

Update on Open Payments



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Agenda

- System Enhancements and Validation Updates
- Teaching Hospital List
- Ownership and Investment Interest
- Group Purchasing Organizations (GPOs) / Physician Owned Distributors (PODs)
- Physician Fee Schedule Reminders
- Compliance
- Question and Answer

2016 System Enhancements

Stakeholder Feedback

- Ability to exchange reporting entity and covered recipient contact information to facilitate review and dispute
- All limitations on entering special characters in text fields will be removed
- Ability to download reported records will be enhanced to include dispute information and also extended to covered recipient users (up to 400,000 records)
- The covered recipient interface will allow users to distinguish whether a record identifies them as a covered recipient or a principal investigator
- Attestation of Deletions

2016 System Enhancements

Help Desk Feedback

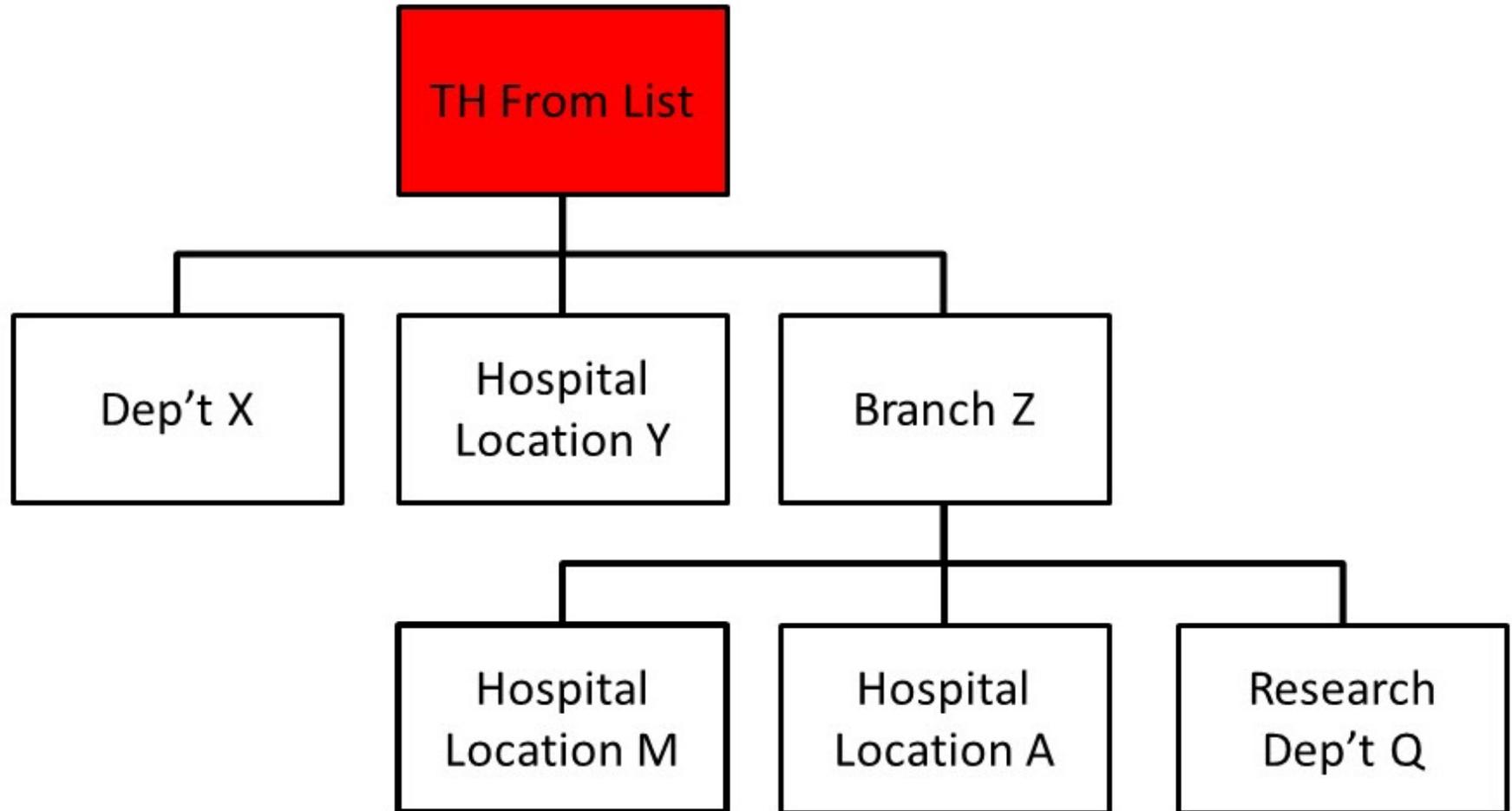
- Reporting entities may delete records with a status of “system processing”
- Recipient type and details on payment records and principal investigator information on research records cannot be changed after final submission. Changes require the original record to be deleted and a new record with updated information to be submitted.
- Character limit for physician/principal investigator state license number has been increased (25 characters for manual submission; 28 characters for bulk file upload – 25 license, 1 hyphen, 2 state code)

2016 System Enhancements – Validation Edits

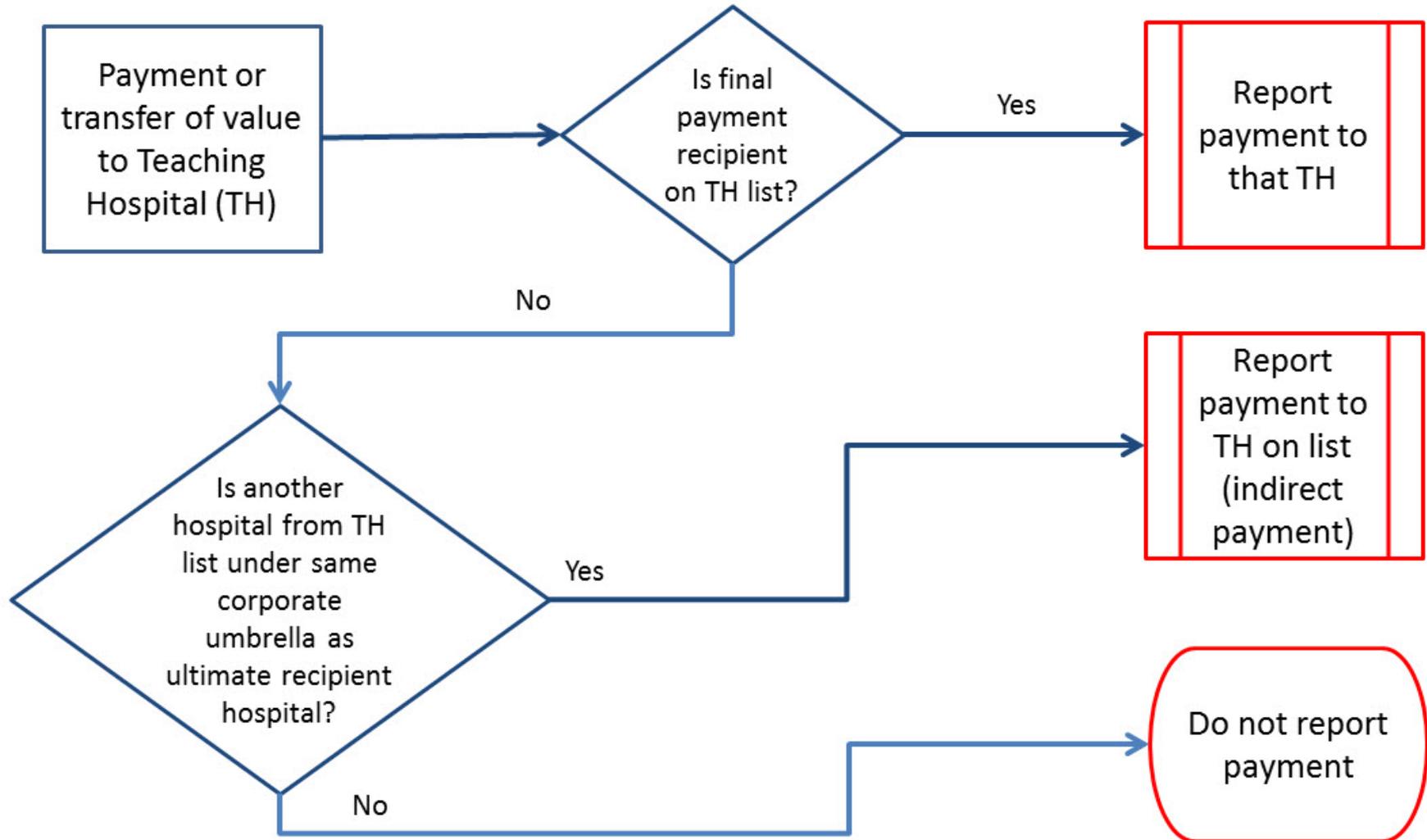
Validation Edits

- NDC
 - In the 2015 program year, CMS will reject records submitted with an NDC and without a marketed name
 - 17% of 2014 reported data included NDC but no marketed name as required
 - NDCs will also be validated for proper format, dashes must be included in appropriate positions
- No Zeros
 - Research and general payment amounts may not contain a “\$0” amount
 - For ownership records “\$0” may only be entered in “Total Amount Invested” or “Value of Interest” field, but not both at the same time
- Records that contain data in physician-specific fields and hospital-specific fields simultaneously will now be rejected
- Principal Investigator / Covered Recipient Physician Indicator = “Y” (Field # 43 for Research Payments)

Teaching Hospital (TH)



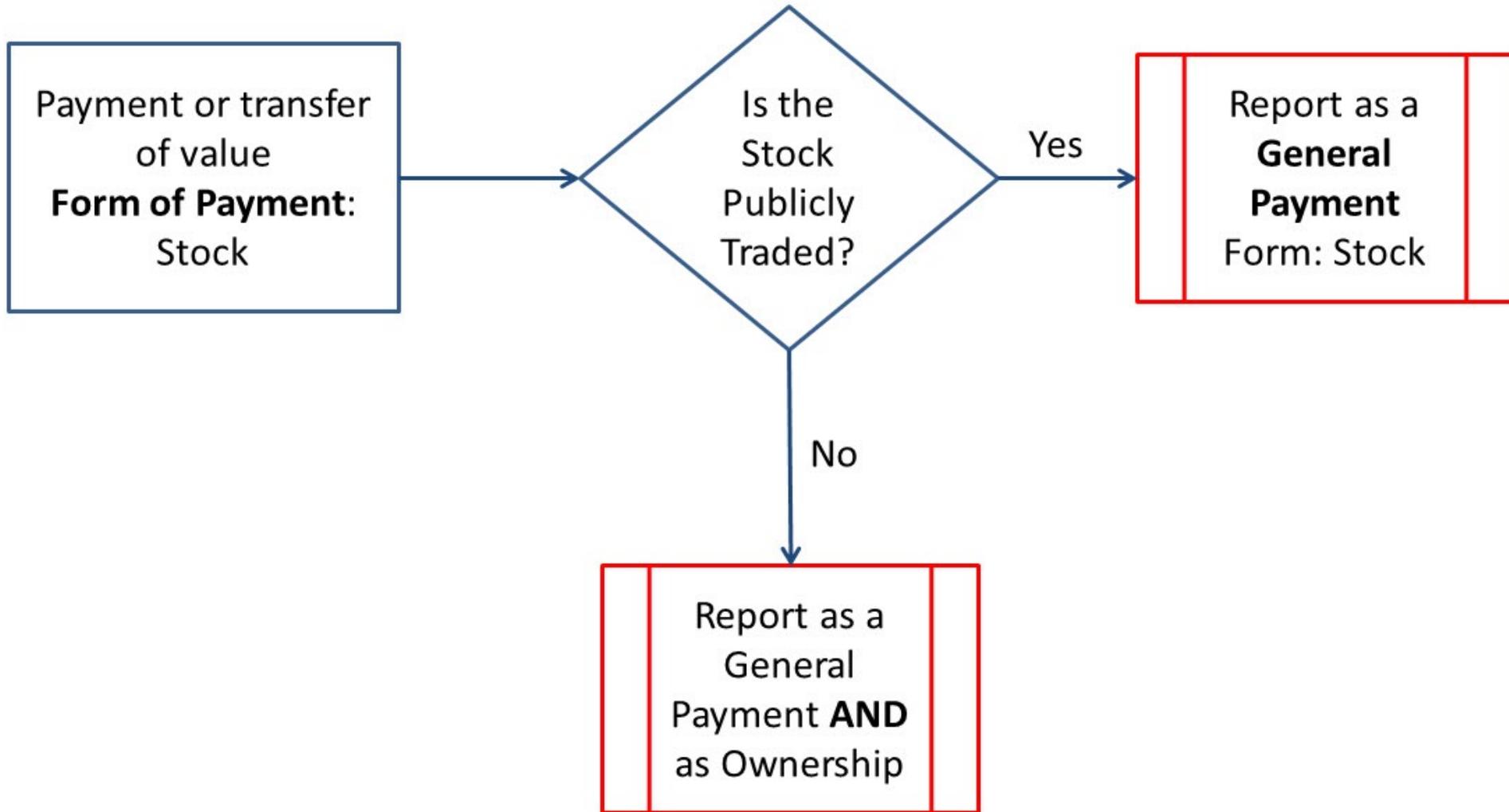
Teaching Hospital Payment Reporting Logic



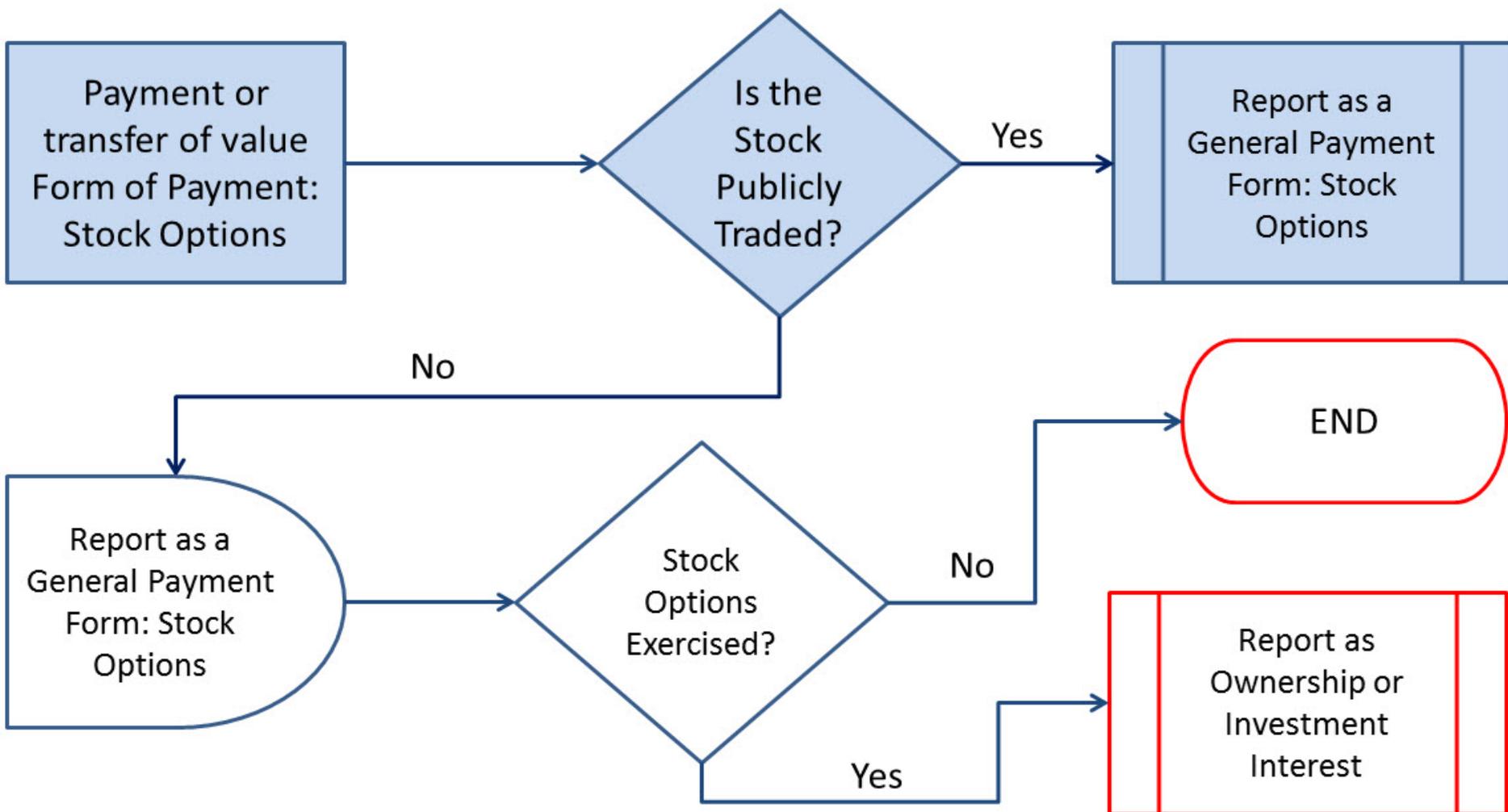
Clarification on Teaching Hospital Payment Reporting Logic

- Several questions have been submitted since the webinar regarding any requirements this logic introduces.
 - No new reporting requirements are presented as a result of this resource. CMS is preparing this resource for industry to utilize as they evaluate payments made to hospitals and whether the financial relationship implicates an indirect payment made to a teaching hospital covered recipient. The use, or non-use, of this resource does not require or exclude reporting of payments.

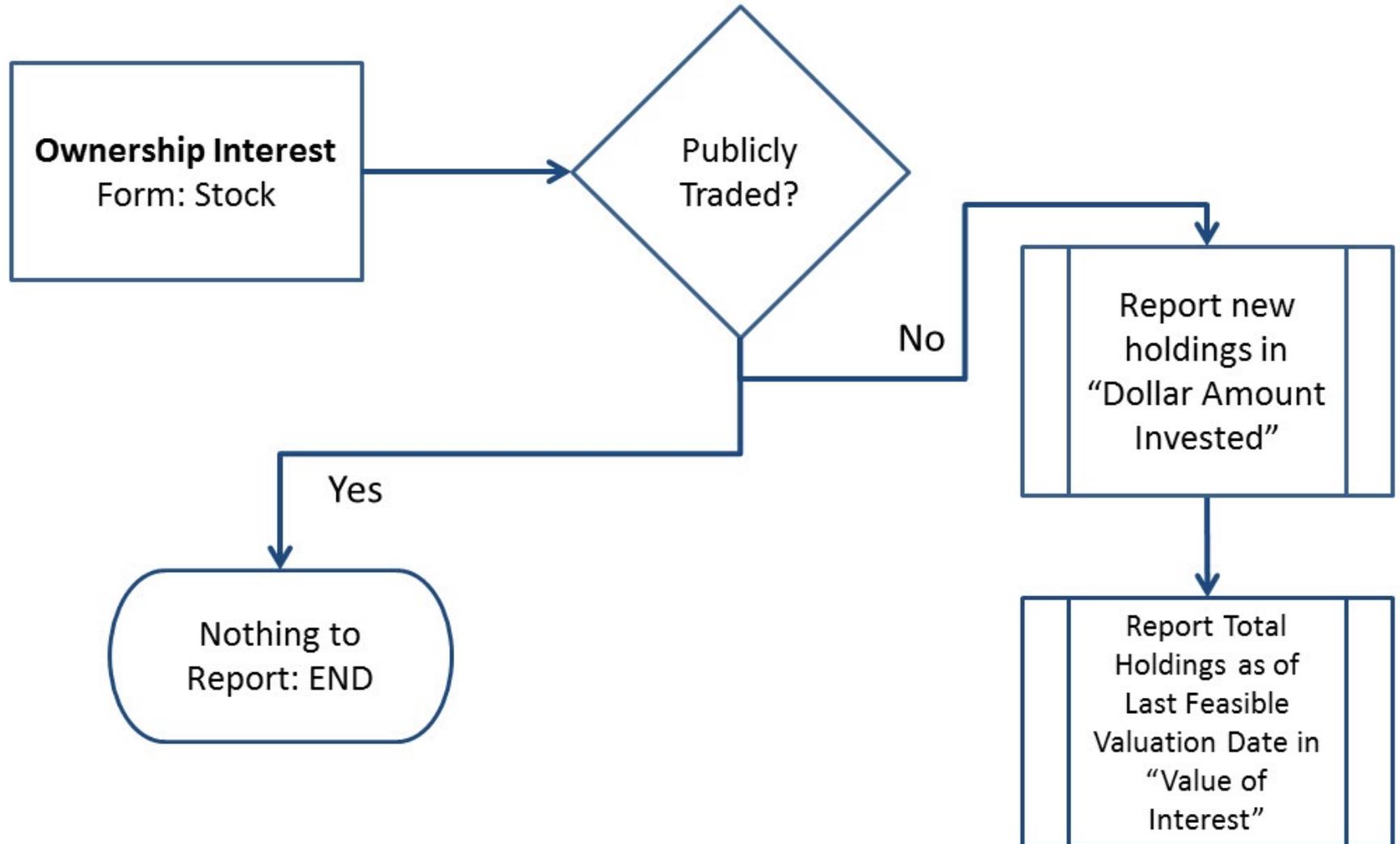
Stock as a Form of Payment



Stock *Options* as a Form of Payment



Ownership and Investment



GPOs and PODs

- Applicable GPOs include, but are not limited to, PODs (*See 78 FR 9493*)
- CMS defined GPOs and intended to capture entities (including physician-owned entities) which purchase, arrange for or negotiate the purchase of covered drugs, devices, biological, or medical supplies for resale or distribution to others
- Includes PODs of covered drugs, devices, biologicals, and medical supplies

GPOs and PODs

- A manufacturer must report each payment to a physician owned distributor (POD) (e.g., LLC, etc.) as an indirect payment to a covered recipient physician (*Refer to definition of indirect payment*)
- PODs (a subset of GPOs), must report their physician ownership interests annually

2015 Physician Fee Schedule Reminders

- 2015 Physician Fee Schedule (Implemented Nov. 13, 2014) – regulation changes for consistency in reporting:
 - Marketed name reporting requirement
 - Device and medical supply names **now** required
 - Therapeutic area and product category **are optional**
see following slide for clarification
 - CME payments
 - Must report compensation (that meets the definition of a direct or indirect payment) for physician speakers at accredited or certified continuing education events

Note: These changes impact data collected in CY 2016 and reported to CMS in 2017

Clarification on Therapeutic Area & Product Category

- During the live webinar held on October 29, 2015, the Therapeutic Area and Product Category data field was discussed in what was likely a misleading way. The following points are made to clarify how industry should report this data element.
 - Therapeutic Area or Product category is a required field when reporting covered drugs, devices, biologicals or medical supplies.
 - Reporting entities have the option of reporting either Therapeutic Area or Product Category
- We have released additional clarifying information here:
 - <https://www.cms.gov/OpenPayments/Downloads/2017-summary-chart.pdf>

Compliance

- Failure to timely, accurately, or completely report each payment or transfer of value, or ownership or investment interest is subject to a penalty of \$1,000 - \$10,000 per payment/interest (Maximum annual penalty \$150,000)
- Knowing failure to timely, accurately, or completely report each payment or transfer of value, or ownership or investment interest is subject to a penalty of \$10,000 to \$100,000 per payment/interest (Maximum annual penalty \$1,000,000)

Resources Available

- CMS conducts periodic webinars and Q&A sessions – announced via listserv messages
- Sign up for the Open Payments listserv on the [Contact Us page](#) on the Open Payments website
- Learn more about the program on the Open Payments website: <http://www.cms.gov/openpayments>
- If you have any questions, you can submit an email to the Help Desk at openpayments@cms.hhs.gov