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RE: TRICARE/ESI 2015 Compounding Claims Recoupment

Dear Col. Gmehlin:

On behalf of the Alliance for Pharmacy Compounding, the National Community Pharmacists Association, and PAAS National, thank you for our recent phone call and the opportunity to relay our organizations' concerns in writing. As relayed on the call, our members are extremely concerned by the overreaching findings outlined in Express Scripts' demand letter and the associated recoupment. While the temporary pause in the recoupment action is appreciated, our members require rescindment of the demand letter and restoration of recouped amounts.

Recoupment Action

Our members dispute multiple elements of this recoupment action:

A. Errors and Deficiencies in ESI's Recoupment Letter

By ESI's own admission, the April 7, 2020 recoupment letter was dated in error. Our members received this letter on various days early in the month of June. ESI's error has created significant confusion regarding the timeframe for our members to appeal this action. Moreover, to the extent the recoupment letter was intended to serve as a demand letter for purposes of an overpayment recovery pursuant to 32 CFR 199.11, then few of the requirements of 32 CFR 199.11(f)(6)(ii) appear to have been met. Additionally, the misdated letter does not appear to meet the requirements of 32 CFR 199.11(f)(6)(iii). Accordingly, the validity of the demand letter and the recoupment action is in doubt.

B. No Foundation for Recoupment

According to TRICARE and ESI, the basis for the recoupment is a purported absence of a physician-patient relationship ("PPR") underlying the prescription. However, neither TRICARE nor ESI have provided any information to support that conclusion. In fact, the only substantive statement offered by TRICARE or ESI as to its rationale is the purported absence of a medical claim to TRICARE for the

physician's professional services. There is no requirement under law, regulation, or the pharmacy provider manual to support a standard that a medical claim to TRICARE for the physician's professional services is required to establish a physician-patient relationship. Many of our members dispensed prescriptions issued by prescribers who do not bill TRICARE. Further, in some cases TRICARE may have served as a secondary insurance payor and had no responsibility for the medical claim. Additionally, many prescriptions were written and physically signed and given to the patient or else were electronically submitted directly from the prescriber's electronic health record system, indicating the physician-patient relationship. Simply put, there is no basis for TRICARE and ESI's conclusion that a physician-patient relationship does not exist.

C. Data Discrepancies in ESI's Recoupment Letter and DHA's Discrepancy Report

Serious questions as to the accuracy of the underlying "Discrepancy Report" attached to the April 7, 2020 recoupment letter by ESI have been raised by our members. For example, many of our members have reported that the Member ID shown on the Discrepancy Report does not match the cardholder ID as reflected in the pharmacy's claims system—for some pharmacies, up to 95% of the Member IDs shown on the Discrepancy Report do not match. If DHA ran an incorrect Member ID when attempting to establish a corresponding patient visit with the prescribing physician, then it is not likely to match resulting in a finding of no prior PPR and thus an incorrect recoupment.

Another inaccuracy within the Discrepancy Report relates to the "Paid Amount"/"Discrepant Amount". Many of our members have shown that the amount listed under the "Paid Amount" and "Discrepant Amount" columns does not reflect the actual amount paid to the pharmacy for that claim. This is verified in the pharmacy's Claims Reconciled Report pulled from ESI on the same claims. Thus, the DHA Discrepancy Report frequently shows an inflated amount that will purportedly be recouped from the pharmacy above the amount that was actually paid to the pharmacy for identified claims. In other cases, correct paid amounts are misaligned from the correct claim by several lines on the Discrepancy Report. TRICARE's reliance on this flawed data set undermines any confidence in its analysis.

D. ESI's Medical Documentation Requirements are Virtually Impossible to Meet

ESI is apparently requiring that our members (i) provide medical documentation demonstrating a proper PPR existed within 365 days prior to the date of the claim, which is accompanied by "metadata or similar validating facts that substantiate the records creation date" and (ii) a signed attestation by both the prescriber and pharmacy. This is a burden that pharmacies simply cannot meet for many claims.

First, unless the physician utilized an electronic health record system in 2015, and still has access to that system, the physician documentation establishing the PPR will not contain the requested metadata. It is unclear to our members how to substantiate the creation date of paper records.

Second, the requirement to provide medical documentation with metadata or similar validating features is an arbitrary requirement. There is no rule, statute, or contract between the pharmacy and ESI or DHA which mandates that the validation of a proper PPR must be shown through medical documentation with metadata or similar validating features. It is unclear to our members how metadata could even be evidenced without direct access to the physician's electronic health record system by a qualified information technology professional.

Third, because many prescribing physicians were not TRICARE participating physicians and therefore are not at financial risk, a number of prescribers will not devote the resources to cooperate with the pharmacy's request for medical records. This is particularly true when it requires locating paper records

from 2015. Unlike TRICARE, the pharmacy has no legal instrument to require document production from a physician.

Fourth, some prescribers have moved, retired, or died, so that obtaining copies of these medical records will be extremely difficult or impossible.

Fifth, many prescribers practice in states which do not require retention of medical records dating to 2015. In those cases, obtaining medical records may be impossible.

E. ESI is Imposing on Pharmacies an Obligation that the Law, the ESI Contract and Provider Manual did not Impose in 2015

ESI is requiring the pharmacy to prove the existence of a proper 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 was not until the last half of 2017 that ESI added language to the Provider Manual requiring the pharmacy to confirm a valid PPR in certain situations. Moreover, in some states, the prescription itself is evidence of a physician-patient relationship.

Our members have no duty, or available legal instrument, to obtain medical records from a prescriber. No such record requirement is imposed on pharmacies under 32 CFR 199.6 or any other law or regulation. Further, our members have no duty, or available legal instrument, to obtain metadata or physician certification of medical records. These appear to be insurmountable appeal standards invented to dissuade pharmacies from attempting or succeeding in record collection or else to dissuade physician cooperation.

ESI Communications

As noted on our call, our members have variously received one, two, three, or four different communications from ESI in connection with this recoupment. Some members have received direction regarding record requirements for an administrative claims review. Other members have received communication indicating the recoupment has been paused. Still other members have received communication that the 90-day appeal period has been tolled. Many members, however, have received no communication besides the initial demand letter.

The lack of consistent and simultaneous communication is a significant frustration to our members and has created confusion. Additionally, ESI has provided members with a single point of contact, auditor Christine Hartman Dunse. To our members' frustration, Ms. Dunse's voicemail box is often full, calls to her are not returned, e-mails to her are infrequently and not substantively answered, and she has taken vacation during the recoupment period. Recent communications from Ms. Dunse to some members indicate ESI will not provide any further information or answer any questions without direction from DHA. A responsive, informed, and authorized point of contact must be designated.

Specific Questions

In addition to addressing the concerns raised above, our members have a number of specific questions which we would appreciate your addressing:

Basis for Recoupment

- What is the legal authority for this recoupment?
- What information supports a conclusion that a physician-patient relationship is absent?
- What information supports a finding of program abuse?
- Why is the absence of a medical claim by a prescriber a relevant consideration?
- Why is the data attached to the recoupment letter so significantly flawed?

Recoupment Process

- Why have the requirements of 32 CFR 199.11, including 32 CFR 199.11(f)(6)(ii) and 32 CFR 199.11(f)(6)(iii) not been followed?
- Why was the recoupment letter dated April 7, 2020 but not served on pharmacies until June?
- Why did recoupments begin in some cases prior to delivery of the demand letter?
- How can our member pharmacies obtain an accounting of recouped amounts to date?
- Why did TRICARE only target recoupment of compounds when many patients received commercially available products prescribed at the same time by the same prescriber?
- If TRICARE and ESI doubt a physician-patient relationship exists, why have TRICARE and ESI not contacted the prescribers or patients?
- Why did TRICARE pay ESI for these claims if it contends a necessary standard was not met?
- Why does TRICARE not seek recoupment from ESI if it believes these claims were not administered correctly?
- Why is this recoupment coming five years after the dates of service?

Record Production Standard

- What obligates pharmacies to provide prescriber medical records to support an appeal?
- What obligates pharmacies to obtain metadata to support an appeal?
- What obligates pharmacies to obtain certifications from prescribers and the pharmacy as to the accuracy of the medical record?
- How is a pharmacy empowered to collect such records from a prescriber?
- How would paper medical records be handled?

- Why would an attestation letter from a prescriber or patient not be accepted?
- What alternative documentation would be satisfactory to support the physician-patient relationship?
- What obligates a pharmacy to prove a physician-patient relationship?

Procedural Next Steps

- Will the April 7, 2020 demand letter be rescinded?
- Will recouped funds be restored to pharmacies during the suspension of the recoupment?
- How will a determination of which pharmacies receive ESI audits and which pharmacies receive administrative recoupments be made?
- When will ESI audits take place and in what form?
- When will the suspension of recoupments be lifted and administrative recoupments proceed?
- What is the appeal process?
- Who will be evaluating the administrative review of indebtedness documentation from pharmacies – ESI or DHA?
- What is the timeline for a response to an appeal?

Future considerations

- Will TRICARE and ESI recoup similar claims dispensed prior to 2015 or during 2016 – 2020?
- Why does TRICARE and ESI continue to pay for similar claims today (including claims for the same patient, prescriber, and product)?

Alternative Proposal

To the extent DHA/ESI do not immediately rescind the demand letter, ESI and DHA should make the following changes, at a minimum, to ensure pharmacy due process rights are protected:

1. DHA/ESI should verify and provide an accurate Discrepancy Report to pharmacies.
2. DHA/ESI should permit paper copies of medical records without document creation substantiation requirements. In situations where the prescriber cannot or will not provide copies of medical records, DHA/ESI should allow signed attestations by prescribers or patients in place of medical documentation.
3. DHA/ESI should allow due process by ceasing recoupments and refunding all recouped monies until Reconsideration appeals have been completed.

4. DHA/ESI should issue a clear communication, simultaneously to all pharmacies, explaining a) its renewed recoupment procedure; b) appeal standards and process; c) the timeframe for DHA/ESI's response to appeals; and d) a responsive point of contact for pharmacies.

Conclusion

Our organizations appreciate your willingness to continue to discuss this recoupment. Our members are committed to safeguarding against fraud, waste, and abuse. Accordingly, we hope to assist TRICARE and ESI in correcting this flawed recoupment so that resources can instead be expended to undertake enforcement actions against actual instances of fraud, waste, and abuse.

Respectfully,



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