



Alliance for
Pharmacy
Compounding

Formerly IACP



NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION

ISSUE BRIEF: DHA's Recoupment Action Against Compounding Pharmacies

SUMMARY: In June 2020, hundreds of compounding pharmacies across the United States received letters from Express Scripts, Inc., stating on behalf of TRICARE and the Defense Health Agency that ESI was recouping money from the pharmacies for compound drug claims submitted to TRICARE back in 2015. The letters made clear that this was no ordinary clawback resulting from an audit of claims; rather, it was an enforcement action against pharmacies for what DHA had decided were fraudulent claims.

Recoupment amounts varied by pharmacy – from a few hundred dollars to hundreds of thousands of dollars. Recoupments on these compound claims began on or around the date of receipt of these letters; ESI simply began withholding funds from pharmacies' current reimbursements without any due process.

The letters alleged the compounders' reimbursements for the drugs dispensed were improper because of a lack of a proper physician-patient relationship (PPR) – in other words, alleging the physicians had no documented relationship with the patients for whom they'd written prescriptions for compounded medications (because there was no associated medical visit billed to TRICARE) – *a situation over which pharmacists and pharmacies have no control*. Each letter included a report that purported to set out the prescription number, fill date, Member ID number, and the discrepant dollar amounts to be recouped.

In late June, in response to concerns raised by our organizations, ESI and DHA issued a *temporary* suspension of recoupment actions related to the letters dated April 7, 2020, and said the 90-day time period to submit information and documentation in support of a request for an administrative review is being stayed until further notice. On a June 15 phone call, DHA and ESI leaders told APC and NCPA representatives that they are reassessing the data that led to the recoupment actions *but said there is no plan to return any funds already recouped until the reassessment is completed*.

The rationale for this recoupment effort is unjustified, and the process followed by ESI in executing it is rife with errors and runs counter to the ESI contract with the compounding pharmacies and the provider manual for 2015. Moreover, ESI's decision not to return previously recouped funds risks creating a cash-flow crisis for many pharmacies that are already strained by the economic effects of the current pandemic.

CONCERNS:

1. **The rationale for the recoupment is flawed because compounding pharmacies have no control over physician-patient relationships or access to records of same, and thus holds pharmacies accountable for data they cannot provide.** ESI is requiring that the pharmacy, within 90 days, (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. In other words, the requirements for documentation will not be satisfied by letters from physicians simply attesting to the PPR. This is a burden that pharmacies simply cannot meet for many, even most, claims.
 - a. No state law or regulation requires pharmacists to document a relationship between patient and physician. This is an obligation that, absent suspicion of a fraudulent prescription, a pharmacy is

not required to generally undertake. The requirement to provide medical documentation with metadata or similar validating features is an arbitrary requirement. Moreover, there is no rule 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.

- b. Unless the physician utilized an electronic health record system in 2015, the physician documentation establishing the PPR will not contain the requested metadata. It is unclear how to substantiate the creation date of paper records.
- c. Because the prescribing physician is not at financial risk in this recoupment action, 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.

2. **The process followed by TRICARE's contractor, ESI, is rife with errors and runs counter to ESI's own contracted policies with the compounding pharmacies.**

a. Errors:

- i. Although the letters were dated April 7, 2020, most letters were postmarked and received by pharmacies in early June. This is salient because the letters provide only 90 days in which pharmacies must respond.
 - ii. ESI began the actual recoupment without giving notice or opportunity for pharmacies to be heard.
 - iii. Serious and widespread discrepancies have been found between the information contained in ESI's claim reports and the actual claim information in the pharmacy's records. For instance, Member ID shown on the ESI 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 Discrepancy Report do not match); or the Paid Amount/Discrepant Amount shown on the ESI report does not match the actual amount paid as reflected in the pharmacy's claims system (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).
 - iv. ESI provided no specific evidence upon which DHA determined the absence of a proper PPR.
- b. Multiple attempts by pharmacies to address these concerns and to have ESI/DHA verify the accuracy of the Discrepancy Report have been completely ignored by ESI. ESI's stance is that the onus should be placed on the pharmacy to demonstrate that a proper PPR had been established to support each of the 2015 claims by providing medical documentation—effectively sidestepping the pharmacies' Discrepancy Report questions.

ACTION REQUESTED: We ask members of Congress to contact DHA about this egregious accusation of fraud by compounding pharmacies and improper recoupment action. Please make the following points:

1. DHA/ESI cannot hold pharmacies accountable for producing evidence or documentation to which they do not have access and are not required by law to document and produce.
2. DHA/ESI should allow due process by ceasing recoupments and refunding all recouped monies until thorough reevaluation of the data on which this flawed effort was based.
3. DHA/ESI should, at a minimum, verify and provide an accurate Discrepancy Report to pharmacies.
4. 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, DHI/ESI should allow signed attestations by prescribers or patients in place of medical documentation.

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