialty pharmacy, it may not always be in an optimal package size or dosage (for example, the specialty pharmacy might send vials of medication that are smaller than what the practice would typically use, thereby requiring more Closed System Transfer Devices – supplies used to prepare hazardous drugs – which requires additional time and money on the part of the practice, in addition to creating unnecessary risks for the patient).

Finally, each of these scenarios caused by mandatory white bagging can negatively impact VBC arrangements, where the practice works collaboratively with payors to improve care, while reducing costs, namely by following American College of Rheumatology (ACR) pathway guidelines, quality metrics, tracking, following the patient in real-time on treatment efficacy, and cutting down on extra visits and avoiding waste or unnecessary treatment. When a drug is thrown out because a physician alters the dosage in the time between when the prescription was ordered and when the patient is set to receive administration, this too creates unnecessary spending.

**Question: What steps will <<Insurance Company>> and its affiliated specialty pharmacy take to prevent delays or interruptions in treatment (including guaranteeing delivery by a certain date, providing replacing damaged or incorrect medications free-of-charge, and identifying available patient assistance for out-of-pocket costs)? Please confirm that <<Insurance Company>> not to penalize our practice under VBC contracts as a result of any delays caused by <<Insurance Company>> and/or its affiliated specialty pharmacy, or if the originally ordered medication is discontinued or modified after it has been filled by the affiliated specialty pharmacy?**

1. **Physician Liability**

In October 2012, 64 people died and over 700 people became sick as a result of contaminated compounded steroid injections supplied by New England Compounding Center (NECC). The medications had been ordered by physicians for in-office administration to their patients in clinics and surgery centers. However, due to insanitary conditions at the pharmacy, several batches of the medications had become tainted with fungus, causing many patients to develop fungal meningitis and become seriously ill or die.

In the wake of this, dozens of lawsuits (including multiple class actions) were filed against not only the pharmacy, but also the clinics, surgery centers and underlying physicians. In several of these lawsuits, plaintiffs not only accused the physicians of negligence (particularly in their selection of the pharmacy), but sought to invoke strict liability for the clinics, meaning the facility could be held liable for selling a defective product even without knowledge of a defect. Many physicians faced years of litigation and, in some cases, liability was found. With strict product liability, all people or entities in the distribution chain are potentially liable, and several states’ laws explicitly permit product liability claims against healthcare providers. Thus, as the NECC disaster has demonstrated, physicians and clinics are increasingly also being scrutinized for their part in prescribing and administering drugs received from pharmacies.

Worse yet, it is not clear or established the degree to which medical malpractice policies or other insurance policies would safeguard our practice and our providers against these types of claims. In sum, this leaves our practice and our providers particularly exposed in being forced to source product outside the normal distribution channel – over which it has no control of or confirmation as to its integrity – and bear the risk of potential uncovered suits of negligence, consumer protection violations, or products liability.

**Question: What insurance coverage does <<Insurance Company>> and its affiliated specialty pharmacy hold, and how will it be extended to cover our practice and our providers administering the products filled and dispensed by <<Insurance Company’s>> affiliated specialty pharmacy? Please confirm <<Insurance Company>> and its affiliated specialty pharmacy will obtain written patient consent to have their medication supplied by the affiliated specialty pharmacy in the form of consent attached within Appendix B. Please confirm <<Insurance Company>> and its affiliated specialty pharmacy will assume any and all liability for any issue with the drug that results in harm to the patient, and will agree to defend and indemnify our practice and our providers against any third party liability, as set forth within Appendix B.**

1. **Patient Steering Laws**

Our practice is contracted with <<Insurance Company>> to provide medical services to <<Insurance Company’s>> members. We are particularly concerned that the mandate that we write prescriptions and send them to <<Insurance Company’s>> designated specialty pharmacy will run afoul of State patient steering laws, which generally prohibit health care providers from agreeing to send prescriptions to a particular pharmacy. As an example, New Jersey law provides that “[i]t shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner, or any institution, facility or entity that provides health care services, for the purposes of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient’s freedom of choice to select a pharmacy.”[[5]](#footnote-5) As another example, Georgia law likewise specifically prohibits pharmacies from presenting (and prohibits pharmacy benefits managers from paying) claims for reimbursement that were received pursuant to a referral from an affiliated PBM.[[6]](#footnote-6) Under both of these States’ anti-steering statutes (and many other States’ analogs), health insurers like <<Insurance Company>>, and their affiliated specialty pharmacies, are swept within the scope of “health care providers.”

**Question: How does <<Insurance Company’s>> mandate that our practice send prescriptions to <<Insurance Company’s>> affiliated specialty pharmacy for white bagging not run afoul of State anti-steering laws?**

1. **Concerns Regarding IMPROPER Double Billing**

When a prescriber’s practice submits a claim to an insurer for in-office administration of a drug to its patient, it typically submits a CPT Code for the professional services associated with the administration (e.g., CPT 96413), as well as a J-Code or Q-Code for the medication. CPT Code 96413 corresponds with “Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance.” Thus, when submitting claims in this manner, the physician receives his or her fee for the professional services associated with mixing the drug and administering it to the patient, but is also reimbursed for the costs of the medication, the diluents, the supplies, the tubing, as well as the associated overhead.

When the prescription is mandated to be filled by <<Insurance Company’s>> affiliated specialty pharmacy, it is unclear how the pharmacy intends to bill for the medication. For instance, because this is in relation to in-office administration of chemotherapy, it is possible that the affiliated specialty pharmacy could be submitting a claim to the patient’s medical benefit directly through <<Insurance Company>>. This being the case, the affiliated specialty pharmacy could conceivably bill the J-Code for the medication, as well as potentially an S-Code. Because HCPCS code descriptions are ripe for potential misinterpretation, we have serious concerns of whether there is overlap between the J-Code or S-Codes being submitted by the affiliated specialty pharmacy, and the CPT Codes being submitted by the practice, and need adequate assurances from <<Insurance Company>>.

Alternatively, we have similar concerns about the risks of potential double-billing in the event that the affiliated specialty pharmacy uses an NDC number to bill the patient’s pharmacy benefits manager (PBM)[[7]](#footnote-7) – the intermediary contracted by <<Insurance Company>> to administer pharmacy benefits. Most PBM contracts prohibit pharmacies from dispensing medications in their unfinished form, and prohibit billing medications that require reconstitution (e.g., injectable medications) as compounds (suggesting that reimbursement for the diluent and other supplies necessary for administration are included within the total payment). In addition, many PBMs pay a “dispensing fee” on all claims in addition to the reimbursement for the drug, which is intended to cover costs that are incurred at the point of sale in excess of the ingredient cost of the drug, including the “measurement or mixing of the drug,” “filling the container,” physically providing the completed prescription to the patient, “delivery,” “special packaging,” “salaries of [workers],” “costs associated with maintaining the [ ] facility and acquiring and maintaining technology and equipment necessary to operate the [ ] facility.”[[8]](#footnote-8) While the affiliated specialty pharmacy will be selecting the product, processing the claim, and causing delivery to the practice, many of these items for which the affiliated specialty pharmacy will be receiving reimbursement are actually tasks that will ultimately be completed by the practice. The practice will continue to be responsible for mixing the drug, procuring the diluent and other necessary supplies, and physically administering the medication to the patient. Thus, this has the risk of the affiliated specialty pharmacy being paid by the patient’s PBM for the same services that are also being reimbursed by <<Insurance Company>> to our practice (and which in fact are being performed and provided by our practice).

**Question: How does <<Insurance Company’s>> affiliated specialty pharmacy intend to bill for the medications it dispenses (i.e., to the medical benefit using a J-Code or to the pharmacy benefit using an NDC number), and what specifically will be submitted as part of the underlying claims? Please explain how <<Insurance Company’s>> affiliated specialty pharmacy’s planned method of claims submission will not constitute double-billing, and also please provide specific assurances that the practice may continue to submit claims for appropriate CPT codes to <<Insurance Company>> without being alleged to be double-billing. Please confirm that <<Insurance Company’s>> affiliated specialty pharmacy will not be submitting any S-Codes or other HCPCS codes when dispensing white bagged medication.**

1. **Compliance with Track-and-Trace and Drug Pedigree Laws**

Our practice is equally concerned about its compliance with track-and-trace and drug pedigree laws, including the Drug Supply Chain Security Act (21 U.S.C. § 360eee, *et seq.*) and other state laws. The purpose of the Drug Supply Chain Security Act (DSCSA) is to track and trace prescription drugs, requiring pedigree (i.e., a step-by-step account of where a drug product has been located and who has handled it). The law also established product verification to ensure that a drug product is legitimate and unaltered. Wholesale distributors must follow many steps and documentation requirements in maintaining product integrity from the time they receive it from the manufacturer until the time it is delivered to a facility’s inventory.

The DSCSA tracing obligations apply to “dispensers,” which not only includes physicians who are dispensing and/or administering directly to patients, but also specialty pharmacies fulfilling prescription orders. A hallmark of this is that, prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product shall provide the subsequent owner with Transaction Information[[9]](#footnote-9), a Transaction History[[10]](#footnote-10), and a Transaction Statement[[11]](#footnote-11) for the product (collectively, “transaction data”). <<Insurance Company’s>> white-bagging mandate does not contemplate providing this transaction data[[12]](#footnote-12) required under DSCSA to ensure the integrity and sourcing of all medications that practices administer to the patient.

Likewise, virtually every state regulates the wholesale distribution of drugs, and places several requirements upon the industry. About 24 states recognize Drug Distributor Accreditation (DDA) (formerly known as VAWD), and standards for such accreditation prohibit sales by wholesalers to pharmacies, who will in turn, redistribute them to another entity.  Some states, such as Indiana, even require DDA accreditation as a condition for wholesaler licensure. Finally, many payors (including health insurers and PBMs) require all purchases to come through DDA suppliers. There is reason for this, as several of the DDA -required standards directly impact the integrity and safety of the drug products (for example, DDA requires that a wholesale facility’s storage areas be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing). With our practice being required to receive the medications from <<Insurance Company’s>> affiliated specialty pharmacy, we cannot see how those transactions would not implicate the requirements for wholesale licensure, and more importantly, the safety and integrity of the drug products at issue.

**Question: How does <<Insurance Company’s>> mandate that we obtain medications through <<Insurance Company’s>> affiliated specialty pharmacy comply with the DSCSA, including tracing and product verification requirements. What pedigree information will <<Insurance Company’s>> affiliated specialty pharmacy provide to our practice in order to ensure the integrity of the drug’s supply chain? Please explain how <<Insurance Company’s>> mandate that we obtain medications through <<Insurance Company’s>> affiliated specialty pharmacy complies with DDA standards prohibiting redistribution by pharmacies. Detail all policies, procedures and steps to guarantee the integrity of the product to the same standards as DSCSA and/or DDA and provide a specific guarantee the product integrity.**

\*\*\*

It is the general policy of our practice not to accept white bagged or brown-bagged medications. As noted above, while our practice will not accept brown bagged medications under ***any*** circumstances, our practice cannot even consider accepting white-bagged medications until both <<Insurance Company>> and its affiliated specialty pharmacy satisfactorily respond to the questions in Appendix A, and further, that both <<Insurance Company>> and its affiliated specialty pharmacy sign and return the attestation found in Appendix B.

As treating physicians, we are the guardians of patient safety. We cannot and will not allow financial interests to compromise this. Our concerns articulated above are legitimate. If we are to accept medications provided outside the normal distribution channels, any partner must equally recognize and support our paramount duty of protecting the best interests of our patients.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

<<Practice>>

cc: Board of Pharmacy

Board of Medical Examiners

**Appendix A**

**Questionnaire**

|  |  |
| --- | --- |
| **1.** | **How does our practice’s acceptance of white-bagged medications comply with applicable state laws?** |
| **2.** | **What steps will <<Insurance Company>> and its affiliated specialty pharmacy take to prevent delays or interruptions in treatment (including guaranteeing delivery by a certain date, providing replacing damaged or incorrect medications free-of-charge, and identifying available patient assistance for out-of-pocket costs)? Please confirm that <<Insurance Company>> not to penalize our practice under VBC contracts as a result of any delays caused by <<Insurance Company>> and/or its affiliated specialty pharmacy, or if the originally ordered medication is discontinued or modified after it has been filled by the affiliated specialty pharmacy?** |
| **3.** | **What insurance coverage does <<Insurance Company>> and its affiliated specialty pharmacy hold, and how will it be extended to cover our practice and our providers administering the products filled and dispensed by <<Insurance Company’s>> affiliated specialty pharmacy? Please confirm <<Insurance Company>> and its affiliated specialty pharmacy will obtain written patient consent to have their medication supplied by the affiliated specialty pharmacy in the form of consent attached within Appendix B. Please confirm <<Insurance Company>> and its affiliated specialty pharmacy will assume any and all liability for any issue with the drug that results in harm to the patient, and will agree to defend and indemnify our practice and our providers against any third party liability, as set forth within Appendix B.** |
| **4.** | **How does <<Insurance Company’s>> mandate that our practice send prescriptions to <<Insurance Company’s>> affiliated specialty pharmacy for white bagging not run afoul of State anti-steering laws?** |
| **5.** | **How does <<Insurance Company’s>> affiliated specialty pharmacy intend to bill for the medications it dispenses (i.e., to the medical benefit using a J-Code or to the pharmacy benefit using an NDC number), and what specifically will be submitted as part of the underlying claims? Please explain how <<Insurance Company’s>> affiliated specialty pharmacy’s planned method of claims submission will not constitute double-billing, and also please provide specific assurances that the practice may continue to submit claims for appropriate CPT codes to <<Insurance Company>> without being alleged to be double-billing. Please confirm that <<Insurance Company’s>> affiliated specialty pharmacy will not be submitting any S-Codes or other HCPCS codes when dispensing white bagged medication?** |
| **6.** | **How does <<Insurance Company’s>> mandate that we obtain medications through <<Insurance Company’s>> affiliated specialty pharmacy comply with the DSCSA, including tracing and product verification requirements. What pedigree information will <<Insurance Company’s>> affiliated specialty pharmacy provide to our practice in order to ensure the integrity of the drug’s supply chain? Please explain how <<Insurance Company’s>> mandate that we obtain medications through <<Insurance Company’s>> affiliated specialty pharmacy complies with DDA standards prohibiting redistribution by pharmacies. Detail all policies, procedures and steps to guarantee the integrity of the product to the same standards as DSCSA and/or DDA and provide a specific guarantee the product integrity.** |

**Appendix B**

**ASSUMPTION OF LIABILITY AND INDEMNIFICATION AGREEMENT**

This Assumption of Liability and Indemnification Agreement (“Agreement”) is made and entered into between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(“Health Insurer”), with a principal place of business located at\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Specialty Pharmacy”) with a principal place of business located at\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and <<Practice>> (“Practice”) (collectively “Parties”), with corporate offices located \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. This Agreement is effective as of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Whereas**, the Practice is a specialty physician group encompassed of physicians duly licensed to practice medicine under the laws of the state of \_\_\_\_\_\_\_\_\_,

**Whereas**, Health Insurer has partnered with Specialty Pharmacy, that provides oral and injectable pharmaceuticals to Health Insurer’s patients,

**Whereas**, Practice has agreements in place with payors to be able to submit claims for pharmaceuticals administered to its patients,

**WHEREAS**, Practice is assured that quality controls are secured for pharmaceuticals provided by Practice,

**Whereas**, Health Insurer has created a policy mandating the use of Specialty Pharmacy to provide certain injectable medications to Health Insurer’s patients, which shall be filled as outpatient prescriptions, delivered to healthcare providers and clinics (including Practice), and administered in office to patients by healthcare providers and clinics (including Practice),

**Whereas**, Health Insurer has refused to allow Practice to provide the pharmaceuticals for in-office administration to its patient, and insists on delivery to the Practice from Specialty Pharmacy (hereinafter “white-bagging”) or delivery to the clinic by the patient (hereinafter “brown-bagging”),

**Whereas**, it is the intent of the Parties to remove any and all risk and liability from Practice arising from pharmaceuticals that are potentially mishandled during procurement and / or delivery to Practice clinics by either white-bagging or brown-bagging, at the direction of Health Insurer,

**Now**, therefore, Health Insurer and Practice hereby agree to the following:

1. **Assumption of Liability**. Health Insurer hereby agrees that neither Practice, nor any of its physicians, shall be liable for any act or omission arising from the procurement and delivery of pharmaceuticals to Practice by Health Insurer, Specialty Pharmacy, or any representative, subcontractor or employee, or third party acting on the direction of the Health Insurer and/or Specialty Pharmacy, including but not limited to brown-bagging and white-bagging activities. Health Insurer and Specialty Pharmacy hereby expressly agree that because of issues in Practice’s ability to fully verify the chain of custody of these pharmaceuticals to ensure proper handling and delivery, Health Insurer and Specialty Pharmacy shall jointly and severally bear the express burden of any liability resulting from the negligent handling of these pharmaceuticals by a third party, including all risks and not limited to any medical malpractice claims, products liability claims, or other claims that may arise in connection therewith. Health Insurer and Specialty Pharmacy shall also jointly and severally bear the express burden of any liability resulting from any contributory negligent handling of these pharmaceuticals by Practice, including any employee or agent of Practice, which may have contributed to any liability incurred but not limited to any malpractice claims that may arise in connection. Health Insurer and Specialty Pharmacy agree to be one hundred percent (100%) liable, jointly and severally, for any occurrence as outlined above.

2. **Indemnification**. Health Insurer and Specialty Pharmacy shall jointly and severally indemnify, defend, and hold harmless Practice from any and all actual or alleged claims, demands, loses, causes of action, injury, lawsuits, judgment, arbitration costs, related costs, including all attorneys’ fees and costs, any actions imposed by the administrative action of any federal, state, or local government body or agency incident to any acts or omissions caused by, arising out of, or relating to the handling of pharmaceuticals by Specialty Pharmacy or any other third party in the chain of delivery of the pharmaceuticals to Practice, as well as Practice’s administration of said pharmaceuticals to patients.

3. **Obligation to Pay for Defense, Control of Defense, and Cooperation**. In the event of, but not limited to, litigation, arbitration, or any federal, state, or local government body or agency action where legal fees are incurred and an attorney must be obtained, Health Insurer and Specialty Pharmacy hereby agrees that Practice shall have complete control and discretion over all legal decisions, including but not limited to choice of the attorney(s), attorneys’ reasonable fees, and any acceptance or rejection of any settlement offers. Should any settlement offers be reasonably rejected, Health Insurer and Specialty Pharmacy are jointly and severally responsible for any continued costs. Health Insurer and Specialty Pharmacy shall pay all legal expenses and any related expenses, including but not limited to attorneys’ fees, fines, costs, discovery expenses, and any settlements. Health Insurer and Specialty Pharmacy also have a duty to cooperate in any defense of any third party claims that are brought against Practice, or any of its physicians or employees, including but not limited to production of any and all related documents and witnesses upon request, and any other reasonable requests by Practice, or any employee or representative of Practice.

4. **Patient Consent**. For each patient that Health Insurer mandates receive their pharmaceuticals from Specialty Pharmacy for in office administration by Practice, Health Insurer shall obtain written consent from the patient, acknowledging Health Insurer’s mandate, and agreeing to have their prescriptions filled by Specialty Pharmacy and delivered to the Practice. Such consent shall be obtained in the form found in Exhibit 1 hereto. It shall be Health Insurer’s sole responsibility to obtain this form from the patient, prior to Practice’s acceptance of any medications filled by Specialty Pharmacy.

5. **Avoidance of Undue Delay.** Specialty Pharmacy shall agree to provide a guaranteed date of delivery by which it shall provide any medications to Practice for in office administration. If Specialty Pharmacy fails to deliver the correct medication (including quantities and dosage), Health Insurer shall permit Practice to source the medication from its own inventory, and receive reimbursement for such medication in accordance with then applicable Medicare Part B rates.

6. **Representations and Warranties.** Health Insurer and Specialty Pharmacy hereby represent and warrant (i) that the Practice’s acceptance of medications supplies by Specialty Pharmacy complies with all Federal and State laws (including, without limitation, patient steering laws and laws regulating white and brown bagging); (ii) that Specialty Pharmacy has sourced, stored, handled and shall dispense medications in accordance with all applicable laws, regulations and industry standards; and (iii) guarantee that the quality and integrity of any pharmaceuticals provided by Specialty Pharmacy.

7. **No Impact on Other Arrangements.** Health Insurer hereby agrees that Practice’s acceptance of medications supplied by Specialty Pharmacy, and any consequences thereof (including potential waste, damaged goods, or additional patient visits) shall not have any negative impact on Practice’s other arrangements or agreements, including any value based care arrangements with Health Insurer or its affiliates.

8. **Authority to Enter Agreement**. Each Party warrants that the individuals who have signed this Agreement have the legal power, right and authority to bind each respective Party to this Agreement.

9. **Amendment and Modification**. The Parties agree that any amendment or modification to any terms in this Agreement shall be negotiated and executed in a separate writing and signed by the Parties.

10. **Recitals**. All recitals above are hereby incorporated into the Agreement as an explanation of the clear intent of the Parties to eliminate any and all risks of liability to Practice for any incident arising out of pharmaceuticals provided by Specialty Pharmacy (or any third party) at the direction of Health Insurer.

IN WITNESS WHEREOF, the Parties have entered into this Agreement, effective\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**I HAVE READ, ACKNOWLEDGED, AND UNDERSTAND THE LEGAL OBLIGATIONS AS STATED IN THIS AGREEMENT**:

**FOR HEALTH INSURER: FOR SPECIALTY PHARMACY:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title Title

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Date

**FOR PRACTICE:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**EXHIBIT 1**

**Patient Consent**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby acknowledge that my health insurer has required that I receive certain medications requiring in-office infusion from an affiliated specialty pharmacy, despite any preference to have them filled and prepared by my physician’s office. I hereby give permission to <<Practice>> to send a prescription for such medications to my health insurance company’s affiliated specialty pharmacy, and further give permission to <<Practice>> to accept such products for in-office administration. I understand this practice known as “white bagging” has certain inherent risks, and that <<Practice>> does not have any role or ability to select the source of the medications being used for administration. The integrity, safety, and quality of the medications being used for administration rests solely on my health insurer’s affiliated specialty pharmacy. To this end, I acknowledge and understand that my health insurer and its affiliated specialty pharmacy have assumed all risk and responsibility associated with properly filling, storing and delivering this medication to <<Practice>>.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Print Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Telephone Number

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address

1. Commonwealth of Massachusetts, Health Policy Commission, “Review of third-party specialty pharmacy use for clinician-administered drugs” [↑](#footnote-ref-1)
2. 247 CMR 09.01(4). [↑](#footnote-ref-2)
3. CA Health & Safety Code §1637.02 (2019). [↑](#footnote-ref-3)
4. Schwartz RN et al. NCCN Task Force Report: specialty Pharmacy. J NCCN Newwork.2010;8(Supp 4):S1-S12. [↑](#footnote-ref-4)
5. N.J.A.C. 13:39-3.10. [↑](#footnote-ref-5)
6. Ga. Code Ann. § 26-4-119. [↑](#footnote-ref-6)
7. Of note, many PBMs are owned by or affiliated with health insurance companies. In this case <<Insurance Company>> owns <<PBM>>. [↑](#footnote-ref-7)
8. 42 C.F.R. § 100 [↑](#footnote-ref-8)
9. The “Transaction Information” is specific information regarding the details of the purchase, which shall include the proprietary or established name or names of the product, the strength and dosage form of the product, the NDC number of the product, the container size, the number of containers, the lot number of the product, the date of the transaction, the date of the shipment (if more than 24 hours after the date of the transaction), the business name and address of the person from whom ownership is being transferred, and the business name and address of the person to whom ownership is being transferred. [↑](#footnote-ref-9)
10. The “Transaction History” is a statement in paper or electronic form, including the Transaction Information for each prior transaction going back to the manufacturer of the product. [↑](#footnote-ref-10)
11. The “Transaction Statement” is a statement, in paper or electronic form, in which the transferring entity confirms that it is authorized to distribute the product, that it received the product from a person that was authorized, that it received Transaction Information and a Transaction Statement from the prior owner of the product, that it did not knowingly ship a suspect or illegitimate product, that it had systems and processes in place to comply with verification requirements, that it did not knowingly provide false Transaction Information, and that it did not knowingly alter the Transaction History. [↑](#footnote-ref-11)
12. 21 U.S.C. § 360eee-1 [↑](#footnote-ref-12)