

Update on Federal Regulation Regarding Treatment INDs and the Potential Financial Impact on Hospitals

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**Objectives**

1. Describe the treatment IND rule changes
2. Identify institutional implications related to the changes
3. Discuss potential strategies for managing the changes



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**Introduction**

- Main Point – Hospitals are now being charged for medications that had been provided to an institution to treat a patient at no cost under a Treatment IND
- Current issue at hand – Fairview struggling with how to handle the rule change
- We have had requests for three different medications since 6 months
- Have spent over \$200,000 on drugs that have not been reimbursable.



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### Purpose of New Rule

- Add clarity to existing rule
- Add new types of expanded access for treatment use



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### FDA Rule Changes

- §21 CFR Part 312 and 316 Amendments:
  - Part 312 Investigational New Drug Application
    - 312 New Subpart I: Expanded Access to Investigational Drugs for Treatment Use
    - 312.7(d): Charging regulation modified
    - 312.8: New section describes the general requirements and conditions for charging investigational new drugs
  - Part 316 Orphan Drugs
    - 316.40 Treatment use of a designated orphan drug
- Changes effective October 13, 2009



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### Significant Changes

- Clarifies intention to apply to all those patients with a “serious disease or condition” regardless of whether the patient is currently seriously ill with the specified disease or condition
- Expands investigational new drug access to individual patients and medium-sized populations in addition to large-sized populations
- Defined sponsor requirements for investigational new drug charging in either a clinical trial or an expanded access use



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### Benefits of Rule Changes

- The changes will allow greater access to medications that are not FDA approved.
  - Will allow access for patients that do not qualify for a clinical trial
  - Allow for individual access in emergency and nonemergency settings.

*Be careful of therapeutic misconception– these drugs are not FDA approved*



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### Charging for Investigational New Drugs

- In a clinical trial:
  - sponsor may only charge treating hospital for direct costs
  - may charge for duration of the trial
- In expanded access:
  - sponsor may charge the treating hospital for direct costs + costs directly associated with administration of the treatment use program (costs of monitoring the use, complying with reporting requirements, etc.)
  - may charge for up to one year and then renew



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### What to do with charges?

- Per Medicare's Clinical Trial Policy it is not permissible to bill Medicare for Investigational New Drugs (unless otherwise covered outside a clinical trial)
- Majority of commercial insurers exclude reimbursement for Investigational New Drugs in their medical policies



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## Comments regarding Rule Change

*It was stated that with the new rule change, it was hoped that insurers would recognize the potential benefit and importance of access to these medications and therefore provide reimbursement.*



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*"The debate over expanded access will certainly continue and will have broad implications for all those involved. As patients become more determined in their efforts to seek access, open dialogue and direct confrontation of the issues surrounding this topic must take place among a **broad range of stakeholders** including patients, physicians, drug developers, FDA, advocacy groups, and policymakers."*

Natalie Douglas, "Expanded Access to Investigational Drugs. New FDA Regulations Provide Effective Framework, But Questions Remain," [Genetic Engineering & Biotechnology News](#), (15 Jan 2010).



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## The Providers' Dilemma

Want to provide access to – and deliver - the best care possible.

Purchase the Investigational New Drug to treat the patient or subject.

*Ethical and financial questions arise...*



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### Fairview Approach

- Review each request by Treatment Use
- Decisions by Committee review
  - Medical expertise, financial officers, ethicist, pharmacy, research administration, payer contracting.



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### Decision-Making Outcomes

The decision-making process will result in one of the following outcomes:

- Approved with no restrictions on use
- Approved with restrictions on use (e.g., number of patients, timeframe, dollars expended)
- Request for more information (with a deadline for response before rejection)
- Not approved



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### Guiding Principles for Decision Making

- Decisions on whether to allow the use of drugs covered by a treatment IND, for which the Sponsor is charging the hospital, will be made in consideration of the following principles:



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### Guiding Principles for Decision Making (cont)

- Solicit the input of appropriate clinicians prior to rendering a decision regarding approval of the drug in question.
- Base decisions on an assessment of available scientific literature and research published in peer-reviewed journals.
- Acknowledge ethical considerations regarding the socio-economic status of patients, quality of life issues, and expanded access to new/experimental therapies.



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### Guiding Principles for Decision Making (cont)

- Develop a process for balancing the use of hospital resources to support research, clinical care, and education.
- Apply the principles of sound financial stewardship when assessing the requests, including recognition of the fact of a low probability of reimbursement.
- Recognize that the use of drugs covered by treatment INDs may be more economically sound than conventional therapies.



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### Criteria for Decision-Making

Decisions on whether to allow the use of drugs covered by a treatment IND, for which the Sponsor is charging Fairview, will be made by assessing the relative merits of the drugs in terms of:



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### Criteria for Decision-Making (cont)

- Efficacy of the drug in question
- Availability and efficacy of alternative therapies
- Assessment of risk and patient safety
- Therapeutic outcome
- Cost of the drug and any concomitant services



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### Reminders and Recommendations

- Institutional Review Board approval
  - Patient Consent
- Manage the documentation required
- Determine a process to purchase the drug



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### Receipt and Storage

- Drug should be kept in a designated area, away from the commercial medications
- Track receipt and dispensing on Drug Accountability Record
- Keep copies of all packaging slips and prescriptions
  - ASHP article titled: *Guidelines on Clinical Drug Research*



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### Purchasing Process

- May need to set-up vendor within hospital system to enable purchasing
- Require sponsor to provide the approved date range for charging.
- Manage the process via purchase agreement or PO depending on organizational and sponsor preference



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### Purchasing Process (cont)

Determine approach to manage charges

- Hospital will absorb the cost;
- Hospital will make an attempt to bill commercial insurance for reimbursement, allow denied charges to flow to patient bill.



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### Conclusion

- Challenge to balance risk and benefit.
  - Risk of financial exposure and unknown clinical benefit
  - Potential benefit include increased patient access
  - Marketing potential of institution



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Discussions & Questions



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