From: Lewis, Lynn
To: AGO - Info
Cc: Tudor, Rosa
Subject: VT - Open Records Request - Quarterly Medicaid Claims level data
Date: Friday, August 21, 2020 12:45:35 PM
Attachments: image001.png
DNA Introduction Letter .pdf

EXTERNAL SENDER: Do not open attachments or click on links unless you recognize and trust the sender.

Under the **Vermont Public Records Law, §315 et seq.**, we are requesting an opportunity to obtain the quarterly Medicaid claim level data that supports the manufacturer's summary level Medicaid rebate invoices.

Please consider this email our "formal" open records data request for **2nd quarter 2020** claims level data which support the state's summary level Medicaid Drug Rebate Invoices.

Data Niche represents about 30 pharmaceutical manufacturers with over 185 labeler codes. (An "introduction to DNA" is attached.)
Each quarter we standardize the claims level data files we receive from over 40 state Medicaid programs.
Our manufacturer clients access their own claims via a secure portal to validate their MDRP summary level invoices prior to payment.

Data Requestor:	Rosa Tudor, Data Acquisition Administrator (on behalf of Lynn Lewis) Data Niche Associates, a unit of QuintilesIMS 3 Parkway North, Suite 110N Deerfield, IL 60015 Phone: (847) 444-2468 E-Mail: rosa.tudor@IQVIA.com Lynn.lewis@IQVIA.com
Data Requested:	• Medicaid covered drug claims data as invoiced under the Medicaid Drug Rebate Program • 2nd Quarter 2020 claims data as invoiced to participating manufacturers • **Fee for Service and Expansion** (state does not currently have Medicaid MCOs in place) • **Pharmacy and Medical claims data** (including unit conversions if available) • **Original claims as invoiced and prior quarter adjustments**, where applicable • Claims should support the quarterly summary level manufacturer invoices • Dispensing Pharmacy and Prescriber details - NPI is preferred (or state Medicaid ID, name and address - if applicable)
Timing of Delivery:	• Post invoice validations – i.e. immediately after manufacturer invoices have been generated to ensure the detail claims match the manufacturer summary level invoiced values. • If files will be delayed by more than 5 days from date of manufacturer invoice post-mark date, please let us know.
Method of Delivery:	• Data should be provided in a pipe delimited .txt file format. • Data files to be sent via a secured file transfer method. (An sftp account can be setup on the IQVIA sftp for use by the state to send the files.) • Please provide a data layout document which describes the content of each data field provided.

If there are any fees for coding a file extract and/or for sending the quarterly cld files, please let us know the estimated IT effort hours and the IT hourly cost prior to initiating the programming effort.

This information is not being sought for commercial purposes. The cld would be utilized by our manufacturer clients to validated their summary level MDRP invoices prior to paying the state.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.
Thank you for considering this request.

If you should have questions or would like to setup a call to discuss this request, please contact Rosa Tudor or me.

Have a great day
Lynn Lewis

Lynn Lewis, CPA, MBA
Director, Government Programs
Data Niche Division

Learn more about IQVIA

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RE: Introduction to Data Niche

Data Niche Associates ("DNA") was founded in 1991, at the inception of the Medicaid Drug Rebate Program ("MDRP"), with a goal to help drug manufacturers validate state rebate claims. Today, DNA continues to serve many of the largest drug manufacturers in the United States who represent potentially hundreds of millions of dollars in Medicaid drug rebates each year.
The purpose of this letter is to explain the role DNA can play in the MDRP rebate validation process and to request that your state Medicaid agency or their MDRP rebate processing vendor provide the state's MDRP pharmaceutical claims-level data to DNA on an ongoing basis so that DNA can assist these manufacturers and enhance their participation in the MDRP.

Background on DNA's Services

Prior to paying the states requesting such rebates, drug manufacturers are generally required by their auditors to perform validations on MDRP rebates. Drug manufacturers review claims-level details prior to issuing rebates to verify invoiced amounts, identify duplicate rebate claims within and across Medicaid programs, and confirm that claims were reported in the correct unit of measure. To perform such validations, drug manufacturers need to obtain and process data from all fifty states and the District of Columbia, which is a challenging and onerous task.
DNA can help streamline and expedite the validation process. To assist in the process, DNA obtains, standardizes, and provides pharmaceutical claims level data and validation software to drug manufacturers, enabling drug manufacturers to efficiently validate state MDRP rebate claims. This also reduces the work for the states, because instead of providing the data to a large number of manufacturers, the data can be provided to DNA on behalf of its participating manufacturers.

DNA's Response to MDRP Challenges

DNA understands that the MDRP rebate validation process involves challenges for both states and drug manufacturers. A recent Informational Bulletin from CMCS entitled "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid" recommends that states consider providing claims level data to manufacturers and/or their third-party data company in an effort to "facilitate compliance and ensure there are no duplicate (340B) discounts."[1] DNA requests the invoiced Medicaid pharmacy and medical claims for each of the state's Medicaid programs. The goal is to receive both original and any adjusted claims which support the summary level ROSI and PQA manufacturer invoices. DNA's services are designed to address the state and manufacturer challenges by acting as a central repository of claims data in a common format and making such data available to manufacturers at no cost to states or the Federal government.

DNA is also taking a proactive approach to improve the MDRP rebate validation process. DNA regularly conducts meetings with various states, drug manufacturers, CMS, the OIG, and other key stakeholders to better understand and address the challenges underlying Medicaid drug rebate validation activities. Additionally, DNA is investing in new systems and personnel to provide better-quality services to drug manufacturers and to make it easier to standardize data received from states. For example, DNA's new validation software – named OV3 – is used by drug manufacturers to quickly validate their claims data to flag potential errors. The reports generated by the tool were designed to facilitate more effective communication between states and drug manufacturers, potentially leading to more timely payment by drug manufacturers, faster dispute resolutions and less administrative burden on the states.

Benefit and Cost of DNA's Services

Gathering and transmitting vast amounts of claims-level data to hundreds of participating drug manufacturers on a quarterly basis is an added burden on state personnel and systems. DNA's services can potentially benefit states and drug manufacturers by acting as a central recipient and source of claims-level data, reducing the effort on both entities to provide and obtain claims-level data in a useful format for analysis.

[1] CMCS Bulletin, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid", January 2020 https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf

Although states may realize some of the benefits of DNA's services, DNA and its drug manufacturer clients bear the brunt of the cost. DNA understands that no two states' systems are the same, and that extracting the correct data in the correct format may require the state to engage the support of IT professionals. DNA has entered into arrangements with states to reimburse them for their reasonable costs to develop data extracts to be provided to DNA, as well as reasonable costs to deliver claims level data to DNA with each invoicing cycle.

Data Requested by DNA

Drug manufacturers desire to obtain access to non-encrypted, timely and complete MDRP data. To assist drug manufacturers in the MDRP claims validation process, DNA requests the data elements necessary for validation purposes, including unique claim identifiers, date of service and paid dates, quantities, product and entity identifiers such as prescription identification numbers, transactions types, plan identifiers, and reimbursement dollar amounts.[2] Most states already provide many of these data elements directly to drug manufacturers upon request, but states may not realize the full benefits of DNA's services if they do not provide a complete set of claims level data. In 2018, CMS published a list of suggested data fields for MDRP validation purposes.[3]

State Concerns regarding Permissible Disclosure

DNA often receives questions regarding whether it is permissible for a state to disclose claims level data to a third-party data vendor that provides services relating to the MDRP validation process, such as DNA. Indeed, it is not only permissible under Federal law for a state to disclose claims level data to DNA for this purpose, but Federal government agencies including HHS have issued specific guidance on the topic. Assuming that the data fields received by manufacturers and requested by DNA in this context constitute "Protected Health Information" under the HIPAA Privacy Rule, it is clear under the Privacy Rule that states are in fact permitted to make disclosures of this information for the "payment" purposes of the state, consistent with the HIPAA Rules. HHS in fact has issued specific guidance that addresses this particular disclosure under the HIPAA Privacy Rule. In an "answer" to a "Frequently Asked Question," HHS has stated that "The Privacy Rule permits State Medicaid agencies to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors that assist the pharmaceutical manufacturers, for purposes of validating claims submitted under the Medicaid Drug Rebate program.[4] This same guidance has been adopted by the Medicaid program generally.[5] The HHS guidance on this point also has made clear that "A business associate agreement is not required to make these disclosures." In this circumstance, DNA is acting as an agent of the pharmaceutical manufacturers, and protects this data pursuant to contracts with these manufacturers. DNA is not acting "on behalf of" any state Medicaid agency, and therefore no business associate agreement is necessary or appropriate in this circumstance.

DNA's Use and Protection of the Data

DNA limits the use of claims level data received from the states. After DNA receives claims level data from the states, DNA makes it available to its drug manufacturer clients for validation of their Medicaid drug rebate invoices. DNA will not use claims level data requested here for marketing purposes and does not re-identify any patients that are the subject of the data. Upon request, DNA is willing to enter into a data use agreement outlining DNA's permitted uses.

DNA also strongly protects the data received from the states. DNA maintains Medicaid claims level data in a protected and secure environment. Although DNA became a subsidiary of IMS Health in 2003, DNA segregates the data from the rest of the IMS Health network by redundant firewalls, routers, switches and internet circuits. Furthermore, individuals dedicated to DNA who work in its Deerfield, IL office receive and load the quarterly files separately from the rest of the IMS Health support team. DNA has sufficient

[2] The specific list of fields requested is included as Attachment A

[3] Claim Level Data Fields and Definitions, August 2018 https://www.medicaid.gov/medicaid/prescription-drugs/downloads/medicaid-drug-rebate-program/claim-level-data-fields-definitions.pdf

[4] HHS' statement on disclosures under the HIPAA Privacy Rule is available at the following URL: http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures/456.html

[5] https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/dp-drp/drp-hippa-privacy-rule.pdf

administrative, technical, and procedural safeguards in place to protect the data it receives in compliance with applicable law.

Next Steps

For instructions on how to transmit claims level data to DNA, or to further discuss the benefits the state can obtain by providing its quarterly Medicaid claims level data directly to DNA, please contact Lynn Lewis, Director Data Acquisition and Integrity, via email at Lynn.Lewis@IQVIA.com or phone at (973) 908-5273. DNA also provides the same benefits with respect to SPAP and ADAP program rebates, and DNA would be happy to discuss those programs with the state. We look forward to working with you.

Thank you,

Lynn A. Lewis
Director Data Acquisition and Integrity

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ATTACHMENT A
Medicaid Drug Rebate Claim Level Data Request

Data Requested

- Claims Level Data ("CLD") pertaining to all Medicaid drug rebate-eligible programs whereby the State has invoiced the drug manufacturers for rebates.
- Rebate-eligible programs may include, but are not limited to, the Federal Medicaid Drug Rebate Program, State Prescription Assistance Programs and Aids Drug Assistance Programs.
- CLD includes Medicaid Fee for Service ("FFS") as well as Managed Medicaid programs ("MCO"), if applicable. Also, drug rebate claims for the state's Expansion population, if applicable.
- CLD includes pharmacy drug claims related to point-of-sale adjudication and physician administered medical drug claims.
- CLD includes transactions related to original invoiced claims (i.e. Reconciliation of State Invoice, or "ROSI" transactions) and any subsequent prior period claim adjustments or reversals (i.e. Prior Quarter Adjustment Statements, or "PQAS").

Timing of Data Extract Submission

- Data extract to be generated as part of the state's rebate quarter close invoicing process (i.e. post invoice validations) shortly after invoices have been submitted to manufacturers. The goal is for the cld to match to the summary level manufacturer invoices 100%.

Data Extract Specifications

Claims Level Extract

- The preferred format of the data extract files would be in a pipe ("|") delimited flat file/text file with double quote ("") text qualifiers.
- Include a header record to indicate the contents of each field using the state's naming convention.
- Include a Data Layout with field definitions to include a cross-reference list for any fields that may contain multiple values. E.g. A23 Claim type

REF	Field Name	Field Description
A1	Rx ID	Unique identifier assigned to claim by pharmacy
A2	External Claim ID	The claim record identification number received from the claims processor. E.g., Internal Control Number or Processor Claim number + sequence number
A3	Claim Status	Identifier assigned to indicate status of claim, such as paid, reversed, voided, or adjusted
A4	Dispensing Entity Identifier	Prefer the National Provider ID ("NPI") or state-specific provider ID if NPI is not available
A5	Date of Service	Date drug dispensed to patient or administered by physician, formatted as: YYYYMMDD or MMDDYYYY
A6	Refill code	The refill code submitted by the pharmacy
A7	Prescriber ID	NPI or state-specific identifier related to physician who prescribed the drug
A8	National Drug Code	The 11-digit product id from the claim record
A9	Date Paid	The date that the billing provider was paid for the claim, formatted as: YYYYMMDD or MMDDYYYY
A10	Run Quarter	Invoicing cycle quarter, formatted as YYYYQ
A11	Original Quarter Paid	The rebate quarter that the claim applies to – also known as the URA quarter. Formatted as YYYYQ (The Run Quarter and the Original Quarter Paid fields should provide the details needed to bucket the cld into the appropriate quarter/year as originals or prior quarter adjustments.)
A12	Provider Quantity	The quantity dispensed by the provider. i.e. pre-converted units as originally reported. For pharmacy claims, these are likely reported in the NCPDP unit of measure. For medical claims, this corresponds to the Medical HCPCS units that were submitted by the provider.
A13	Invoiced Units	The units invoiced in CMS Medicaid Rebate invoicing units. As summarized on the MDRP manufacturer invoices.
A14	Conversion Factor	Factor required to convert units from provider or Drug NDC quantity to the CMS invoiced unit quantity. Applies to both medical and pharmacy unit conversions, where applicable.
A15	Days Supply	The days of supply value submitted by the pharmacy provider, from the claim record
A16	Amount Billed	The amount billed by the pharmacy or physician, on the incoming claim, to include the ingredient cost and dispensing fee, if applicable.
A17	Medicaid Amount Paid	The Medicaid amount paid by the state (i.e. Plan amount Paid for the claim).
A18	Other Payer Amount Paid	The amount paid by third parties. i.e. The total amount paid by other payers. May include Medicare reimbursement for Part B medical cross over claims.

A19	Patient Co-Pay	The total amount paid by the patient
A20	Dispensing Fee Paid	Dispensing Fee paid to the service provider
A21	Program Code	Invoicing programs specific to state. e.g. Expansion patients, etc.
A22	Medical Procedure Code	For physician-administered drugs only. The Healthcare Common Procedure Code System ("HCPCS") code reported on the medical claim.
A23	Claim Type	Code indicating the type of Medical claim. Example types: - Pharmacy claims - HCFA 1500 Medical claims - HCFA 1500 Dual eligible crossover claims - UB92 Dual eligible outpatient crossover claims - Compounded pharmacy claims
A24	Medical Service Location Code	For physician-administered drugs only. Medical Service Location Code
A25	Plan Unique Routing Numbers	"BIN" or "BIN/PCN" combination relating to MCO programs, where applicable.
A26	Medical Claim Modifiers	Applicable modifiers as reported to the state in one string, separated by a comma. e.g. JW - To identify discarded drug from single use vials. Please provide all the modifiers which are stored in the state's system. If separate fields are preferred, please add as many as necessary. (A26.1, A26.2, A26.3, A26.4 …)
A27	ROSI/PQAS identifier	Value reflecting if transaction relates to an original claim or a prior quarter adjustment.
A28	From Date of Service	First date of service; typically applies to Medical drug claims, formatted as: YYYYMMDD or MMDDYYYY
A29	To Date of Service	Last date of service; typically applies to Medical drug claims, formatted as: YYYYMMDD or MMDDYYYY
A30	Detail Line	The detail line on the claim for the specific HCPCS or NDC code.

Dispensing Entity and Prescriber Information

REF	**Field Name**	**Field Description**
B1	State Identifier Used	NPI or state-specific Medicaid ID number used as primary identifier in State's Medicaid Management Information System
B2	Name	The name of the pharmacy provider or the prescribing physician

B3	Address 1	The value of "address line 1" attribute for the pharmacy service provider or prescribing physician business address type
B4	Address 2	The value of "address line 2" attribute for the pharmacy service provider or prescribing physician business address type
B5	City	The value of "city" attribute for the pharmacy service provider or prescribing physician business address type
B6	State	The value of "state" attribute for the pharmacy service provider or prescribing physician business address type
B7	Zip	The value of "zip/postal code" attribute for the pharmacy service provider or prescribing physician business address type
B8	Alternate Identifier(s)	Any other identifiers for pharmacy or prescriber active. For example, State MMIS primary identifier may be NPI, but State still assigns state-specific Medicaid ID.

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Financial Considerations

- Reimbursement for programming the data extract files is available and would be based on the estimated hours of effort for programming, testing and ftp setup. Reimbursement would reflect the fair market value ("FMV") rate of technical support staff. Estimates should be provided to DNA prior to work being performed.
- Generation of historical quarterly data files is again reimbursed base on the estimated hours of effort to generate and transmit the extract. Reimbursement would reflect the fair market value ("FMV") rate of technical support staff.
- Future generation of quarterly extracts could be reimbursed based on an agreed upon value that is intended to reflect the estimated hours of effort to generate and transmit data extract. A flat dollar amount is preferred to facilitate the pre-payment for quarterly data if required by the state. (Ideally there would be no need for an invoice from the state for the quarterly data due to the known amount expected per quarter.)
- The state can determine which party should be reimbursed for each of the above mentioned costs – either the state or their fiscal agent. The decision should be communicated to Data Niche when the estimated hours and dollar rate is submitted prior to the work being performed.
- Payments may be submitted to state via ACH. The payee's bank name, routing number and account number is required to setup the ACH payment processing. If ACH payment is not available, the alternative would be for Data Niche to send payment for each new quarterly data extract within 30-45 days after the end of each calendar quarter. The payment would be in anticipation of receiving the prior quarter's Medicaid claims data extract(s).
- In the event of unanticipated system issue that delays the submission of a quarterly data extract after payment has been made by Data Niche, any future quarter payments will be placed on hold until the missing data extract has been received. If the impacted data extract is not eventually provided, the state or fiscal agent who was paid, would be required to reimburse Data Niche.