Specialty Pharmacy: Issues and Opportunities

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NCPDP®

Policy, Pilots, & Patients:
Forces Shaping the Healthcare Experience

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Samm Anderegg, Pharm.D., MS, BCPS is Chief Executive Officer at DocStation and healthcare technology consultant. As CEO, Samm is responsible for product design, data architecture, business strategy, marketing, finance, and customer engagement. In his role with the Pharmacy HIT Collaborative, Samm is focused on developing standardized data sets (i.e. value sets) for clinical pharmacy documentation. Value sets are the foundation for integrating pharmacist providers into health information exchanges (HIEs) and value-based quality programs. Samm is active in several professional associations including the American Society of Health-System Pharmacists (ASHP), Academy of Managed Care Pharmacy (AMCP), Pharmacy Quality Alliance (PQA), and several state pharmacy organizations.

Jocelyn Keegan, Payer/Provider Product Lead, Point of Care Partners

Jocelyn Keegan, Senior Consultant, Payer/Provider Product Lead. Jocelyn is a senior health care information technology consultant with expertise in health care product design, payer/provider collaboration, prior authorization workflows and software product development, and currently is the co-lead of the NCPDP Maintenance and Control specialty task group. Jocelyn is currently leading projects to improve Long Term Care facilities ability to improve ePrescription rates of specialty medications. Prior to POCP, she's previously led integration teams to implement X12, NCPDP and HL7 standards including leadership on the NCPDP ePA draft standard pilot with CVS Caremark, CoverMyMeds and Surescripts. In addition, she provided tactical and strategic advisement to the leadership team at NaviNet/NantHealth on how to move NaviNet from a custom development organization to a SaaS product company. Jocelyn previously led change, product and project management organizations for Thomson Financial /Thomson Reuters.

Faculty Disclosure

- Sammuel Andregg Chief Executive Officer, Doc Station, has no conflicts of interest to disclose.

- Jocelyn Keegan, Senior consultant, Payer/Provider Product Lead, Point of Care Partners, has no conflicts of interest to disclose.

Accreditation Statement

The Institute for Wellness and Education, Inc., is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants of the session who complete the evaluation and provide accurate NABP e-Profile information will have their credit for 1.0 contact hours (0.10 CEU) submitted to CPE Monitor within 60 days of the event. Please know that if accurate e-Profile information is not provided within 60 days of the event, credit cannot be claimed after that time.

ACPE program numbers are:
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Initial release date is 11/7/2017.

Learning Objectives

1. Describe the problems associated with current manual workflow for specialty prescribing.

2. Explain importance of data capture and its role in improving the specialty prescribing process.

3. Articulate standards development organizations efforts, specifically what NCPDP is doing to automate the specialty prescribing process.

4. Identify additional opportunities for data capture and exchange.

Pre-Test Questions

1. What are the barriers to industry adoption of standardized solutions for specialty? NCPDP's efforts?

2. What can be done to overcome these barriers?

3. What is NCPDP doing to engage the necessary experts to address these priority issues? How do we move the work forward?

Specialty Pharmacy Industry

- High-cost, complex regimens
- Special handling, special monitoring
- Supply chain & contracting have created a new class of medications called Limited Distribution Drugs (LDDs)
- Trend towards outcomes-based payer contracts

Data Driven Industry

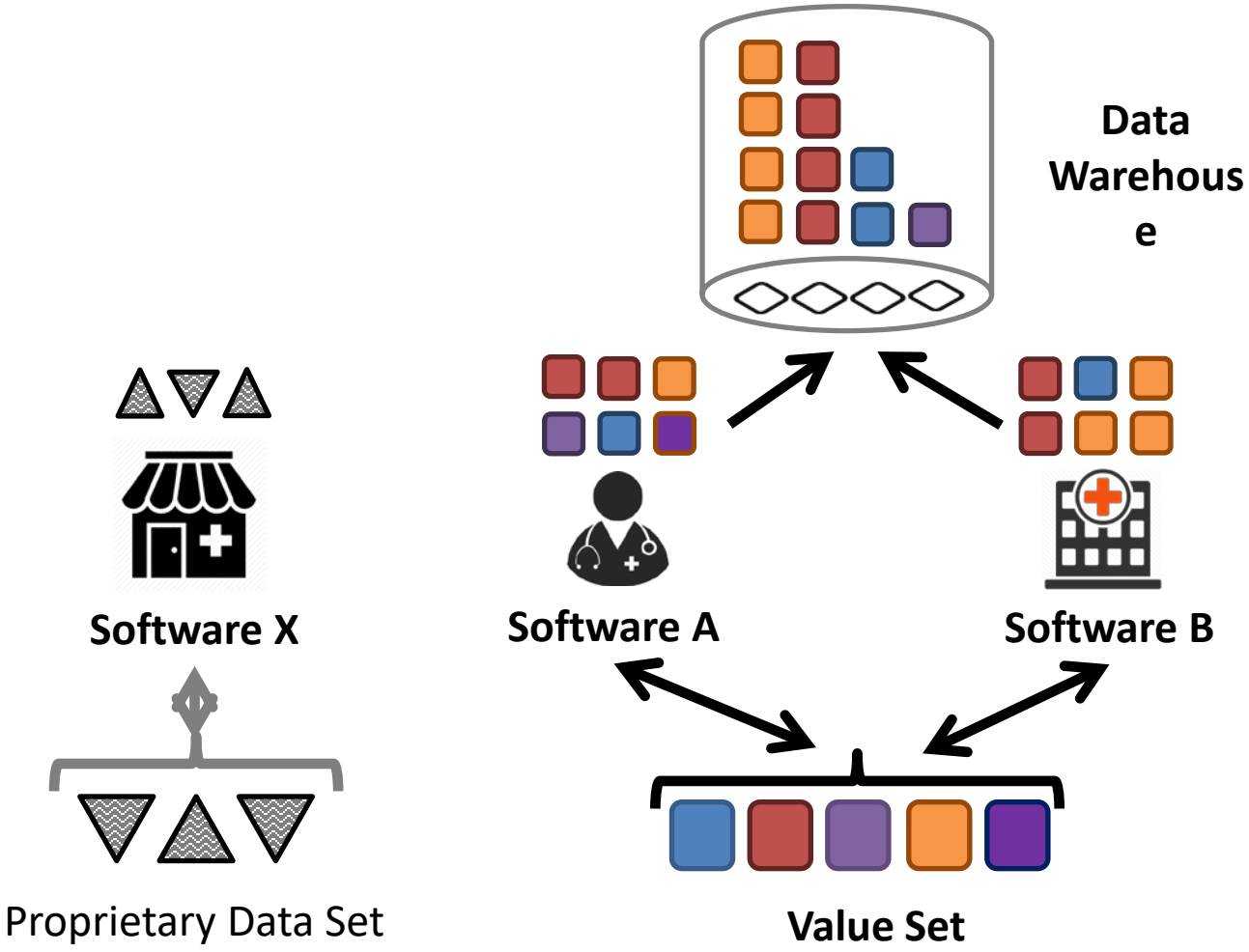
- Access to LDDs can be gained with data & outcomes
- Issues & Barriers
  1. Complex care processes & workflows
  2. Many software systems involved
  3. Lack of data standardization
  4. Lack of interoperability

Current Landscape

- Data stored in many software systems that don't talk to each other
  - Clinical Data – EHRs, case management software
  - Medication Data – pharmacy software
  - Labs/Genomic Data – lab software, EHRs

- **No standard data set** to facilitate interoperability and unified data reporting

Reporting



Drivers

- PHARMA wants safe handling & use of existing medications, expanded indications, new medications
- PAYERS want improved outcomes, reduced costs
- PROVIDERS want improved outcomes, more reimbursement, access to payer contracts & LDDs

Assets

- PHARMA has money & control LDD distribution
- PAYERS have money & control contracts
- PROVIDERS improve outcomes when incentivized by reimbursement, contracts, & LDDs

Outcomes-Based Incentives

- Incentivize improved outcomes through outcomes-based programs
- If outcomes are achieved…
  - PROVIDERS get more reimbursement, new/better contracts, & access to LDDs
  - PHARMA delivers on the outcomes-based contracts, increase revenue
  - PAYERS have lower costs

Data, Data, Data

- PAYERS and PHARMA must lead change
  - Establish outcomes-based provider programs
  - Adopt industry standards for data exchange and reporting
  - Couple data standards with outcomes-based incentive programs
  - PROVIDERS must comply with data standards to qualify, and get more if better outcomes are achieved

- **Note:** Focus on outcomes first, then

Role of Standards Organizations

- Private industry approach to incentivize rapid change
- All stakeholder incentives aligned
- Improve overall health, decrease overall costs
- Opportunity for NCPDP, HL7, & the Pharmacy HIT Collaborative to develop standards and work with industry on implementation.

NCPDP Activities

- Electronic Prescribing
- Prior Authorization
- REMS
- Real Time Pharmacy Benefit Inquiry
- Reporting

NCPDP Historical Activity

November 2013
- Specialty Requirements for ePrescribing Task Group formed

February 2015
- Proposed revisions to SCRIPT Standard submitted for membership approval

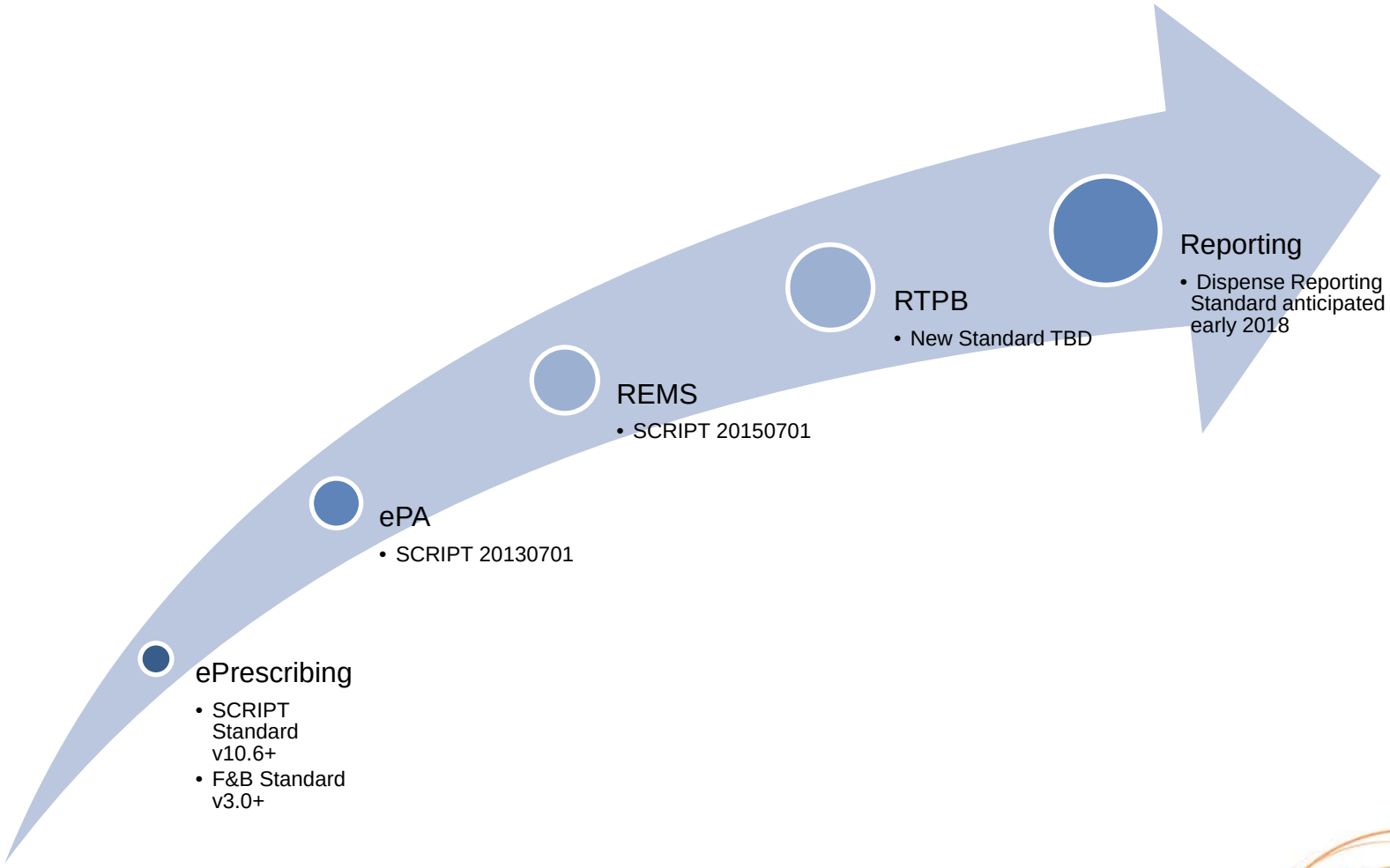
November 2015
- Specialty Reporting Sub Task Group formed

April 2016
- Stakeholder Action Group meeting held

February 2017
- MC Specialty Task Group formed

August 2017
- Specialty Pharmacy Reporting Data Standard submitted for membership approval

Standards Continuum



Electronic Prescribing (eRx)

- **Added guidance to Recommendations Document to improve use of existing elements in SCRIPT 10.6**
  - Diagnosis
  - Height/Weight
  - Insurance Information
- **Added elements to SCRIPT Standard to support:**
  - e-prescribing of specialty medications
  - Agency and service information
  - IV administration
  - Patient information (i.e. hospice status, alternate contact)
  - Clinical information specific to wound care
  - Enhanced e-prescribing of compounded medications
- **Regulation to name new version of SCRIPT expected to be published Fall 2017**
  - Implementation anticipated in 2019-2020

Electronic Prior Authorization (ePA)

- Transactions within the NCPDP SCRIPT Standard
  - First published in July 2013
  - Supports prospective and retrospective models
  - Allows for cancel and appeal functions
  - Supports pharmacist-initiated requests; trading partner agreements may determine applicability
- Enhancements continue to be brought forth
- Guidance from industry implementation available in NCPDP's SCRIPT Implementation Recommendations Document
- Anticipate that the transactions will be named when the new version of SCRIPT is named in federal regulations.

Risk Evaluation and Mitigation Strategies (REMS)

- Industry needs a way to exchange information related to Elements to Assure Safe Use (ETASU) requirements.
- FDA agreed to modifications to the Structured Product Label requirements so that REMS information could be supported by drug knowledge databases (compendia) and be readily available within EMRs.
- NCPDP created new message types, modeled on ePA, and enhanced existing messages to support information exchange.
  - The changes were published spring 2016
- Regulation to name new version of SCRIPT expected to be published Fall 2017
  - Messages from prescriber to REMS Administrator prior to sending prescription
  - Telecommunications Standard was modified to allow REMS processing to leverage claim adjudication process

Real-Time Prescription Benefit (RTPB)

- Maintenance and Control Task Group is developing a standard to support a real time benefit check initiated by the prescriber.
  - Will enable use of two syntaxes – EDI and XML
  - Request and Response model
- 12 use cases and associated data elements have been identified.
- Industry efforts, both pilot and production, are underway; feedback will be shared with NCPDP.

Reporting – Specialty Pharmacy Initiated

- Specialty Pharmacy Data Exchange Sub-Task Group (within WG 7 - Manufacturer and Associated Trading Partner Transaction Standards)
- Develop standardized reporting to support contractual arrangements between the manufacturer and specialty pharmacy. There are four categories the group has considered:
  - Dispense
  - Patient Census (Aggregate)
  - Performance Metrics/Case Management
  - Inventory
- Dispense Report Standard was presented to the membership for approval in August 2017; publication is anticipated in early 2018.

Maintenance and Control – Specialty

- A new task group was formed in February 2017
- Intended to
  - coordinate specialty related task groups and activity
  - provide communications and website development to position NCPDP as relevant in regards to specialty pharmacy
  - identify additional opportunities for standardized data exchange

NCPDP Efforts around Specialty Patient Enrollment

Specialty ePrescribing Complexity

CARE COORDINATION

Prescription	Benefit Determination	Enrollment	Copay Assistance	Prior Auth	REMS	Dispense	Deliver	Med Adherence
Identify Payer and Network Restrictions					Regulatory	Pharmacy or Hub Driven		Payer
Specialty medications generally not ePrescribed. Sent using fax or paper script	No single source to identify payer, Hub or pharmacy restrictions	No standard agreed upon data; medication and often pharmacy specific	No standards, custom integration, manual or portal solution	Narrow audience, but critical to those affected	Improvements in retrospective, upstream data remains barrier for prospective	Significant burden on intermediaries or pharmacists to complete full picture	Improvement in enrollment will create efficiency here	Ability to reduce time, improve prospective data should drive better adherence

There is a significant amount of complexity involved with ePrescribing of Specialty medications and a number of areas to focus on in regards to standards and moving processes electronic

NCPDP Stakeholder Action Group

- NCPDP Stakeholder Action Group on the Potential for Specialty Automation
  - One day session held April 2016
  - Stakeholders from around industry (pharmacies, HUBs, EHR vendors, providers, intermediaries)
  - Prioritized areas of focus for NCPDP task groups
- WG11 Task Group: Focus on Specialty Enrollment Transaction

WG11: Specialty Requirements for ePrescribing Task Group Update

- Specialty Enrollment Transaction (SET)
  - Separate transaction under SCRIPT standard
  - Bi-directional transaction to include: Patient, Demographic, Prescriber, Medication, Clinical, Insurance and Consent
- Potential cross standards organization for clinical information
  - Looking at HL7 FHIR

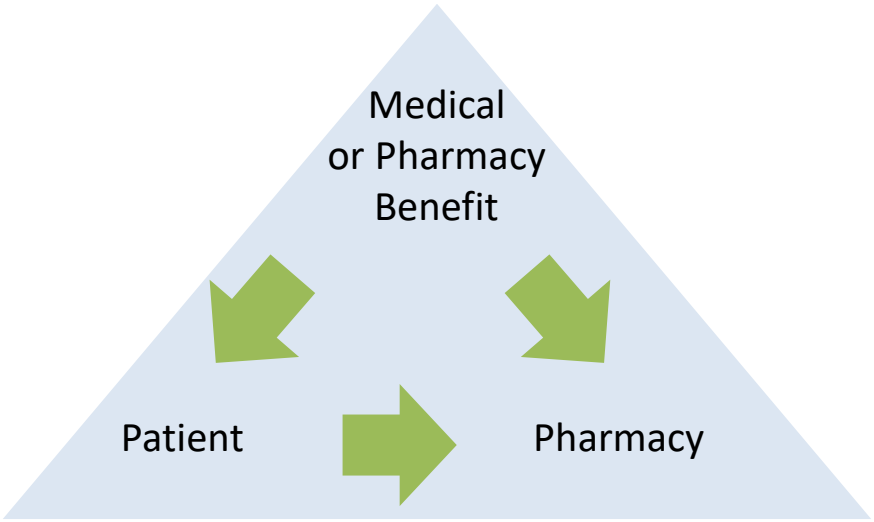
- Current Use Cases identified
  - Submit SET to SP, receive Affirmative response
  - Submit SET to HUB, receive Affirmative response
  - Submit SET to SP, receive a Negative SET response for:
    - mandatory HUB
    - optional HUB
    - cannot dispense medication
    - for cannot process enrollment
  - Submit SET to HUB, receive a Negative SET response for:
    - mandatory HUB
    - optional HUB
    - cannot process enrollment

Two Key Specialty Enrollment Transaction Challenges

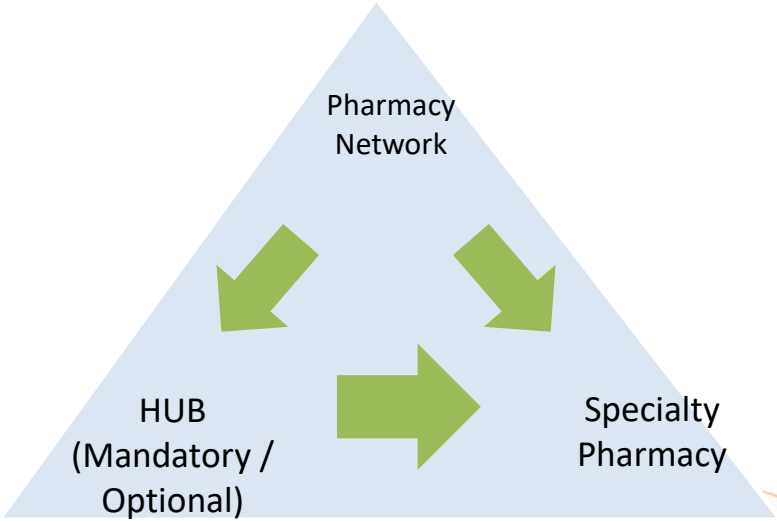
Two key specialty enrollment transactions identified:

1. Identification of a medication as a specialty medication
2. Prescription and Enrollment transaction routing

IS SPECIALTY MEDICATION?



PRESCRIPTION AND ENROLLMENT ROUTING?



Post-Test Question 1

1) What is the main driver behind automating the specialty prescribing enrollment form?

a) Regulatory requirements
b) Speed to therapy for patient
c) i-STOP legislation in New York
d) Help pharmacies save money

Post-Test Answer 1

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Post-Test Question 2

2. What is the average time it takes for a patient to receive their specialty medication after it is prescribed?

a) 1-2 hours

b) 2-4 days

c) one week

d) 3-6 weeks

Post-Test Answer 2

2. What is the average time it takes for a patient to receive their specialty medication after it is prescribed?

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Post-Test Question 3

3. What priorities were identified by the Stakeholder Action Group for NCPDP to consider?

a) ePrescribing

b) Eligible pharmacy identification

c) Reporting

d) Prior Authorization

e) all of the above

Post-Test Answer 3

3. What priorities were identified by the Stakeholder Action Group for NCPDP to consider?

a) ePrescribing
b) Eligible pharmacy identification
c) Reporting
d) Prior Authorization
e) all of the above

Post-Test Question 4

4. Which of the following is the largest barrier to real-time data reporting in specialty pharmacy?

a) Data standards do not exist

b) Vendor technology do not support standards

c) Lack of provider interest

d) All of the above

Post-Test Answer 4

4. Which of the following is the largest barrier to real-time data reporting in specialty pharmacy?

a) Data standards do not exist
b) Vendor technology do not support standards
c) Lack of provider interest
d) All of the above

Post-Test Question 5

5. Which major stakeholders can impose technology standards to streamline industry data reporting across the specialty industry?

a) Providers

b) Payers

c) Pharma

d) Both B & C

e) All of the above (A, B & C)

Post-Test Answer 5

5. Which major stakeholders can impose technology standards to streamline industry data reporting across the specialty industry?

a) Providers

b) Payers

c) Pharma

d) Both B & C

e) All of the above (A, B & C)

Q & A

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