Northwestern Medicine®

Regulatory aspects of Investigational Drug Service (IDS) Pharmacy

Presented by: Eunice Lee Pharm D, JD

Protocol Management Pharmacist

IRB Brown Bag Series / Date:

August 19, 2026 12 noon

Objectives:

- **Overview of IDS Pharmacy Services**
  - Scope of service
  - Regulatory records related to RX, IDS SOP
- **Handling of Investigational Product (IP)**
  - Licensing, preparation, shipping
- **Life cycle of a study (site selection to closeout)**
  - Feasibility, SIV, CAPA, Record keeping/ release

IDS satellites/ sites

IDS pharmacy leadership:

Manager: **Alan Yee**

Practice coordinator: **Nish Patel**

NMH

- **Graylake Cancer Center**
- **Lake Forest Cancer Center**
- **Old Irving Cancer Center**
- **Orland Park Cancer Center**
- **Glenview Cancer Center**

Central Dupage Hospital: (Western region) both oncology and non-onc

- **Warrenville Cancer Center**
- **Delnore Cancer Center**
- **Kishwaukee Cancer Center**
- **Oak Brook Cancer Center**

IDS Overview (IDS Staff at NMH)

IDS pharmacy leadership:

Manager: **Alan Yee**

Practice coordinator: **Nish Patel**

Oncology:

- **Jesus Gracia**
- **Bushra Muneer**
- **Kathryn O'brien (Kayte)**
- **Yvonne Tsao**
- **Steven Zhang**
- **Samra Zvizdic (Sam)**

General (Gen IDS) / non-oncology:

- **April Bitner**
- **Eunice Lee**
- **Laura Lofky**
- **Robert Southard (Rob)**

Staff: IDS pharmacy technician specialists

- **Denise Cleveland CPhT**
- **Temitope Fadonugbo CPhT**
- **Annora Johnson CPhT**
- **William Magana CPhT**
- **Tinesha Moore CPhT**
- **Brenda Perez CPhT**
- **Roderick Wolley CPhT**

IDS Staff Serving Western Region

IDS pharmacy leadership:

Manager: **Alan Yee**

Practice coordinator: **Nish Patel**

Western Region:

Marice Morrissey (oncology & non-oncology) at CDH

- **Central Dupage Hospital (peds cancer institute)**
- **Warrenville Cancer Center**
- **Delnor Cancer Center**
- **Kishwaukee Cancer Center**
- **Oak Brook Cancer Center**

Contact : phone 630-933-4450
cdhinvestigationaldrugservice@nm.org

Operational Division: oncology vs gen IDS

- Necessary for workflow management to match staff expertise
- Send all communications to group email (invdrugser@nm.org) for task assignments and accountability
- Internally both groups have a different workflow to fit their needs
- All afterhours paging goes to a gen IDS RPh (#16557)
- All investigational drugs are considered hazardous unless otherwise assessed for risk. Rationales: NIOSH list of hazardous drugs in healthcare settings 2024 language “it is prudent to handle them as hazardous drug…”

IDS Overview (Licensures)

- **We practice under the Northwestern Memorial Hospital Inpatient Pharmacy License**
  - Institutional Licensures:
    - Licensed under the NMH hospital Pharmacy License (state; pharmacist-in-charge)
      - Scope of service: all research protocols involving investigational drug (more details later)
      - Prescribers (MD/OD) must be a practitioner at NM campus (more details) and listed under the protocol
    - DEA Controlled Substance Registration Certificate (C 2,3,4,5)
      - Capable of handling controlled substance but feasibility assessment must be done before start-up
      - PI shall hold a valid controlled substance registration (both state and federal; Form 225 CFR 1301.18)
      - Order Form 222 (for ordering and returning C1&C2)

(Individual Licensures)

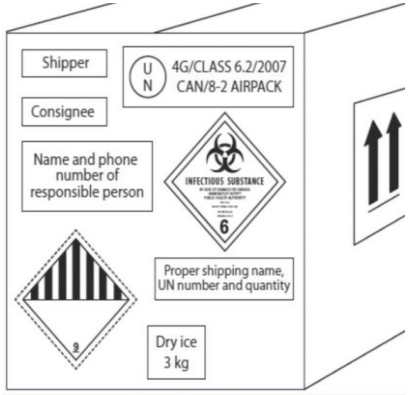
- Individual licensures:
  - State pharmacist, pharmacy technician license
  - GCP certificates (all IDS staff)
  - Pharmacist CV (signed and dated every 2 yr for NIH studies; no FDA regulation, but a GCP requirement. Sponsor can set its own standard of qualification of education and experience)

All above records are available upon request.

IDS do not keep a centralized, annual CV file of all pharmacists

(Individual Licensures cont.)

- Individual certificates:
  - IATA (category A: infectious, B: biological subs) (tech only)
  - DOT (hazardous material, incident response & transport security)
    - 49 CRF 171& 172 requirements for shipping and receiving of dangerous goods (UN IDs required)
    - All IDS pharmacy technicians have IATA & DOT cert.
    - Specific shipping requirements (packaging, container, materials, labeling, dry ice, size/ weight/ carrier restrictions) IDS' role is mainly for receiving
    - International shipments may require custom documents



Category A

Category B

Hazard Class 9

(miscellaneous dangerous good)

Shipping study drugs:

- IDS may ship new, unused IP back to Sponsor
  - Receiver must be a qualified drug depot with airbill, shipping materials provided

- Key highlights for shipping considerations
  - Some exempted drugs may have other restrictions (e.g. marine pollutants – labeled as toxic)
  - Need Sponsor approval (arrangements for home RN, signing package etc.)
  - Clinical labeling (OSHA), secondary container, carrier service
    - Does not ship Category A or B
  - Air bill from the study team / Sponsor
  - IDS shipping fee applies

- Request IDS to ship study drug to patient's residence (Hazardous drug/cytotoxic label; not DOT class label)
  - IDS does not ship drug to patients

IDS location: Galter Building , 17th Floor, suite 17-250, 17-180

- **Virtual tour on YouTube** https://youtu.be/VNr4EOrIytc

IDS location: facility and equipment

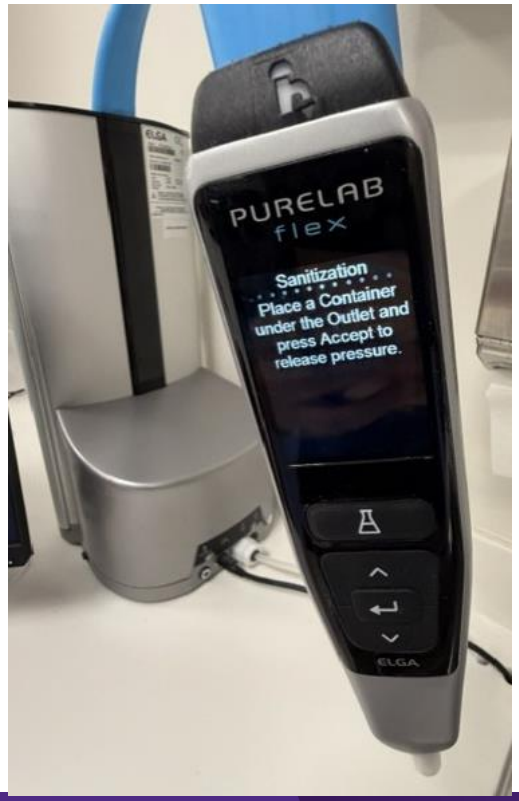
- **Non-sterile & non-compounding IP storage & handling area is in room 17-180**

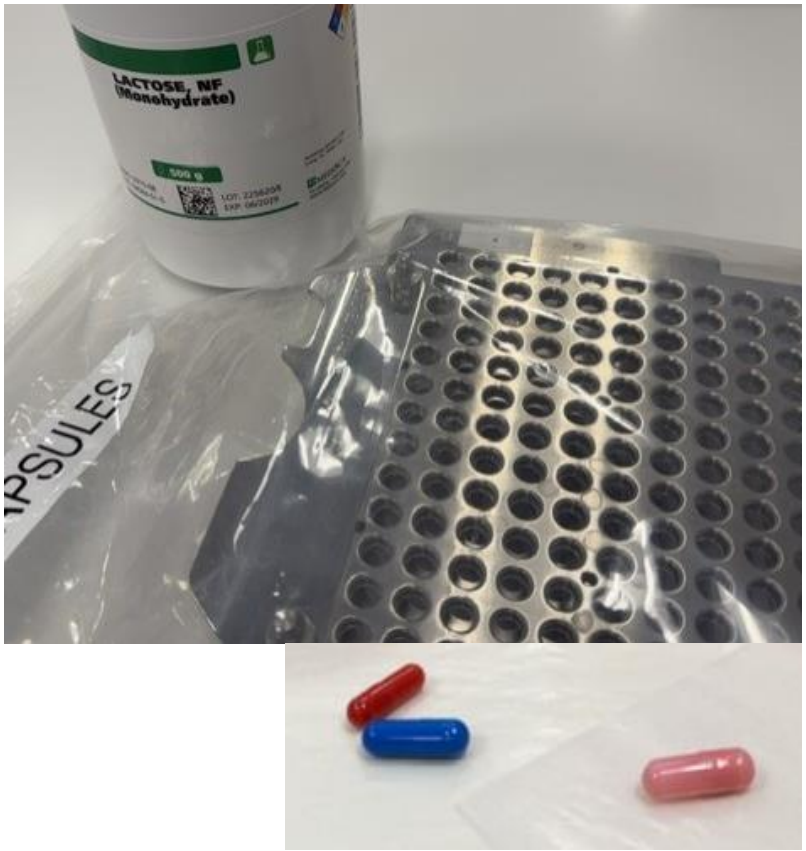
- **Continuous temperature monitoring 24/7**

➢ Format and display cannot be altered per Sponsor needs

Encapsulation capability 17th Floor, 17-180

- **Feasibility test needed (size 0 and size 00 gelatin capsule)**
- **Manually encapsulated**
- **Lactose (exclusion criteria)**





Sterile compounding area 17th Floor

- **Available equipment**
  - -20 c Freezer
  - -80 c Freezer
  - 2-8 c refrigerators
  - Class 2 biohazardous hoods for IV prep (in ISO 5)

Injectable compounding area 17th Floor

- **Available equipment (cont.)**
  - Biohazard isolator hood (in ISO 5)
    - Will require IBC review prior to utilization
    - Contain more than 100 nucleotides
    - Capable of gene modification
    - Potential to replicate
    - Can translate or transcribe
    - Human gene transfer
      - DNA or RNA recombinant
      - Include bacteria, virus or other microorganism

See NIH Section III Guidelines

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm#_Toc3457037

robert.foreman@northwestern.edu (contact Biosafety Officer, Robert Foreman for determination)

Closed system transfer device (CSTD)

- **Use for almost all oncology studies, few gen IDS studies**
- **A device that mechanically prohibits escape of hazardous liquid or vapors to the environment & human (oral, inhalation, dermal) for both preparation and administration**
  - Required by USP 800 and OSHA
    - Need to prepare in IV hood & wear appropriate PPE, has an attachment for administration by RN; dispose as hazardous waste
    - Limitations: loss volume in device, not feasible for small volume



When to engage IDS?

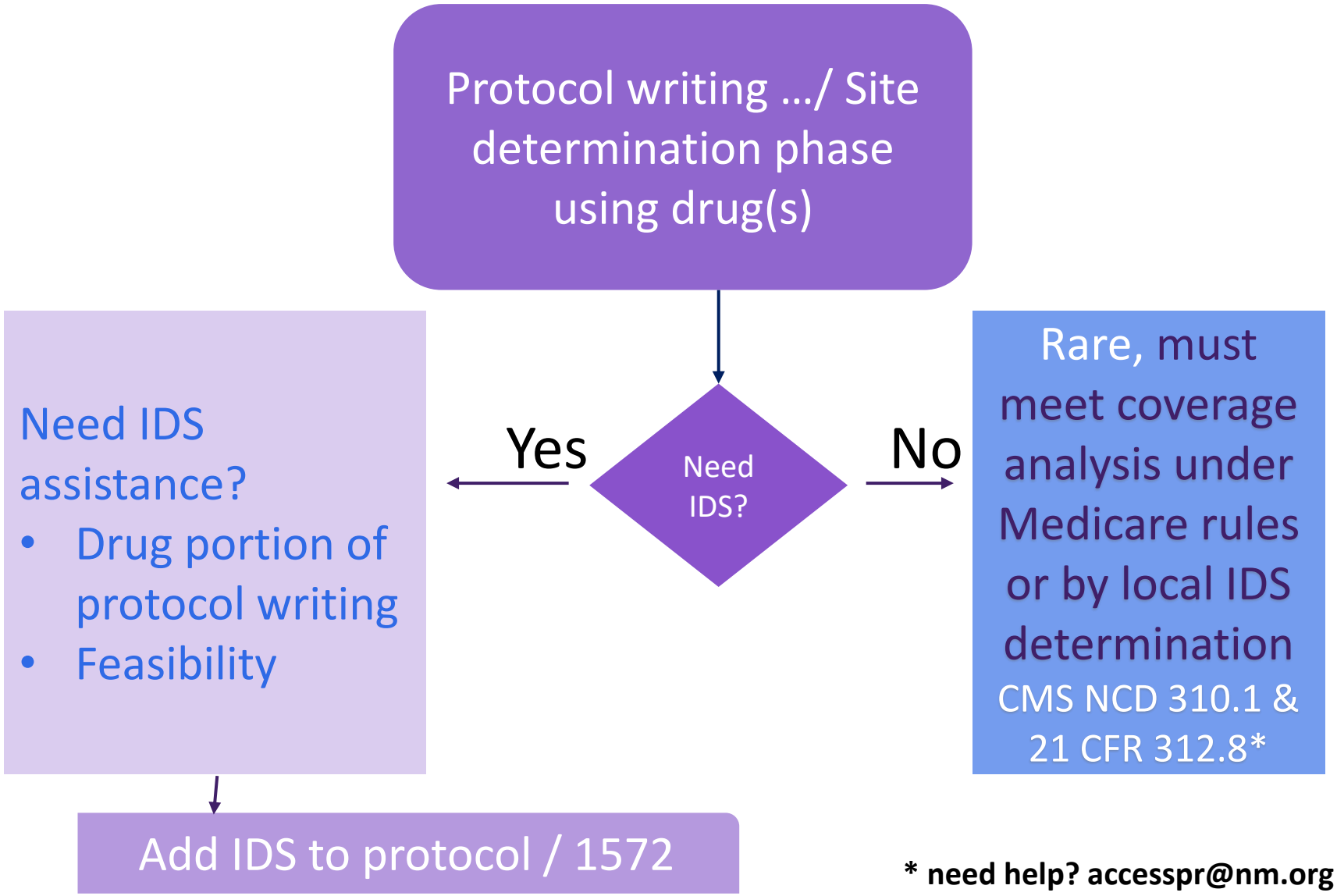
- **Timing: Before start-up /Site Initiation Visit (SIV) 6 weeks in advance (protocol, pharmacy manual, IB)**
- **Scope: All protocols involving Investigational drugs at Northwestern (NMHC spaces) must utilize the Investigational Drug Services (IDS) Pharmacy***
  - Exceptions (nature of study design, contrary to IDS SOP etc. – determine on a case-by-case basis) contact NMHC Access Program accesspr@nm.org for determination

* **NMHC PC 05.0046**

IDS SOP (shareable)

- **Frequently requested SOPs**
  - Delegation of Authority
    - Only one pharmacist will be assigned
  - IP destructions
    - Used and unused IP may be destroyed by IDS on-site; no used IP will be saved for viewing
  - Temperature monitoring
    - 30-minute temp excursion will only be reported internally; calibrate annually
  - IDS pharmacy training log (not available; unless Sponsor required/ electronic preferred)
  - Other SOP also available upon request

Before start-up



*** need help? accesspr@nm.org**

Local Protocol ; FDA 1572 Form

- **Sample language for LPA**
- **Info for 1572 Form**
- Study Intervention/Investigational Agent:

Northwestern Medicine Investigational Drug Service Pharmacy (IDS) will receive, store, and prepare study drug per IDS SOP and per the sponsor's pharmacy manual. All pharmacy staff are GCP trained and experienced in handling of study drug.

Address: 675 N Saint Clair Street 17th floor Suite 17-250 Chicago, IL 60611

Feasibility in more details

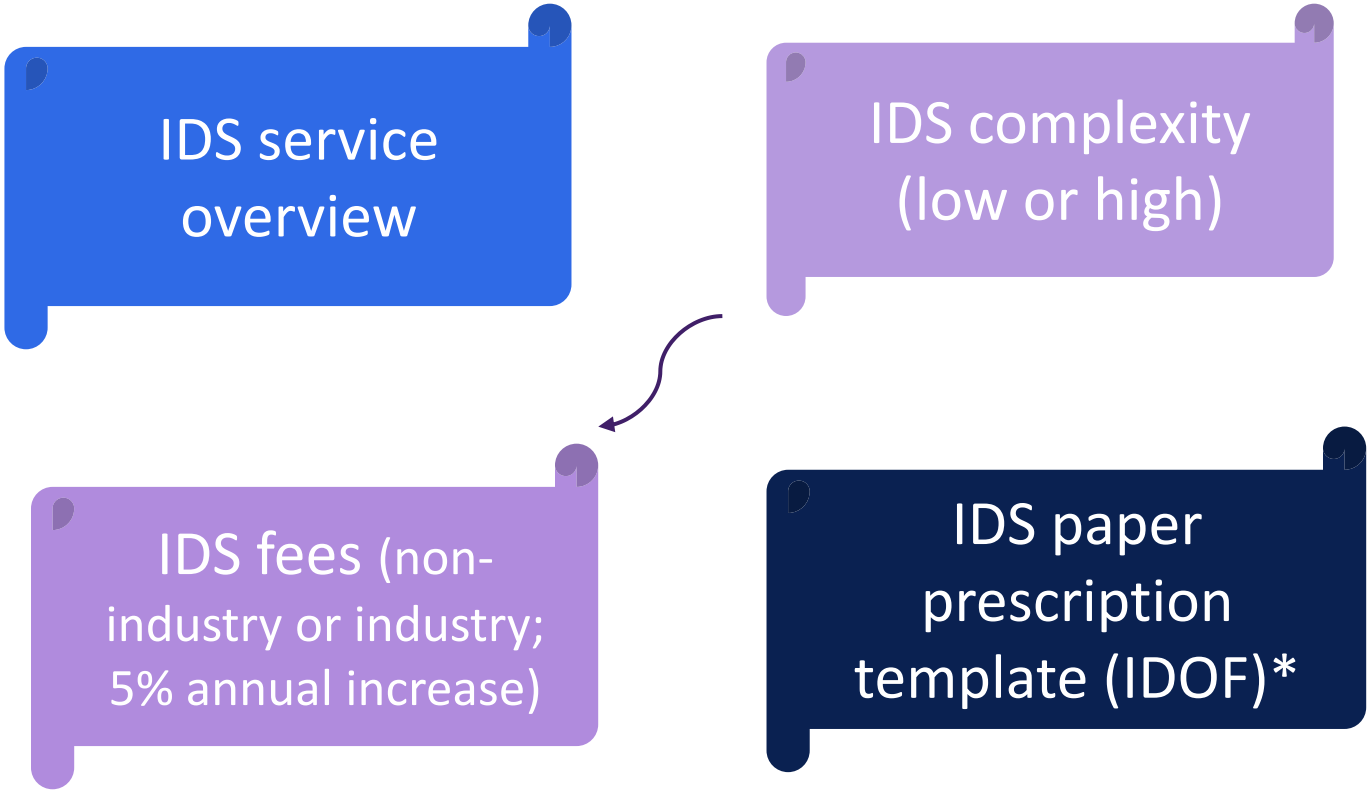
- **Pre-site qualification visit**

  Feasibility assessment (encouraged)

  - Hardware limitations
  - Drug handling issues /SOP
  - Encapsulation of study drug/placebo (no batch analysis)
  - IDS do not routinely issue Pharmacy Letter of Support (available for study grant purposes)

Receiving Endorsement email from OOR

- **Endorsement package (4 pharmacy documents)**



* IDOF to CPOE (computerized provider order entry) conversion to be completed by 2026

How IDS are notified of the SIV?

- **Study team must email IDS for all start-up**
- **Lead pharmacist is assigned based on SIV date**
- **Must send the protocol, pharmacy manual, IB to IDS prior to the SIV date (prefer 6 weeks in advance)**

Must send the protocol & pharmacy manual to IDS prior to the SIV date

- Main responsibilities of the IDS pharmacist
  - ✓ **Review protocol materials in details**
  - ✓ **Submit and create Epic /computer build**
  - ✓ **Liaise with the study staff and Sponsor**
  - ✓ **Maintain protocol modifications**
  - ✓ **Send all amendments, IP re-testing memo to IDS**

invdrugser@nm.org

- ✓ **IDS training log: only when provided by Sponsor, lead pharmacist only**

Corrective and Preventive Action/CAPA

Findings: (errors vs. record deficiency)

- Sponsor / Internal
- FDA: Form 483 (respond within 15 business days)
- FDA: Warning letter /Official Action Indicated (OAI)

➢ Study team-led written response

  ❖ Involve IDS in discussion and formulating a written plan of action before submission

➢ OAI would require a broader view & planning

CAPA steps (SMART):

- ✓ Time of discovery
  - Event description, identify error types
- ✓ immediate action taken?
  - Notification & containment
- ✓ Root cause analysis
- ✓ Action Plan
- ✓ Regulatory reporting
- Notification timeline to Sponsor, IRB, safety reporting
  - Completion date & sign-off

CAPA Action Plan involving pharmacy (with effectiveness check in mind)

- Error /deficiency due to:
  - Individual action deviates from the RX SOP or usual workflow
  - Protocol complexity (varying dispensing, crossover, dosing change)
  - IDS Workflow or SOP deficiency
    - Built-in risks (turnaround time, IDS limitations)
- Solutions:
  - Recommendations & expectations must be realistic (training)
  - Redesign workflow / add guardrail (double checker, system programming)
  - Any additional tools? (thinking outside the box)
    - Ask questions (effectiveness check & feedback)
  - Will the plan substantively improve and prevent its recurrence?

Audit (routine or for-cause)

- Sponsor / Internal
- FDA
  - Engage IDS leadership ASAP for pre-audit record reviews
    - ✓ IDS Manager must be copied in all requests
    - ✓ Review: (acct log- hard copy, DOA, shipping doc)
  - convene a readiness meeting before the audit
  - during the audit: log any records provided to the auditor, keep response concise
  - Invite IDS to the audit meeting (IDS leaders +/- designated staff /lead pharmacist)
  - Participate in exit meeting

RX record keeping

Study binder

- Physical binder (packing list, IRT)
- Electronic binder
  - gen IDS: local drive
  - Oncology: Notis
- SIV attendance & training documents (initiated by the study team or Sponsor; electronic records such as Complion or Docusign are managed and kept by the study team)
- Electronic records 21 CFR Part 11
  - IDS management software: master log: dispensing & returns, subject log, packing list, monthly temperature log
  - Prescription (Epic Wam), Epic (inpatient and Clinic administered med).

End of study recording keeping

- **IL Pharmacy Law: prescription retention= 5 years***

DHHS Federal Grants	3 years after the expiration of the funding period (final financial report) 45 CFR 74.53
FDA	2 years after the last marketing approval 21 CFR 312.62(c)
HIPAA Authorizations/Waivers	6 years after completion of the study 45 CFR 164.530(j)(1)
IRB Records	3 years after study completion 45 CFR 46.115(b); 21 CFR 56.115(b)

- IDS release physical records back to the PI
  - Acct log, IRT, packing lists, any relevant communications or training records if available
  - After Release and Surrender, IDS can only retrieve electronic records from Epic or IDS electronic system

* Ill. Adm code 68, § 1330.500

Thank you

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