**FY23 Data Request List (DRL)**

*Highlighted areas indicate a change/addition from FY22 DRL.*

For any questions, contact Komplete 340B Solutions at 214-773-7967

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| **Data Request – Covered Entity (CE)** |
| 1. **Provide policies and procedures on the topics listed below:**
2. Description of CE’s registration and recertification process
3. Process for ensuring that the 340B Office of Pharmacy Affairs Information System (OPAIS) record is up-to-date and accurate for the parent, applicable off-site facility(ies), and contract pharmacy(ies) (including regular review and timely update of 340B OPAIS records)
4. Process for determining what sites are eligible; address whether each service area in which 340B drugs are purchased, ordered, or provided is reimbursable on the CE’s most recently filed Medicare cost report (MCR) (for hospitals) or included on the grant (for grantees)
5. Description of procurement process (including contract pharmacy(ies), if applicable)
6. Prevention of GPO violations (applies only to *Disproportionate Share Hospitals, Children’s Hospitals, and Free Standing Cancer Hospitals)*
7. Definition for any exclusions to the definition of covered outpatient drugs (i.e. bundled drugs, orphan drugs, or inpatient drugs)
8. CE’s process for conducting oversight of its contract pharmacy(ies) including:
* Internal audits
* Independent audits
1. How the CE accounts for 340B inventory (physical inventory and virtual inventory replenishment)
2. Prevention of diversion at **CE** – Process for confirming the following:
* Site eligibility location
* Referral or responsibility of care remained with CE
* Medical or patient health record
* Patient eligibility (including patient status change for hospitals)
* Provider eligibility (relationship)
* Service in the scope of the grant (applies to grantees)
* Documenting and accounting for wastage of a drug not dispensed or administered to a patient
1. Prevention of diversion at **contract pharmacy(ies)** – Process for confirming the following:
* Site eligibility location
* Referral or responsibility of care remained with CE
* Medical or patient health record
* Patient eligibility
* Provider eligibility (relationship)
* Service in the scope of the grant (applies to grantees)
1. Mechanism to prevent duplicate discounts at **CE** and off-site facility(ies) for:
* Physician administrations
* Outpatient prescriptions
* Billing multiple state Medicaid agencies, if applicable
1. Mechanism to prevent duplicate discounts at **contract pharmacy(ies)** for outpatient prescriptions
2. When and how CE would self-disclose and CE’s definition of non-compliance or material breach
3. Definition of an eligible site when the location is not on the MCR (for hospitals) or grant (for grantees) for special circumstances (e.g. COVID-19, flooding, etc.)
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| 1. **Provide CE eligibility documentation:**

**Hospitals:** 1. A list of locations where health care services are provided to individuals for which the hospital deems itself responsible for the health care services provided for purposes of meeting 340B eligibility, including physical address.
2. The applicable MCR(s), including the encrypted signature stamp on worksheet S:
* The MCR that was used at the time of the last recertification in OPAIS
* The MCR filed most recently to the start of the sample period **(April 1, 2022, through September 30, 2022)**
* The MCR(s) filed since the start of the sample period through the date of the on-site/remote audit
1. For each off-site facility that utilizes 340B drugs at the facility or through contract pharmacy(ies), provide the trial balance that was submitted to CMS with the MCR(s). For each MCR and corresponding trial balance, include a trial balance crosswalk.
* For each off-site facility, the trial balance crosswalk should include:
	+ 1. 340B ID
		2. Name, as identified on OPAIS
		3. Address
		4. MCR line number and cost center description, as listed on MCR Worksheets A & C
		5. Trial balance name and department code/account
		6. Location code or shorthand used to identify the site in the electronic health record (EHR)
		7. Indicate if 340B drugs are utilized during encounters at each site
1. If a hospital is owned or operated by a State or local government, provide documentation that indicates the hospital is owned or operated by a State or local government.
* Examples of documentation to demonstrate the hospital is owned or operated by a State or local government may include:
	+ 1. Law that created the hospital
		2. Documentation from the state or local government demonstrating ownership
		3. Hospital charter
		4. Bylaws
		5. Documentation from the IRS describing the hospital

*Note: More than one document may be necessary to demonstrate eligibility. Any documentation provided should clearly state the hospital’s ownership, the date ownership was established, and the name of the hospital.*1. If the hospital is private nonprofit with a contract with a unit of State or local government to provide health care services to low income individuals, provide the contract and documentation that demonstrates the hospital’s private nonprofit status.
* Please highlight the following in the document:
	+ 1. Provision stating that the hospital must provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan under this title
		2. Name of the hospital and government agency
		3. Signature of hospital and government agency representative(s)
		4. Effective date of the contract
* The following are examples to demonstrate the hospital’s private non-profit status:
	1. Hospital charter
	2. Articles of incorporation
	3. Bylaws
	4. Other documentation from the State that may certify the hospital is non-profit
	5. IRS Form 990 (most recently filed)
	6. Other official IRS documentation

*Note: More than one document may be necessary to demonstrate eligibility.*1. If the hospital is a public corporation or private non-profit corporation, which is formally granted governmental powers by a unit of state or local government, provide documentation that demonstrates the hospital’s status.
* Examples of documentation to demonstrate a public corporation may include:
1. Law that created the hospital
2. Documentation from the State or local government demonstrating ownership
3. Hospital charter
4. Bylaws
5. Documentation from the IRS describing the hospital
* Examples of documentation to demonstrate the hospital’s private non-profit status include:
1. Hospital charter
2. Articles of incorporation
3. Bylaws
4. Other documentation from the State that may certify the hospital is non-profit
5. 501(c)(3) certification
6. IRS Form 990 (most recently filed)
7. Other official IRS documentation

*Note: Documents should clearly state the hospital’s ownership, the date ownership was established, and the name of the hospital. More than one document may be necessary to demonstrate eligibility.** In addition, provide documentation that confers governmental powers, the documentation should contain ALL of the following elements:
1. Identify the government entity granting governmental powers
2. Describe the governmental powers granted to the hospital and explain why the powers are considered governmental
3. Provide official documentation issued by the government, to the hospital, granting formal governmental powers
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| 1. **Provide a 340B universe for the sample period (April 1, 2022, through September 30, 2022):**
2. Include a narrative describing the methodology and system or software used to gather the data; note any limitations, exclusions, and inclusions (e.g. reversed transactions, direct purchases, etc.).
3. Provide a crosswalk to describe each column header included in each universe of data provided.
4. Provide a list of all 340B drugs that were administered or dispensed to patients from the parent site, off-site facility(ies), and pharmacy(ies) during the sample period (April 1, 2022, through September 30, 2022) (preferably in Excel format).

 Include the following data elements:* 1. Drug/product name
	2. NDC
	3. Acquisition price
	4. Type of account the drug was purchased on, purchase account, and associated 340B ID number
	5. Quantity issued
	6. Patient ID number (this is typically the medical record number or prescription number, but can be any number assigned that will allow tracking through CE’s system to retrieve all information associated with the order)
	7. Payer (all payers including Medicaid, primary, secondary, and tertiary payers)
	8. Date the drug order or prescription was written
	9. Ordering provider
	10. Location
		1. For medical encounters, the location/site the drug was ordered/administered.
		2. For prescriptions dispensed at contract pharmacy(ies) and any other pharmacy(ies) that dispensed the CE’s 340B drugs, including the location/site that prescribed the drug and the pharmacy location that dispensed the drug.
	11. Date the drug was administered or dispensed

A sample of administrations/dispensations will be selected for testing during the on-site/remote audit. For the selected items, individual records will need to be available in either electronic or paper format. If EHRs are utilized, please provide an individual with system knowledge to navigate the EHR (including billing information) and the split-billing/third-party software. The CE may be requested to upload selected documents to the National Institutes of Health (NIH) secure workspace.*Note: The CE must ensure that uploads to the NIH secure workspace do not include protected health information (PHI) and personally identifiable information (PII) (e.g. patient name, date of birth, address, etc.).* |
| 1. **Provide a provider list:**
2. Provide a list of the CE’s eligible providers, including:
	* First name
	* Last name
	* National provider identifier (NPI)
	* Indicate employed or contracted, include start and termination dates of employment or contract (preferably in Excel format)

*Note: The CE should be prepared to show the auditor proof of employment, contract, or credentialing for providers during the on-site/remote audit.* |
| 1. **Provide purchasing documentation:**
2. Provide a list of all accounts (wholesaler, direct, and consignment) used to purchase drugs for the parent, off-site facility(ies), and all pharmacy(ies). For each account, provide the following (preferably in Excel format):
	* Wholesaler name
	* Account number
	* Account name
	* Location that receives the drugs (e.g. unique identifier for CE site or pharmacy)
	* Location(s) that dispenses the drugs (e.g. unique identifier for CE site or pharmacy)
	* Pricing associated with each account (e.g. 340B, GPO, WAC, etc.)
	* Indicate if the account is used in a controlled substance ordering system (CSOS)
	* 340B ID associated with each 340B account (i.e. the 340B ID used to open or establish the account)
3. Provide one invoice, during the sample period (April 1, 2022, through September 30, 2022), for **each** account identified above. If an invoice for an account is not available during the sample period, provide the most recent invoice available.
4. Provide a list of CE (parent, off-site facility(ies)), and all pharmacy(ies) 340B drug purchase orders during the sample period (April 1, 2022, through September 30, 2022), (preferably in Excel format).

Include the following data elements:1. Ordering location (parent, off-site facility(ies)) or contract pharmacy(ies))
2. Wholesaler name
3. Account number
4. Invoice number
5. Invoice date
6. Drug description
7. Drug NDC
8. Quantity ordered
9. Price paid
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| 1. **Provide contract pharmacy documentation:**
2. Provide a list of all CE’s contract pharmacy(ies) from the start of sample period through date of on-site/remote audit.
	* For each contract pharmacy, identify whether the pharmacy is utilized or not utilized by the CE.
3. For each contract pharmacy, provide the original agreement and any amendments and addendums.
* Highlight the following areas in each contract pharmacy agreement, amendment, and addendum:
1. Signatures of both parties executing the contract, including dates
2. Name and address for each contract pharmacy location participating in the contract pharmacy agreement
3. Each CE location by name and address or a general statement that inclusively identifies the parent and all CE location(s) participating in the contract pharmacy agreement
4. Provide the cover page or a statement on letterhead from the organization that conducted the last independent audit of the CE’s contract pharmacy(ies).
	* The document should include:
		1. Audit date
		2. Period audited
		3. Who performed the audit
		4. Scope of the audit
5. Provide supporting documentation of any internal contract pharmacy audits conducted by the CE during the start of sample period through date of on-site/remote audit.
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| 1. **Provide documentation for any pharmacy that is not registered as a contract pharmacy and is dispensing the CE’s 340B drugs:**
	1. Provide a list of pharmacy(ies) (other than contract pharmacy(ies)) utilized during the start of sample period through date of on-site/remote audit.
* For each pharmacy, provide the following:
	+ 1. Name and address of the pharmacy. If the pharmacy is located within a registered off-site facility, include the 340B ID.
		2. Pharmacy Type (e.g. retail/community, infusion, specialty, compounding, mixed-use, etc.)
		3. Documentation to demonstrate ownership of the pharmacy (e.g. pharmacy license, business license, certificate of liability insurance, or listing of the pharmacy on the CE’s grant or MCR and corresponding trial balance)

*Note:* *More than one document may be necessary to demonstrate ownership.* |
| 1. **Provide self-disclosure documentation:**
2. Self-disclosures made to the Office of Pharmacy Affairs since the start of sample period through date of on-site/remote audit.
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| 1. **Provide Medicaid fee-for-service billing documentation for EACH CE SITE (340B ID) that carves-in (i.e. provides 340B drugs to patients with Medicaid fee-for-service):**
2. Provide a list of the state(s) billed and the corresponding billing number(s) listed on the claims billed to Medicaid fee-for-service for the particular state.
* Billing number(s) are listed on paper or electronic claims to Medicaid fee-for service, and may include:
1. Billing provider’s NPI
2. State assigned Medicaid number
3. NPI and state assigned Medicaid number

Example Table:

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| --- | --- | --- | --- | --- |
| **340B ID** | **State** | **NPI(s)** | **State Assigned Medicaid Number(s)** | **Medicaid Fee-for-Service Claim Form** |
| 123456 | MA | 12345678901011121314 | 101112 | [Embedded document] |
| 123456 | CT | 1234567890 |  | [Embedded document] |
| 123456A | MA | 1234567890 | 131415 | [Embedded document] |
| 123456A | CT | 1234567890 |  | [Embedded document] |

1. Describe each state’s requirement for billing 340B drugs (e.g. claims modifiers).
2. For each CE site (340B ID), provide one Medicaid fee-for-service claim, during the sample period (April 1, 2022, through September 30, 2022), for each state billed. If a Medicaid bill for a site is not available during the sample period, provide a recent bill.

Be prepared to present additional copies of claims during the on-site/remote audit (all payers including primary, secondary, and tertiary).*Note: The CE must ensure that uploads to the NIH secure workspace do not include protected health information (PHI) and personally identifiable information (PII) (e.g. patient name, date of birth, address, etc.).* |