

ESI RECOUPMENT LETTERS AND PHARMACY RESPONSES

PREPARED FOR

ALLIANCE FOR PHARMACY COMPOUNDING
AND
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION



Brown & Fortunato, P.C.

A LAW FIRM

BY:

JEFFREY S. BAIRD, ESQ.
BRADLEY W. HOWARD, ESQ.
BROWN & FORTUNATO, P.C.
HEALTH CARE GROUP
P.O. Box 9418
AMARILLO, TX 79105
(806) 345-6300
(806) 345-6363 - FAX
JBAIRD@BF-LAW.COM
BHOWARD@BF-LAW.COM
WWW.BF-LAW.COM

ESI RECOUPMENT LETTERS AND PHARMACY RESPONSES

By: Jeffrey S. Baird, Esq. and Bradley W. Howard, Esq.¹

In early June 2020, multiple pharmacies received letters from ESI stating that on behalf of TRICARE and the Defense Health Agency (“DHA”), ESI was recouping money from the pharmacies for compound drug claims submitted in 2015. According to the letter, TRICARE/DHA had determined that for a number of specified claims in 2015, there was not a proper physician-patient relationship (“PPR”). Each letter included a report setting out the Rx number, fill date, Member ID number, and the discrepant dollar amounts to be recouped. The letters were dated April 7, 2020, but were received by the pharmacies in early June 2020. In subsequent correspondence from ESI to pharmacies, ESI acknowledged that the letter should have been dated June 1, 2020.

A number of pharmacies immediately responded by email to ESI. The pharmacies pointed out (i) the delay between the April 7 date and the date the pharmacy received the letter and (ii) the unfairness of recouping without giving notice (and an opportunity to be heard) to the pharmacies. The pharmacies further pointed out: (i) that a comparison of the information contained in ESI’s claim report with the claim information in the pharmacy’s system leads to the conclusion that for a number of claims, the Member ID shown on the ESI report does not match the cardholder IDs reflected in the pharmacy’s claims system; (ii) that for a number of claims, the Paid Amt/Discrepant Amount shown on the ESI report does not match the actual amount paid as reflected in the pharmacy’s claims system; and (iii) that if ESI used the Member ID shown on the report to determine if the prescribing physician shown on the pharmacy claim had seen the patient, then it is not surprising that there is not a match since the Member ID appears to be incorrect.

ESI responded to the pharmacy emails by saying:

- Should the pharmacy decide to provide medical records establishing a PPR existed the year prior to dispensing of the drug, then the records must be accompanied with metadata or similar validating facts that substantiate the records creation date.
- The physician and pharmacy must provide a signed attestation validating that they understand that if they provide false statements, then they are subject to (i) criminal prosecution and (ii) termination from the TRICARE program.
- The requirements for documentation are not satisfied by letters from physicians attesting to the PPR.

We recommend that a pharmacy that received such a letter from ESI dated April 7, 2020, submit a request for Administrative Review (“Review”) to be received by ESI no later than June 30, 2020, and submit all supporting documentation to be received by ESI no later than August 30, 2020. The balance of this white paper discusses options for pharmacies as they respond to the ESI letter.

¹ Special thanks for contributions made to this publication by Hunter W. Jamerson, Esq., of Macaulay & Jamerson, P.C.; Curtis D. Greenwood, Esq., of Brown & Fortunato, P.C.; and Lisa K. Smith, Esq., of Brown & Fortunato, P.C.

Applicable Legal Authority

This recoupment is governed by 32 CFR § 199.11. The Federal Claims Collection Act, 31 U.S.C. 3701, *et seq.*, (the “Act”) as amended by the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996 (DCIA), provides the basic authority under which claims may be asserted pursuant to this section.

DHA is treating the applicable 2015 compounding claims as “erroneous payments” for which it may circumvent the standard auditing procedures set forth in the ESI pharmacy provider manual. Instead, DHA has directed ESI to essentially retroactively deny coverage for the claims and administratively recoup without first affording due process to pharmacies. In executing the administrative recoupment, however, ESI must follow the procedures set forth in federal regulation as found under 32 CFR § 199.11. A number of required procedures, particularly with respect to the content and service of the demand letter, appear to be violated. You should consult with qualified health care counsel to determine your rights and remedies.

DHA’s position is that pharmacies must now produce medical records in accordance with 32 CFR § 199.6(a)(12). A qualified healthcare attorney should advise you as to the extent this regulation applies to pharmacies. By defined scope of practice, pharmacies do not create (and generally do not maintain) medical records. The requirement ESI has communicated for medical records to be supported by metadata and signed certification statements is not found in published law or regulation.

The applicable 2015 ESI Pharmacy Provider Manual, including its federal payor addendum, contains no reference to a requirement to maintain records evidencing a physician-patient relationship.

In dispensing any prescription, pharmacies are obligated to maintain such records as the pharmacy’s resident state law requires. A qualified health care attorney should advise you as to the applicable law governing establishing a physician-patient relationship and record retention as it pertained to the pharmacy in 2015.

Arguments Against ESI’s Actions

No Opportunity to Respond Prior to Recoupment – ESI and DHA failed to undertake the standard audit process in which prior to recoupment, it provides the pharmacy (i) notice that auditing is being conducted for specific claims for a specific time period, (ii) the opportunity to submit information to support the claim submissions, and (iii) the right to engage in the review process in the event of an unfavorable decision. The audit and recoupment process is spelled out in the ESI Provider Manual.

ESI is Imposing on Pharmacies an Obligation that the Law, the PBM Contract and the Provider Manual did not Impose – ESI is requiring the pharmacy to prove the existence of a PPR during the 365 days preceding the dispensing of the drug. This is an obligation that, absent

suspicion of a fraudulent prescription, a pharmacy is not required to generally undertake. It wasn't until the last half of 2017 that ESI added language to the Provider Manual requiring the pharmacy to confirm a PPR in the event the prescriber is from outside the immediate retail service area.

ESI is Imposing on Pharmacies an Obligation that is Virtually Impossible to Meet – ESI is requiring pharmacies to obtain documents from physicians that establish the PPR five or more years ago. Not only that, but the documents must be “accompanied with metadata or similar validating facts” to support the creation date of the record and a signed attestation acknowledging that providing false statements can result in criminal prosecution and termination from the TRICARE program. This is an obligation that most pharmacies simply cannot meet for many of the claims. In essence, ESI is setting pharmacies up to fail. Specifically:

- Some physicians have moved, retired or died.
- Under the guise of “this is not my problem,” a number of physicians will not cooperate with the pharmacy’s request for records and/or signing the requested attestation.
- Unless the physician utilized an electronic health record system in 2015, the physician documentation establishing the PPR will not contain the requested metadata, and it is unclear how to substantiate the creation date of paper records.

Responsive Steps

Each Pharmacy Needs to Participate in the Review Process – While some pharmacies are facing minor recoupments, the demand letter issued by ESI references “program abuse.” Conceding a finding of “abuse” by not challenging the recoupment could give rise to contractual reporting requirements, credentialing challenges in the future, and possible further investigation/enforcement actions. As frustrating and unfair as it is, each pharmacy needs to respond to the ESI letter. In doing so:

- The initial Administrative Review request letter should request that ESI cease recouping payments until the pharmacy and ESI have completed the Review process.
- The pharmacy should “reverse engineer” or “deconstruct” the ESI letter. If the patient information/dollar amounts contained in the ESI letter are incorrect, then these mistakes need to be pointed out in the pharmacy’s response letter. For example: (i) a comparison of the information contained in ESI’s claim report with the claim information in the pharmacy’s system may establish that for a number of claims, the Paid Amt/Discrepant Amount shown on the ESI report does not match the actual amount paid as reflected in the pharmacy’s claims system; (ii) for a number of claims, the Member ID shown on the ESI report does not match the cardholder ID as reflected in the pharmacy’s claims system; and (iii) if ESI used the Member ID shown on the report to determine if the prescribing physician shown on the pharmacy claim had seen the patient, then it is not surprising that there is not a match since the Member ID appears to be incorrect.

- The pharmacy should retain a health care attorney to ghost write the response letter for the pharmacy to submit to ESI in the Review process. The response letter should be very detailed and specific to the pharmacy and factual with no emotion and no editorializing. The attorney is trained to compose such a letter.
- The response letter should discuss every argument the pharmacy can raise and support.
- The response letter should outline the pharmacy's standard operating procedures for confirming physician-patient relationships. This may include processes for direct contact with patients as well as confirmation of prescription details with prescriber offices.
- If the pharmacy believes it can do so without irreparably harming its relationship with the prescribing physicians, then the pharmacy should contact the physicians and (i) request documentation establishing the PPR and (ii) ask if the physicians will be willing to sign the requested attestation. If some physicians comply with the request, then the information/documents provided by them will be included with the pharmacy's response letter. If other physicians decline to cooperate, then the response letter should so indicate.

Reality Check – Unless the pharmacy can produce the documents required by ESI, the chances of the pharmacy succeeding with the Review process are very low. It appears that the goal of TRICARE/DHA is to recover money ... and they have instructed ESI to take the steps to do so. While ESI likely has some decision-making authority, the real decisions are likely being made by TRICARE/DHA. Unless TRICARE/DHA are persuaded ... or forced ... to back off their recoupment efforts, then recoupments will continue. There are two other concerns that need to be addressed: (i) if TRICARE/DHA and ESI conclude that a pharmacy engaged in fraud, then there is a risk that information on that pharmacy will be turned over to the United States Department of Justice (“DOJ”) and (ii) there is possibility that TRICARE/DHA and ESI will pursue recoupment actions for years subsequent to 2015. Engaging in the Review process is important to preserve the pharmacy's rights to contest the recoupment. Equally as important, the information/documents submitted by the pharmacy need to establish that the pharmacy was not engaged in any fraudulent actions and, therefore, there is no basis for TRICARE/DHA to submit information on the pharmacy to the DOJ.

Persuading TRICARE/DHA and ESI –

- Representatives could seek a meeting with TRICARE/DHA. If such a meeting occurs, then the representatives will (i) present the arguments set out above and (ii) seek some type of “middle ground” with TRICARE/DHA. Such middle ground might consist of ESI conducting an audit on behalf of TRICARE/DHA...but the audit needs to be fair and not impose impossible obligations on the pharmacies. Representatives of the pharmacies can be some combination of APC, NCPA, B&F, and the Virginia-based law firm of Macauley & Jamerson, P.C. (that is working with B&F).

- Representatives can request a similar meeting with ESI. However, it appears that ESI is acting at the direction of TRICARE/DHA, meaning that meeting with TRICARE/DHA will be of the greatest importance.
- If it appears that TRICARE/DHA are uncooperative, then the pharmacy may choose to approach elected officials (U.S. Representatives/Senators) and request their intervention. By “intervention,” we mean that the pharmacy will ask the Representatives/Senators to pressure TRICARE/DHA to meet with the pharmacy group representatives.
- The pharmacy trade groups can coordinate a social media campaign against TRICARE/DHA and ESI that points out that what is being demanded is manifestly unfair to the pharmacies and what is being demanded will hurt the veterans.

Forcing TRICARE/DHA and ESI – If the above steps prove to be unsuccessful, then pharmacies may choose to join together and pursue litigation against TRICARE and ESI. Before a lawsuit can be filed, however, pharmacies must first attempt to mediate the issue with ESI for no less than 30 days pursuant to the ESI Provider Manual. If mediation proves unsuccessful, the pharmacies must then provide written notice of their intent to cease discussions with ESI. Thereafter, the pharmacies may file a lawsuit.

Caveat: There is no guaranty that a lawsuit will be successful. A lawsuit is expensive and time consuming. There is a risk that TRICARE/ESI will terminate the contracts with the plaintiff pharmacies.

THIS ARTICLE DOES NOT CONSTITUTE LEGAL ADVICE. THIS ARTICLE WAS PREPARED ON A SPECIFIC DATE. THE LAW MAY HAVE CHANGED SINCE THIS ARTICLE WAS WRITTEN. BEFORE ACTING ON THE ISSUES DISCUSSED IN THIS ARTICLE, IT IS IMPORTANT THAT THE READER OBTAIN ADVICE FROM A HEALTH CARE ATTORNEY.

Jeffrey S. Baird, Esq., is Chairman of the Health Care Group at Brown & Fortunato, a law firm with a national health care practice based in Texas. He represents pharmacies, infusion companies, HME companies, and other health care providers throughout the United States. Mr. Baird is Board Certified in Health Law by the Texas Board of Legal Specialization and can be reached at (806) 345-6320 or jbaird@bf-law.com.

Bradley W. Howard, Esq., is an attorney with the Health Care Group of Brown & Fortunato, a law firm with a national health care practice based in Texas. He is Chairman of the Labor and Employment Law Group and works with numerous health care clients, handling governmental investigations, business disputes, and litigation involving health care providers including pharmacies, DME companies, home health agencies, and hospitals. Mr. Howard is Board Certified in Labor and Employment Law by the Texas Board of Legal Specialization and can be reached at (806) 345-6310 or bhoward@bf-law.com.

Hunter W. Jamerson, Esq., is an attorney with Macaulay & Jamerson, P.C., in Richmond, Virginia, and can be reached at (804) 467-0307 or hunter@macjamlaw.com.

F:\DOCS\2222\188\WHITEPAPER\2HE654702.DOCX