**Purpose:** The purpose of this tool is to list several key compliance-related attributes to consider when evaluating, configuring, and maintaining split-billing software.

**Background:** Most 340B hospitals dispense medications to both 340B eligible and ineligible patients; therefore, the entity must track drug transactions to ensure that 340B drugs are purchased only pursuant to an eligible patient dispense or administration and that non-340B drugs are used for ineligible patients. One way to do this is by maintaining separately purchased physical inventories for 340B and non-340B drugs (DSH/PED/CAN: 340B for 340B eligible purchases, non-GPO/WAC for ineligible outpatient drug purchases, and GPO for non-covered outpatient drug purchases/inpatients; CAH/RRC/SCH: 340B for 340B eligible purchases and GPO for all other purchases). Because of the operational complexities of maintaining physical inventories, hospitals often choose to use a virtual replenishment drug inventory, which enables the entity to dispense drugs to both 340B eligible and ineligible patients using one physical inventory. This model works by establishing a “neutral” inventory, collecting data about each drug dispensed and administered, and then reordering that drug based on accumulations for 340B eligible patients and GPO eligible dispensations. Replenishment inventories are typically managed virtually using split-billing software.

**Process:** To manage a replenishment model, the entity tracks data feeds (such as inpatient or outpatient status, prescriber eligibility, clinic location, Medicaid payer status, drug identifier, and quantity dispensed) and loads these data points into the split-billing software so that patient 340B eligibility can be assessed and then the NDC dispensed/administered can be accumulated. This software uses logic based on configurations, chosen by the entity, to virtually separate 340B from non-340B transactions after they occur. The software then determines from which account each transaction may be replenished once a full package size is accumulated. The term “split-billing” is used to describe this software, which “splits” a purchase order into two or three different accounts (i.e. 340B, GPO, non-GPO/WAC). This software can help the entity place orders in appropriate accounts while maintaining auditable records of the accumulations and purchases.

Key points to remember about split-billing software:

1. Split-billing software acts as a tool for helping track 340B eligibility. All software settings should mirror the 340B patient definition as specified within the covered entity’s policies and procedures.
2. The performance of the software depends on the quality/accuracy of data imported to it, the options selected to configure the software, and the ongoing maintenance of the software by the software provider and entity.
3. Entities have a choice about how to configure their software, but certain configurations are associated with a greater risk of noncompliance.
4. The entity is ultimately responsible for program compliance; this responsibility cannot be outsourced to a split-billing software company.
5. The entity itself is subject to HRSA and manufacturer audits, so it is critical for the entity to take time to carefully select, configure, maintain, and check its split-billing software.

**General Split-Billing Software Attributes**: The following table lists key attributes for how split-billing software functions in a mixed-use setting, defined as an area serving both inpatients and outpatients. This can be helpful for anyone trying to understand how split-billing software works, working to develop a maintenance or audit plan, implementing new software, or choosing which configuration options to use in existing software.

| **Key Attribute** | **Approaches/Options** |
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| **Diversion Prevention** | |
| Data feed and software logic ensure that patient location and status are consistent with the 340B patient definition and HRSA requirements. | Entities most often use a data feed from their electronic medical record (EMR) system, which includes the patient identifier, a time stamp (which shows the patient’s inpatient or outpatient status [including observation patients] at the specific time the drug was ordered/dispensed/administered), and a location code (which shows that at the time captured, the particular patient was receiving services in a specific clinic or location within the hospital).  Consider the following about split-billing software data feeds:   * Location of patient   + When determining patient eligibility, auditors will first look at the location where the service is provided. It is important that the covered entity understands how patient location changes are handled in the EMR and split-billing software.     - Covered entity remote medicine/telemedicine modalities providing health care services to eligible patients should be outlined in 340B policies and procedures.   + Covered entities should maintain a map that shows which trial balance account and Medicare cost report line each 340B eligible EMR service location is accounted to and ensure that the split-billing software is kept up to date with this map. * Capture of patient status   + Does the point of capture in determining outpatient status match the entity’s policies and procedures (e.g., time of order, dispense, administration, or billing)?   + With what frequency is the information sent to the software (e.g., live feed, daily, or at the time of patient billing)?     - Does this change how patient status is captured/ determined?   + How are patient status changes or reclassifications handled?   + Are all the EMR patient status options mapped correctly as “inpatient” or “outpatient” (e.g., “observation” status is mapped as “outpatient,” “inpatient psych” is mapped as “inpatient”)?   The entity should work with the software vendor to understand how it handles each of these unique situations:   * Duplicate data—does the software have a way to identify and remove a duplicate file submitted in error? * Missing files—does the software alert the entity if an expected file was not sent or if the import of the data failed to run correctly? |
| Software uses an 11-digit NDC match for replenishment. | The EMR or pharmacy billing system data feed to the split-billing software should include a drug identifier and quantity to record how much of a particular drug is administered to the patient, as well as the patient status, to determine the replenishment account (e.g., 340B, GPO). The medication administration is typically captured in one of the following ways:   * 11-digit NDC—The NDC administered to the patient is captured (through a barcode scan [BCMA], nurse selection of NDC, and/or IV workflow software) and transmitted to the software.   + Consider what NDC is transmitted in areas where the actual NDC cannot be captured (e.g., non-BCMA areas, patient-specific labels scanned) and how an 11-digit NDC match is ensured in these situations. * CDM/charge code—The medication is captured at the charge code level (e.g., “vancomycin 1 g vial” may be charged as a more general “vancomycin injection”), so it is important to correctly map the charge code to the 11-digit NDC that was administered to the patient in the software (vancomycin 1 g vial, in the example). This can become complex when multiple NDCs use one charge code (e.g., both “vancomycin 1 g vial” and “vancomycin 500 mg vial” are both charged as “vancomycin injection”). The mapping of charged NDC versus used/purchased NDC in the split-billing software is commonly called an *NDC crosswalk table*.   + Drug NDCs can be updated in either the EMR (default NDC in the charge code) or in the software (through the mapping process/ NDC crosswalk table).   + Many software systems have a process for automatically updating the NDC to charge code mapping for the entity. The entity first tells the software which NDCs map to which charge codes and then the software identifies which NDC was administered to the patient based on past purchases. It is very important for the entity to be able to verify that this process accurately matches the units of measure for NDCs administered and purchased through routine audits. * Hybrid—Some software companies offer a solution that captures the actual NDC at the time of administration, when possible, and combines that with the automated processes to look at purchase history to identify the NDC for areas not able to capture the NDC. This is done through a rather specialized build of data feeds being transmitted to the software by the entity. |
| (Cont’d)  Software uses an 11-digit NDC match for replenishment. | The entity will still need to configure the medication records within the software to match the measurable unit from the EMR or billing system (typically in a billing unit, such as mL) to a purchasing unit (such as vials). Some software vendors may offer to do this for the site, but the site should still verify each of these to ensure accuracy. Consider these questions:   * How is a new NDC handled if purchased prior to being mapped in the software? Under which account is this ordered? * Are there software reports or queues to identify unmapped NDCs or charge codes that need to be mapped? * Are there reports to identify outliers (based on large positive or negative accumulations) that may help the entity identify if a drug is mapped incorrectly? * Is there a solution available to help in complicated scenarios—for example, when multiple vial sizes are used for a single charge code?   Other considerations affecting accumulations:   * Can the entity send waste for accumulation in its billing files, and how does this appear in the software? * How are products used on more than one patient (multi-use) billed in the EMR? Are these products over- or under-accumulating based on the way this feeds into the software? |
| Provider list is accurate. | The health care professionals providing 340B qualifying services are employed, under contractual agreement, or other arrangement per 340B patient definition. A feed may be sent from the credentialing office to the split-billing software to accomplish this.  Some software vendors do not complete a provider check because they assume that all providers credentialed to use the entity’s EMR are eligible. Entities should verify that this is true before selecting this option.  Often, multiple providers are listed for a mixed-use setting: ordering provider, attending, and so on. Entities should consult their policies and procedures to determine which field aligns with their definition of “provider.” This is especially important to consider for sites that have medical students or others prescribing under the authority of a licensed prescriber.  Considerations affecting provider eligibility:   * Provider lists may be updated frequently based on new/terminated employment or contracts. Covered entities should work with their credentialing offices to understand how frequently these are updated to determine frequency of data feeds. * Many covered entities have providers who practice in both eligible and ineligible sites. Entities should have measures in place within the split-billing software to ensure that the service is eligible for each patient, in addition to provider eligibility determination. |
| Patient encounter location is eligible per 340B OPAIS record. | Software vendors will match the location captured from the patient data feed with a list of eligible locations, which must be continuously maintained to ensure accuracy. Eligible locations should be cross referenced with HRSA 340B OPAIS for registered child sites or sites located within the parent entity’s four walls. Because the location in the patient encounter files is unlikely to match to a line of the Medicare cost report, many sites maintain a location crosswalk outside the software system to match EMR location codes to cost centers and lines on the Medicare cost report. Involving IT and reimbursement teams is critical in identifying revenue redirection and cost centers behind each location code.  DSH/PED/CAN*:* some sites may have GPO-only areas (in GPO Prohibition hospitals). These may be new offsite locations that are not yet eligible, sites that meet the four criteria for GPO use, or ineligible locations using the same EMR and billing systems. See the https://www.hrsa.gov/sites/default/files/hrsa/opa/prohibition-gpo-participation-02-07-13.pdf for more information. The entity may consider different options for handling these locations:   * Block these locations from the patient encounter data feed and purchase outside the software. * Mark these sites as ineligible in the software, typically leading to non-GPO/WAC account purchasing for these replenishments. * Mark these sites as GPO-only locations within the software, ensuring that the software has a way to replenish through a separate GPO account from the inpatient dispensations for the covered entity (the GPO Prohibition program notice specifies that these are purchased on a unique GPO account). |
| Software supports customized drug purchasing settings. | Most software vendors have functionality to block 340B accumulations of non-covered outpatient drugs with documented audit trail and rationale. These medications are marked within the software to direct purchases of those NDCs directly to the GPO account. This process is often called *excluding* or *blocking* those NDCs.  HRSA expects covered entities to maintain auditable records and policies and procedures related to the definition of covered outpatient drugs and the use of a GPO that is consistent with the 340B statute, as applicable. Hospitals subject to the GPO Prohibition are able to buy non-covered outpatient drugs via a GPO, pursuant to the definition established by the hospital.  Software vendors may also give the option of excluding/blocking to any of the three accounts (340B, GPO, or non-GPO/WAC). This is helpful for sites that may have other reasons to direct purchases to only one account. Examples include:   * DSH/PED/CAN: items with an individual contract that are to be purchased on the non-GPO/WAC account * CAN/RRC/SCH/CAN: orphan drugs to the GPO account * Items that are used only for inpatients or only for outpatients; this is a risk and should be regularly monitored |
| Software allows EMR data to be submitted in multiple formats. | Many entities have patient dispensations that won’t fit the standard data feed. It is important that the software gives a method for capturing these dispensations, either through multiple feeds or through a manual upload. Examples may include:   * Areas of the hospital that use a different medical record or billing system (e.g., operating room, EMT services) * Medications that may have different billing units/mapping based on indications that need to be manually corrected (e.g., blood factors) |  |
| Replenishment purchases are made in a compliant way. | Once accumulations are established in the 340B, GPO, and non-GPO/WAC (if applicable) accounts, as described earlier, the software will then create purchase orders based on these accumulations, sometimes called “buckets.”  The way that the software vendor (or your own settings within the system) determines the order in which the accumulations are accessed is important in maintaining compliance.   * This last account that is used when there are no available accumulations is often referred to as the *terminating account*. For DSH/PED/CAN, purchases of a medication that could be used in the outpatient setting but does not have available accumulations should be done on the non-GPO/WAC account. Examples of this may include initial purchases of a drug, increases in periodic automatic replenishment (PAR) levels, and covered outpatient drug dispenses to Medicaid patients for hospitals that carve out Medicaid. For CAH/RRC/SCH, the terminating account is commonly the GPO account. * When placing a replenishment order, GPO Prohibition hospitals may be able to choose to first use 340B account accumulations, then GPO accumulations, with any remaining non-accumulated drugs being purchased from the non-GPO/WAC account. |  |
| Drug ordering process is efficient and automated with wholesalers and distributors. | Software vendors send and receive important information with suppliers to help ensure compliance during the ordering process. This often includes order transmission (how an order is sent to the supplier), catalogs (what product is available for order on each account), and invoices (what was actually purchased). If this information is available electronically, it is transmitted via an electronic data interface (EDI).  There are important considerations in each of these areas:   * Order generation/submission—ensure that orders can be generated and submitted in an efficient manner based on interfaces with inventory management systems and wholesaler systems, or by using a manual upload process. Consider ordering processes that happen outside of typical purchase orders: Controlled Substance Ordering System (CSOS), consignment, direct purchases. * Catalog—does the system require a catalog to be imported? If so, how are items ordered outside of electronic systems made available through the system (e.g., direct orders)? * Order confirmations/invoices—once accumulations are applied toward a purchase, those accumulations should be removed from the accumulators.   + Can EDI be set up with multiple vendors? Is it possible to add new vendors if they are not already set up?   + If the invoice is not available electronically, what is the process for manually entering these invoices? |  |

| **Key Attribute** | | **Approaches/Options** |
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| **Duplicate Discount Prevention** | | |
| Medicaid patients are identified to prevent duplicate discounts. | If a covered entity chooses to carve out Medicaid patients in its mixed-use areas, the software will need to be configured to capture the payer for each patient and exclude those dispensations from accumulating. For hospitals subject to the GPO Prohibition, the covered entity should ensure that the software is set up in a way that these Medicaid carve-out dispensations would result in non-GPO/WAC replenishment. For rural hospitals, Medicaid carve-out dispensations would default to a GPO replenishment.  Although most entities that choose to carve in handle compliance with the Medicaid requirements through their own patient billing systems, some software vendors offer add-on modules that can also assist with this function.  Both carve-in and carve-out facilities that use their software to help with compliance should consider how the software handles payer changes (e.g., retroactive Medicaid eligibility) to ensure that affected patients are handled according to their policies and procedures. | |
| **Other Operational Considerations** | | |
| Accumulation process is applied consistently for new drug and shortage purchases. | Ensure that the software vendor and settings prohibit accumulations from a previously purchased NDC from being applied to a new NDC. This is important because accumulations and replenishment should happen at the 11-digit NDC level. If a new NDC is purchased for the first time, there will be no accumulations to access and the product should be ordered on the appropriate non-340B account (i.e., non-GPO/WAC for GPO Prohibition hospitals and GPO for rural hospitals). Although this should automatically happen based on the process described previously, entities should target examples and audit to ensure that the software is functioning as designed. | |
| The software keeps record of manual adjustments when an error or noncompliance is detected. | Some systems will allow entities to “go negative” to correct for 340B purchases that should not have been made; HRSA has indicated that this is not an appropriate/ transparent way to correct noncompliance unless approved by the manufacturer.  Some systems allow the user to keep records of when adjustments are made, and why. This can be important in tracking important aspects, such as communication with the manufacturer.  Some systems will not allow buyers in mixed-use areas to buy greater quantities on the 340B or GPO accounts than are in their accumulators.  The system must provide an accessible audit trail to identify individual actions, system actions, and rationales. | |
| Software provides adequate reports for auditing of accumulations vs. dispensations. | Entities should ensure that the software contains reports or views that will allow them to both track and audit each of the compliance areas listed here and to draw attention to areas that appear to be functioning irregularly. One important aspect is comparing purchases captured for a specific NDC versus patient administrations and investigating discrepancies.  The software vendor may send out an annual audit review report. A summary of all filters, data reports, payers, providers, special rules, and other indicators is provided so that the entity can review data for accuracy. The vendor essentially assists with identifying potential areas of liability. | |
| Software provides option for tracking orphan drugs.  *Does not apply to DSH, PED* | For hospitals subject to the orphan drug exclusion, these products are not considered covered outpatient drugs and are therefore not available for purchase at 340B pricing. For this reason, many sites will exclude/block those items in order to direct purchases to the GPO account.  Some entities will still choose to track these items through split-billing software. This may be just for tracking purposes or, in some cases, entities may have chosen to use software to comply with contractual requirements that are included in the contracts that they have directly with manufacturers for voluntary 340B-like pricing.  There is no HRSA requirement that would mean that these orphan drugs need to be tracked through split-billing software. | |

**Initial Considerations for Startup:** For entities choosing to implement split-billing software for the first time or to switch software vendors, here are some key considerations when determining the best software for a site.

| **Consideration** | **Approaches/Options** |
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| The entity is able to support implementation and maintenance costs. | The initial implementation of split-billing software requires resources from multiple departments within the entity.   * + - There may be an implementation cost for the software, which will vary based on the vendor selected. Ask about:       * + Installation fees         + Flat monthly or annual fees based on hospital size (e.g., number of beds)         + Additional costs if considering use in more than just mixed-use setting such as fee structure for retail/contract pharmacies: per-claim charge (all claims or only 340B eligible claims) vs flat fee per site         + Exclusivity clauses that obligate the entity to use the software for both mixed-use and contract pharmacy operations     - Pharmacy staff and pharmacy chargemaster staff will be needed to provide support to create the drug database and provide conversion tables between doses, HCPCS billing increments, and package sizes. Vendors will have a process in place to help.     - The IT department will be required to ensure that locations are linked correctly and interfaces of the entity software are correct to provide information needed to implement. |
| Software implementation is done in a timely manner. | Implementation of the software generally takes 2 to 6 months from the signing of the contract. The time frame for implementation depends on the vendor and the complexity of the entity’s program; it may take up to 12 months for very complex systems or those that experience data issues during implementation.  If possible, assign a dedicated and experienced project manager to ensure adherence to the implementation timeline.  Ensure that test and production files are transmitted to the vendor using a secure file transfer process. |
| Comprehensive training is provided. | The software vendor provides the following:   * + - Ability for the project team to view data and accumulations prior to going live     - Initial education for pharmacy directors, pharmacy buyers, and program coordinators, at a minimum     - Follow-up training sessions to answer more in-depth questions once users become comfortable with the basics of the software   Assess adequate training and training time requirements specific to user roles and access.  Identify access to online and/or hard-copy user manual for assistance. |
| Ongoing customer support provided at no additional cost. | The amount and type of support will vary among vendors. Some will be available onsite in the event of an audit to ensure that all questions concerning software use are accurately addressed; others provide this as a paid service. Some vendors will provide extensive help with reporting and troubleshooting, whereas others leave these tasks up to the entity. The contract should address these arrangements and services.   * + - Ask about turnaround time for support requests and the best mechanism to submit requests for faster resolution (phone call vs. online submission).     - The vendor may offer a strategic account manager.     - If possible, continue regular project management calls with the vendor after going live so new problems can be resolved quickly. |
| Software interfaces with the entity’s current IT systems and wholesaler. | The entity should understand how the software interfaces with its existing EMR; inventory management system; billing or financial software; and admission, discharge, and transfer (ADT) software systems.  Understand what EDI feeds are already in place with suppliers (e.g., wholesalers, manufacturers) and compare with entity suppliers. Discuss the ability to add new supplier data feeds or manual upload processes for those not currently built.  Determine the level of interface and report details needed, such as required data elements, frequency of uploading data, and the vendor’s software interface experience with the EMR and wholesaler.  For each of these elements, determine whether the vendor accepts “flat files” or wants an interface, and how the covered entity’s IT systems can support this method of data transmission. |
| Resources required to implement/maintain software are understood and available. | The entity must have internal IT support, as well as pharmacy support, to provide ongoing management of the program requirements during the implementation and maintenance phases. The amount of support will vary depending on the software and entity size/complexity. A disproportionate share hospital (DSH) with more than 100 beds, for example, could anticipate 0.5 to 1 full-time equivalent (FTE) of a dedicated resource with most systems.  If a report writer is a non-pharmacy staff member, this person must be readily accessible for questions and data corrections.  Dispensing files, ADT files, encounter files, and prescriber lists may come from different departments or different subdepartments within IT. Ensure that the IT project manager is aware of the need for an expert from each source.  Frequent file uploads into vendor software facilitate more rapid attainment of a full package size dispensed and minimize purchasing on the non-GPO/WAC account (for GPO Prohibition hospitals, especially at first). Daily file uploads are ideal. |

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of its program integrity efforts.*

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