Whitepaper

IntegriChain®

Improving Medicaid Rebate Processing Accuracy using Claim-level Detail (CLD) Validation

Only Pay what is Owed!

Medicaid is the fastest growing insurance coverage in the United States, covering more than 94 million Americans. As a result, most manufacturers participate in Medicaid but quickly realize there are definite pros and cons to that participation. Clearly Medicaid programs are essential to ensure therapies are affordable to millions of impoverished and underserved Americans. However, compliance with government programs can be challenging, particularly for new manufacturers that are learning the intricacies of Medicaid processes for the first time.

As part of the Medicaid payment and reimbursement process, state Medicaid offices submit quarterly invoices to pharmaceutical manufacturers for mandatory and voluntary rebates. Naturally, manufacturers want to ensure the details provided in those invoices are valid, therefore only paying what is owed. Validation of invoice level information allows manufacturers to catch the most apparent issues but reviewing and validating the Medicaid Claim Level Detail (CLD) in conjunction with the invoice information opens up the potential for finding additional invalid lines. The value of a more thorough review of Medicaid information is clear: Inaccurate or duplicate medicaid rebate claim payments can amount to a loss of 1%-2% of gross revenue for a manufacturer.

The ABCs of CLD

Given the huge volume of Medicaid rebate claims, even small discrepancies can result in significant revenue leakage for the manufacturer. Manufacturers, however, are at a disadvantage when trying to determine invoice level validity without having the

Medicaid Claim Level Detail (CLD) at their disposal. Unfortunately, obtaining CLDis complicated and resource demanding.

To create the quarterly invoices to submit to manufacturers, the states accumulate and summarize the Medicaid CLD for that period. Unfortunately for manufacturers, the Center for Medicaid and Medicare Services (CMS) does not require the states to provide the CLD to the manufacturers. It is the manufacturer's responsibility to either request and retrieve the needed CLD from state or third-party portals such as Magellan, Conduent, or others, or they must email each state directly to request the needed CLD. Once a manufacturer receives CLD, they can review it for any issues such as duplicate scripts or an invalid provider that cannot be seen nor is readily identified at the invoice level.

Basics of Medicaid Rebate Processing

First let's set the stage and review the Medicaid rebate process at a high level with or without CLD. As with any claim or rebate processing, the objectives are to maintain compliance, have complete transparency, and ***only pay what is owed***. No more, no less.

Medicaid Rebates without CLD

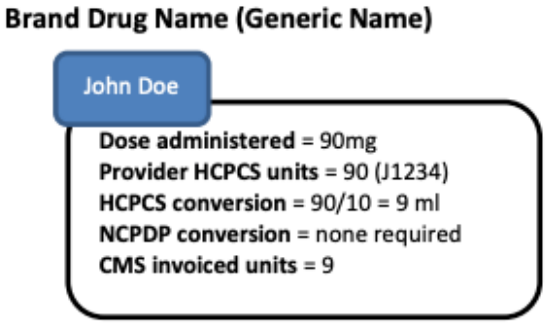
The most common industry practice is to process Medicaid claims at invoice level, and the basic process is shown below.

1. The manufacturer's government pricing team calculates the URA for the product, relying on a foundation of the average manufacturing price (AMP) and best price (BP). Prior to loading the calculated URAs into the Medicaid rebate processing system, the manufacturer's Medicaid team first should verify the calculations against the Drug Data Reporting for Medicaid (DDR) system. This will ensure that there are no discrepancies between the state URA and the calculated URA.
2. Once the URA is loaded in the Medicaid rebate processing system, Medicaid analysts--either within the manufacturer's team or through a managed services provider--will start receiving quarterly claims from state and third-party administrators (TPAs), which manage Medicaid claims on behalf of states.
3. Once the claims are received, they must be processed and validated, generally within 38 days. Every invoice received from the states or TPAs should include the following data:
    - Labeler
    - State
    - Program
    - NDC11
    - Units
    - Scripts
    - URA
    - Requested rebate amount
    - Medicaid Reimbursement Amount
    - Non-Medicaid Reimbursement Amount
4. In many cases, the amount submitted by the state for reimbursements fails to match with the amount calculated by the manufacturer or there are duplicate submissions from the state. Traditionally, many manufacturers simply receive the invoices, process, and pay the rebates without doing any more than invoice level validations or variance tests. This approach can lead to paying erroneous or duplicate claims and have a significant and negative impact on the manufacturer's net-price and gross-to-net calculations. Instead, many manufacturers execute a formal dispute process to resolve the difference between the two amounts.

Adding CLD to the Medicaid Rebate Process

Regardless of the operating model, it is a better practice to request as much Medicaid CLD as the operational team can support and validate at that level of granularity prior to paying the rebate. Examples of these checks include ensuring product Medicaid eligibility; scrubbing out scripts for terminated products; screening for duplicates within Medicaid and across other channels such as 340B, Managed Care, and Tricare and searching for aberrant quantity values such as those outside the min/max and those not in expected increments.

Once beginning validation on Medicaid CLD, it is likely there are some specific CLD lines that are in question that will lead a manufacturer to initiate the normal Medicaid dispute process with the states. It is common to only initiate a dispute when the line(s) in question exceed a value threshold. For issues found at either the invoice or CLD level, best practice is to attempt resolution with the state prior to the due date of the invoice. If the manufacturers can reach agreement on resolution prior to payment, the units can be adjusted on the Reconciliation of State Invoice (ROSI) and/or Prior Quarter Adjustment Statement (PQAS) using the standard CMS adjustment codes without a dispute being created. If agreement is not reached, a dispute is created and reported using the standard CMS adjustment codes on the ROSI and/or PQAS. Regardless of the resolution, it is important to log all disputed units along with the assigned dispute codes to ensure the finance and gross-to-net teams are aware of any open disputes and the amount so that funds are set aside in the event that ultimate resolution is in the state's favor and the amount needs to be paid.



Dosing is provided for illustrative purposes only.

NDC 11	Package Size	HCPCS Code	HCPCS Unit of Measure	Conversion Factors	CMS UPPS	Invoicing Unit of Measure
12345-6789-10	100mg/10ml SUV	J1234	1mg = 1 HCPCS unit	HCPCS units/10 = NCPDP units NCPDP units/1 = CMS units	10	ml

Figure 1 - Example of rebate claim line

Processing Payments

Once invoices are approved internally, data is sent to the financial system (often an enterprise resource planning or ERP application) for payment either via check or Automated Clearing House (ACH). Post payment,the finance team will confirm these amounts against bank statements during month-end closing. While this process can vary from manufacturer to manufacturer, most follow a similar approach and the process is generally completed within eight to ten business days.

Challenges with Medicaid CLD Retrieval and Standardization

Manufacturers are presented with a unique challenge right off the bat when attempting to retrieve the CLD. Surprisingly, CMS does not require the states to make CLD generally available to manufacturers. Most states and TPAs, however, either post CLD on their portals or will send CLD upon request via email. Additionally, CMS does not require certain information to be present on the CLD like is mandated on the invoices. This leads to wild differences in what is actually received from state to state and even quarter to quarter within the same state. Complicating this matter is the fact that every

state has a different file format and type for the CLD. To get all CLD received in a usable format for downstream validation, manufacturers must either build or buy a tool or system that takes all of this data and converts it into a common file format. Increasingly, manufacturers are looking to third-party managed service providers to handle these tasks efficiently and with the up-to-date knowledge needed to handle the state-to-state variations.

Considerations for Incorporation of Medicaid CLD

As noted above, incorporating Medicaid CLD into a standard Medicaid rebate process provides manufacturers the opportunity to identify more invalid lines that can be either adjusted or disputed to more accurately pay only what is owed. However, that is easier said than done. Outlined below are five considerations to walk through to better help manufacturers determine how to bring Medicaid CLD into their Medicaid process.

Consideration	Key Factors
Product & Program Scope	Products to include/exclude Level of rebate/duplication Dosage forms High-risk States Utilization changes Include/exclude re-submissions
In-cycle or Post-cycle Timing	Data retrieval Data conversion Scrubbing Analysis
Data Pull Strategy	Volume Level of automation
Systems and Data	Data retrieval Degree of standardization Validation Level of integration
Direct Impact to Operations	Volume Taxonomy Change management Resource management

Consideration #1: Product and Program Scope

The first consideration is **scope**. There are several important aspects to scope, including:

- **Products.** Manufacturers must first determine for which products they will pull CLD. For some manufacturers, this is simple because they have only one or two labeler codes. However, many manufacturers have a large number of NDCs and multiple labelers, making it more challenging and maybe less worth the effort to retrieve and validate every line of CLD.
- **High 340B Purchases or Heavily Rebatable.** Do certain products have a high percentage of 340B purchases? Are certain products heavily commercially rebatable? CLD validation can deliver significant benefit in terms of eliminating cross-channel duplications for products that are distributed across differing channels.
- **Dosage Form.** Products that are capsules or tablets are less likely to have incorrect unit conversions from the states than 5i or J codes drugs. 5i or J code drugs may provide a better return on the effort when product scope is considered
- **State Programs.** Are there some state programs that have significant, consistent issues via invoice level validation? If so, manufacturers might find even more within these same state programs when validating the CLD.
- **Utilization Changes.** Are there states that have swings in the rebate liability from quarter to quarter? A valid reason for swings could be due to a known URA change resulting in an expected increase or decrease in liability. However, a swing in liability could be a result of a unit conversion issue from the state. A state unit conversion issue may not be as apparent once the CLD is summarized into the invoice as it is when reviewing the CLD. Naturally, states with higher Medicaid utilization overall provides the potential for more disputes across all types of validations.
- **Original Utilization or Re-Submissions**. Keep in mind that the more quarters that CLD is pulled, the more trickle-down effort it's going to require from the entire team on an ongoing basis.

Scope is probably the most difficult challenge a manufacturer faces in getting started with CLD. It is best to take a hard look at the specific programs and products and determine the ideal scope that adds the most value without overburdening operations resources.

Consideration #2: In-Cycle or Post-Cycle Timing

Beyond scope, manufacturers need to assess the operational impact of data retrieval, conversion, scrubbing, and analyses. When is the best time for this to occur? Some organizations are highly concerned about the impact of CLD on meeting their payment dates and choose invoice-level processing only during the cycle with the CLD analysis, retrieval and validation following the cycle. While others feel the added burden during the Medicaid invoice cycle is worth it so that potential disputes can be identified as early as possible and reported to the states.

Clearly, implementing CLD will have some impact on operations resources. It is critical to take time and map the process, including data retrieval, conversion, scrubbing, and analysis. Either answer of CLD timing can be right for your organization. The important takeaway is that the selected timing must align with your scope, operational resources, and risk tolerance.

Data Retrieval. Retrieving CLD from a state or third-party portal can be pretty quick if not much data is being pulled, but it can be a very time-consuming task if your scope includes a large number of labelers, NDCs, and programs as each portal has differences in the way that CLD is requested and retrieved

While some portals make the invoice and data available simultaneously, others have a delay between invoice and CLD availability. For one particular portal, the CLD must be requested, and then the files are available for download 24 hours later. At the present time roughly 70% of CLD is available on state or TPA portals, while the balance must be requested directly from the states via email.

Having your program scope defined will allow you to determine how much additional time will need to be built in to request and wait for the email CLD. Be sure to consider time for follow up with those emails as it often takes several iterations with the states to get what's needed. Given CMS doesn't require states to provide the CLD, except in

the case of a suspected dispute, the states have flexibility to push back on those CLD requests causing possible delays. Likewise, there are no service-level agreements between the states and manufacturers related to email CLD response time. That said, in general the vast majority of states are very helpful with CLD requests, especially if given enough lead time. *(See Consideration #3 for more details.*

Data Conversion and Scrubbing. Once the data is retrieved (regardless of whether it's via portal or via email), it will need to be converted to a load format and then loaded through the validation tool or validation module for potential dispute identification . Depending on the defined scope, this process could add anywhere from a couple of hours to a day or so to your overall timeline. A large labeler with high volumes and many products could result in jobs that run for 24 hours or more.

Analysis. Finally, the time required to analyze the validation output must be considered. Use of a validation tool or module that's fully integrated with the Medicaid processing system is ideal and will dramatically reduce the time required for analysis. However, if the validation tool sits outside of the processing system, additional time will be required to determine which lines need to be disputed.

Using the scope and the output from the previous two steps along with the timing impact for retrieval, conversion, validation, and analysis of CLD, manufacturers can make a more informed decision on whether to pull and scrub CLD during the 38-day processing window or to delay that until after the cycle.

Consideration #3: Data Pull Strategy

Volume. As mentioned above, pulling the data is a major operational decision. Most portals allow pulling CLD by labeler, which is ideal for low-volume labelers that can pull one CLD file per labeler per program. However, as the number of NDCs being pulled grows, the larger the data set becomes and the more cumbersome it becomes to manage. Larger data requests to the portals can also "max-out" the portal, forcing the manufacturer to resort to pulling by NDC 11, which, in the absence of automation, can be very taxing on operational resources.

Automation. If you have concerns about your operational resources having the bandwidth to retrieve CLD via the portal, investing in an automated CLD retrieval tool should be considered. While automation of CLD pulls allows operational teams to focus on higher-value activities, there are downsides to consider as well. First, there is the cost of the automated tool and time and money to get the technical support team familiar. Secondly, the tool will need to be configured specifically for the defined product and program scope. In addition, each portal has its own set of navigation and parameters that are required to successfully pull the data. Also, portals change, so tools require frequent maintenance and updates; there's really no full "set-it-and-forget-it" options for the automated CLD pulls. Having the right technical resources is essential to keeping automated jobs running. In the end, it is critical to finalize the organization's approach to pulling CLD in a way that makes the most sense and is sustainable.

Consideration #4: Systems and Data Capabilities

Until now, most of the focus has been on process definition and alignment with resources. The fourth consideration involves the selection of systems and tools for retrieving, standardizing, and validating the CLD as well as for integrating it into the manufacturer's current process.

Data Retrieval. The first aspect to explore is how the data is delivered by the states. How the data is delivered is determined by the state/program scope. More than half of the states are available on web portals; however, some do require

requesting CLD via email. For those states that are available on portals, some manufacturers choose some form of robotic process automation (RPA). RPA mimics the process a user would follow to download data from the portal. Unfortunately, RPA cannot be used for states that require email requests, as this requires an analyst to request the CLD from the state and wait on the state to respond. As the number of RPA CLD requests increases, so does the level of required maintenance. Serious consideration needs to go into the availability of resources to achieve this level of maintenance.

Standardization. After retrieval, the next step to tackle is standardization. Although the data required on invoices is mandated by CMS, there are no requirements related to CLD. Therefore, it is likely for a manufacturer to receive over one hundred different formats of CLD. Each format received requires its own extract-transform-load (ETL) process to convert it to the standards. Depending on the scope, many ETL processes may be necessary.

Just like RPA, there's no real out-of-the-box solution for ETL. Each file format received will require building and maintaining ETL. Further complicating the issue is the fact that the formats received via email vary from quarter to quarter or even within the same

quarter. This means that the ETL process will also have to be constantly monitored to ensure the CLD loads correctly. Again, availability of skilled resources to maintain the ETL processes must be evaluated.

Validation. After standardization, the CLD is validated. A validation system that can perform all required validations and provides usable outputs should be used for this step. Usable outputs can range from reports, to visualizations, to a feed directly into your Medicaid processing system based on what you deem to be usable for your team. This can be a commercially available system or something built in house. Either option can be costly and requires skilled resources to implement and maintain.

Integration. The final step is integrating the validation results into the current Medicaid system and process. There are many challenges involved in integrating the results:

- Does the current system have the ability to accept the CLD?
- Is the CLD available to be viewed and analyzed within the system?
- Can it automatically create disputes based on the results?

Integrating the data into your Medicaid process and system can be done by manually entering disputes. This could require significant time investment by the processing team. If a feed is available or built it must be monitored for issues and maintained accordingly. This will require skilled resources and time and can be costly to implement. Implementing advanced and automated systems and tools can have a significant impact on the speed and accuracy of your CLD process. However, as with all technical approaches, the organization must be willing to make the investment in tool acquisition, training, configuration, and ongoing maintenance.

Consideration #5: Direct Impact to Operations

By now it should be clear that CLD requires a significant amount of data to be acquired, analyzed, and managed. This can have a significant impact on the operational teams.

Volume. The volume of data is determined by the scope set in previous considerations. The more states/programs or NDCs in scope, the larger the data volume. As the data volume grows, the more stress is put on the systems and resources supporting CLD validation. The increased volume also lends itself to an increase in potential formats and data variations in the data received. Because there is no data standard required by CMS for CLD data, each format received includes different and varying fields. Some provide only minimal data and some provide more fields than are required for validation.

Taxonomy. Furthermore, each state has its own taxonomy and different names or abbreviations for the same data element. This inconsistency can make CLD hard to analyze and make it hard to understand what data is available and what the data means. It can take a large amount of time to train in-house personnel on understanding the CLD and how it's used for validation.

Changes and Evolution. Lastly, these field definitions are not static. Periodically, states change the naming or abbreviation. This puts additional responsibility on operational teams to conduct ongoing research to identify changes, additions, and deletions to the data. Beyond the data, there are many different types of validations that could be run against the CLD data and operations personnel need to understand which are the ones that actually result in disputes.

Resource Demands. With clarity of data and validations, operations teams are well positioned to seek adjustments from the state. However, if agreement is not reached in time to pay within the 38-day due date, the only options are to create a dispute or pay and try to recoup the money later (often referred to as “pay-and-chase”).

Any disputes identified at the CLD level must be rolled-up and reported at the invoice level. Evidence to support the dispute must also be included with the payment documentation sent to the state. The validated CLD results can be used for evidence in most cases, but additional information may also be required. Once disputes are created, the next step is to work with the state to come to a resolution. This can be quite labor-intensive and must be taken into account from a resource management perspective.

340B disputes in particular may take more time, as they may require working with covered entities instead of the state to resolve. There are also potential Coordination of Benefits validation failures found within the CLD. These failures relate to cross channel rebates, specifically Utilization Based Rebates, and cannot be disputed on the Medicaid side, but can potentially be disputed on the commercial side. Again, the question then becomes, does the manufacturer have the bandwidth to handle all of this?

Conclusion

This paper has highlighted the fact that invoice level validations alone cannot bring to light all the potential disputes in the Medicaid data. Without at least some level of use of CLD in your Medicaid process, manufacturers are prone to significant revenue leakage. Adding CLD to the Medicaid rebate adjudication process can be a huge benefit in identifying and resolving additional issues and thus allowing for more accurate payments and accruals. Despite these significant benefits, many manufacturers believe they simply do not have the time, resources, or expertise to effectively implement CLD.

For those manufacturers with the operational and technical capacity, it is probably worth initiating some internal conversations on how to incorporate CLD into your ongoing process. For others, the better answer may be to consider outsourcing parts, or all, of the CLD process. With the systems, processes, and expertise already in-house, IntegriChain is the ideal partner for CLD validation. Our ICyte platform already supports more than 150 managed services customers and provides a stable, high-performance, and scalable foundation for everything from CLD to government pricing, chargeback management, and gross-to-net. In addition, IntegriChain can help walk you through the above considerations and define a Proof of Concept (POC) to prove out the value of incorporating Medicaid CLD into your ongoing process, whether in-house or outsourced. Partnering with IntegriChain allows the manufacturer to remain in control of the strategy as well as determine what to dispute. IntegriChain is responsible for everything in-between including data management, script-level validation, analysis, and reporting. By offloading the operational workload to IntegriChain, manufacturers find themselves better able to identify and reduce revenue leakage while simultaneously improving relationships with state agencies.

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About IntegriChain

IntegriChain delivers Life Sciences' only comprehensive data and business process platform for market access. More than 240 life science manufacturers of all size and complexity rely on IntegriChain's analytics, applications, managed services and expert advisors to power their operations and harness the value of their channel, patient and payer data. IntegriChain has played a vital role in more than 70% of product launches over the past two years including 35 first launches. For more information, please visit www.integrichain.com or ic@integrichain.com.