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Specialty Pharmacy: A Data-Driven Success Story

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Disclosure

Jake Olson, Pharm D., President/CEO Skywalk Pharmacy declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Learning Objectives

- Discuss key data elements necessary to build a value proposition for payers.
- Discuss packaging data for your patients and using data to create a compelling story for your services.

Agenda

- Outcomes definitions
- Accreditation
- Payer Networks
- Manufacture/LDD Access

Stages of Specialty Pharmacy Growth

- (1) No SP capabilities—possibly outsourced to another company?
- (2) Neophyte SP with limited capabilities—pharmacy services just started, 1-2 disease states, in service <1 year
- (3) Immature SP but growing capabilities—3-5 disease states, in service at least 1 year, some data and reporting capabilities
- (4) Near standard SP services—6-8 disease states, centralized SP, in service >2 year, good reporting capabilities, 1-2 payer contracts, 1-2 LDD
- (5) Mature fully functioning SP—all disease states, centralized SP—likely off-site, all systems in place, multiple payer contracts, multiple LDD (very few at this level)

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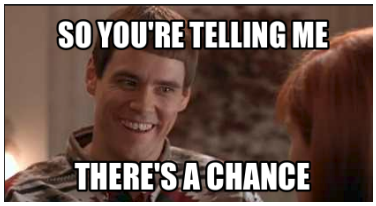
Pharmacy Profitability Examples

	AWP-18%	AWP-22.5%	NADAC (WAC - 3.4%)	Purchasing WAC - 5%
Wholesale Acquisition Cost	$ 4,441.23	$ 4,441.23	$ 4,441.23	$ 4,441.23
Average Wholesale Price (AWP = WAC + 20%)	$ 5,329.48	$ 5,329.48	$ 5,329.48	$ 5,329.48
Reimbursement from Payer (AWP - X%)	$ 4,370.17	$ 4,130.35	$ 4,290.23	$ 4,290.23
Purchase Price from Manufacturer or Wholesaler (WAC-2.75%)	$ 4,319.10	$ 4,319.10	$ 4,319.10	$ 4,219.17
Dispensing Fee	$ 1.00	$ 1.00	$ 12.00	$ 12.00
Gross Margin	**$ 52.08**	**$ (187.75)**	**$ (16.87)**	**$ 83.06**
Gross (% of WAC)	**1.2%**	**-4.2%**	**-0.4%**	**1.9%**
Reimbursment BI/BV Cost/RX	$ (21.00)	$ (21.00)	$ (21.00)	$ (21.00)
Patient Services Cost/Rx	$ (5.00)	$ (5.00)	$ (5.00)	$ (5.00)
Cost of Dispensing	$ (11.00)	$ (11.00)	$ (11.00)	$ (11.00)
Net Profit $/Rx	**$ 15.08**	**$ (224.75)**	**$ (53.87)**	**$ 46.06**
% of WAC	**0.3%**	**-5.1%**	**-1.2%**	**1.0%**

Reimbursement (BI/BV) cost assumes 30mins/Rx @ $30/hr; and 30 minutes for PA on 50% of Rxs

Patient services cost assumes 15 min/Rx at $20/hr



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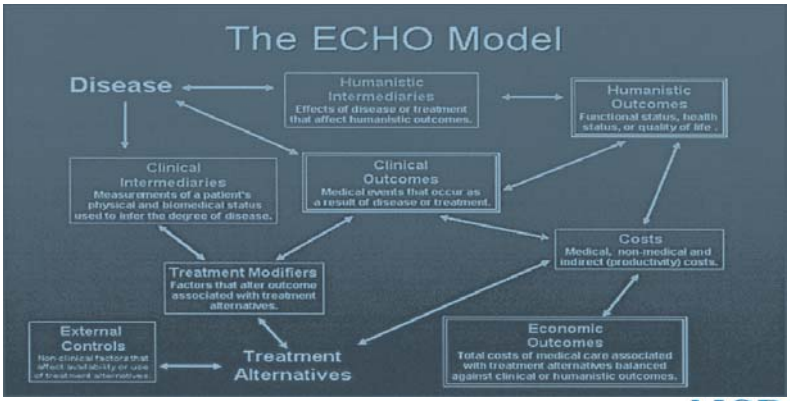
The ECHO Model

- Evaluation of the effect of Health Care Interventions on patient-related outcomes
  - **E**conomic
  - **C**linical
  - **H**umanistic
  - **O**utcomes



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Economic Outcomes

- Patient Assistance/Copay Assistance
- Cost per prescription
- Total cost by category/class
- Per member per month costs
- Cost Avoidance

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Clinical Outcomes

- Medication possession ratio (MPR)
- Proportion of Days Covered (PDC)
- Adverse Events
- Disease Specific
  - Sustained virologic response (SVR) for Hep C
  - Exacerbations for MS
  - FEV1 for CF

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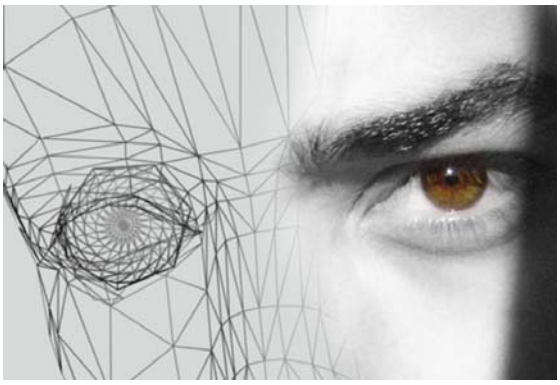
Humanistic (Operational/Service) Outcomes

- Call center statistics
  - Speed to answer
  - Abandonment rate
- Error Rates
- Time to fill
- Turnaround time
- Patient satisfaction



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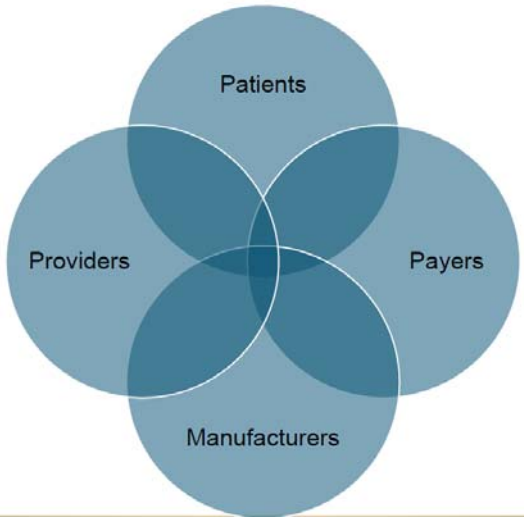
Stakeholders for Outcomes



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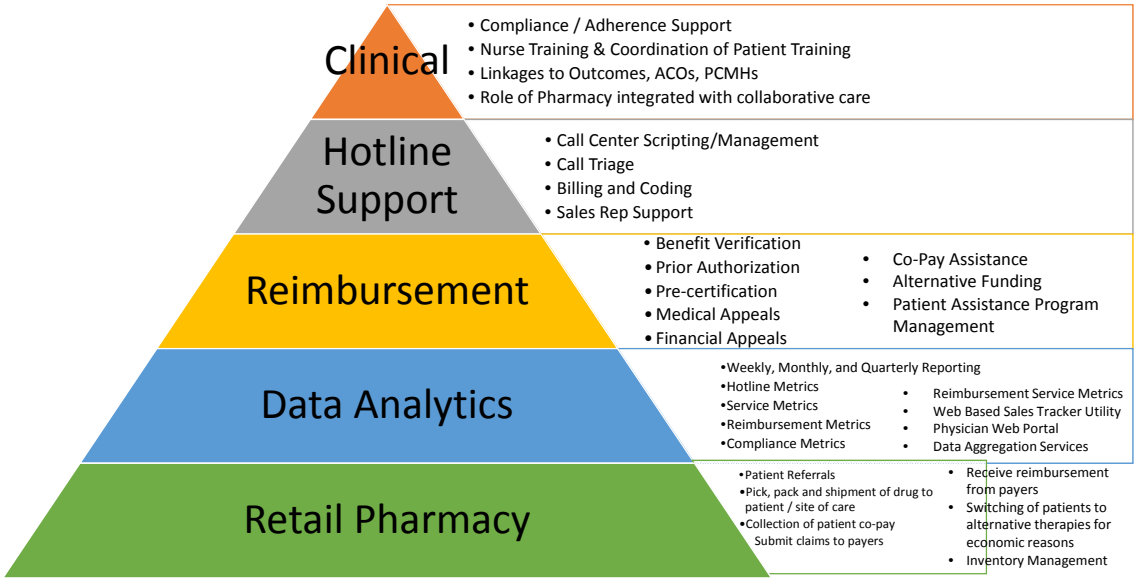
Considerations for Outcomes

- Who is the audience/stakeholder?
- Are there benchmarks?
- What are your competitors reporting?
- What are your differentiators?
- Can you retrieve the required data to report outcomes?
  - Is it in a reportable format?
  - Do you have the required IT infrastructure and resources?

Challenges with Outcomes

- Do I have enough?
- There are often no benchmarks
- The important data outcomes will vary by recipient
- The data needed will often be in multiple systems and may be challenging to obtain
- There will need to be dedicated resources assigned to managing the data to report outcomes



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So where do I start?

- Tools
  - Pharmacy Operating System
  - Medication Synch/scheduling software
  - Excel Spreadsheets for PA management
  - Reporting software companies
  - Communication software (notes in baskets aren't going to cut it)
  - Clinical software platform

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Specialty Pharmacy Data Elements

- New/Refill Prescription numbers
- Profit margin per Rx (drug, payer, overall)
- Broken down by therapeutic category
- Patient numbers per drug, payer, prescriber
- Pull out numbers from traditional business

Accreditation

- In 2016, Specialty Pharmacy Times reported that, "if a pharmacy wants to have access to limited-distribution products and payer coverage, accreditation is near mandatory"
- PBM contracts requiring 2 accreditations, 1 of which must be URAC
- Other accreditations
  - ACHC
  - JCAHO
  - CPPA
  - VIPPS
- URAC 3.0 focuses on a case manage approach to patient management
- Only about 1/3 of the pharmacies with URAC accreditation have achieved the 3.0 standards to date

What Data is required for accreditation?

- As of 2016, measures must be submitted through a certified vendor and externally audited for validity by an independent third party.
- Organizations must enter into service agreements directly with the accreditation companies allied software vendor, and audit vendor
- Luckily this is free (sarcasm font)

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What Data is required for accreditation?

Provide for All Patients:

–A consistent, overarching patient care process that includes for example:

- Patient onboarding
- Past medical history
- Medication history
- Drug allergy check
- ADR documentation including FDA reporting

–Patient interventions including

- Drug problems identified
- Who was notified?
- What was recommended, accepted?
- Ultimate outcome and any hard or soft cost savings?

-Pharmacy must have evidence of

- Initial assessment
- Follow up assessment(s)—ideally the next month, but may be later depending on the program design

–Program must measure

- Total patients on that therapy in the pharmacy
- Total patients who opted in to the program and the number who opted out

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What Data is required for accreditation?

–Drug-Drug Interactions

–Call Center Performance
- Response rate
- Abandonment rate

–Dispensing Accuracy
- Incorrect drug or product dispensed
- Incorrect recipient
- Incorrect strength
- Incorrect dosage form
- Incorrect instructions
- Incorrect quantity

–Distribution Accuracy
- Drugs or products dispensed with incorrect patient address
- Drugs or products dispensed with correct address but delivered to wrong address

–Turnaround Time for Prescriptions
- Turnaround time for clean prescriptions
- Turnaround time for prescriptions requiring intervention
- Turnaround time for all prescriptions

–Proportion of Days Covered (PDC)

–Fulfillment of Promise to Deliver

–Primary Medication Non-Adherence

–Consumer Experience with Pharmacy Services

Patient Satisfaction Data

- Zitter Health Patient Surveys
- NASP Patient Satisfaction Survey
- Levels the playing field with comparisons between different SP
- Accreditation Requirement

General Survey Content
Patient demographics
Specialty Pharmacy benchmarking
How the patient was acquired and uses the specialty pharmacy
Reimbursement Services/Formulary challenges and their impact in affordability
Specialty Pharmacy and Patient interaction
Patient: First Fill experience/Re-fill experience
Net Promotor Score of the Specialty Pharmacy and patient loyalty
Customer service of various facets/roles within Specialty Pharmacy
Patient plan/benefit design
Specialty Pharmacy switching

Value of Accreditation for Improving Operational and Patient Outcomes

Operational

- Quality and Performance improvement requirements
  - Can improve service levels and efficiencies
  - Can save expenses
    - Labor
    - Shipping
- Metrics
  - Measure to manage
    - Improving
    - Declining
- Adherence to regulations
  - HR requirements
  - Licensing requirements

Patient Outcomes

- Initial Assessment Requirements
  - Baseline information gathering
- Follow up Assessment Requirements
  - Compliance, Adherence, Persistency
  - Adverse Events
  - Quality of Life
- Care Plans
  - At risk patient identification
  - Collaboration with other Healthcare providers
- Education Requirements
  - Patient education
    - Literacy levels
    - Cultural

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WHY Outcomes Are Important to the Payer

- Cost Containment
  - Healthcare costs in line with company growth, revenue and projections
  - Sustainable benefit structure
- Improved Quality of Care
  - Evidence of effective treatment regimens (Did they get what they paid for?)
- Mitigation of future medical bills
  - Did proactive pharmacy spend prevent future medical spend?
- Productive workforce
  - Reducing absenteeism
  - Improved Quality of Life
  - Employee satisfaction and retention

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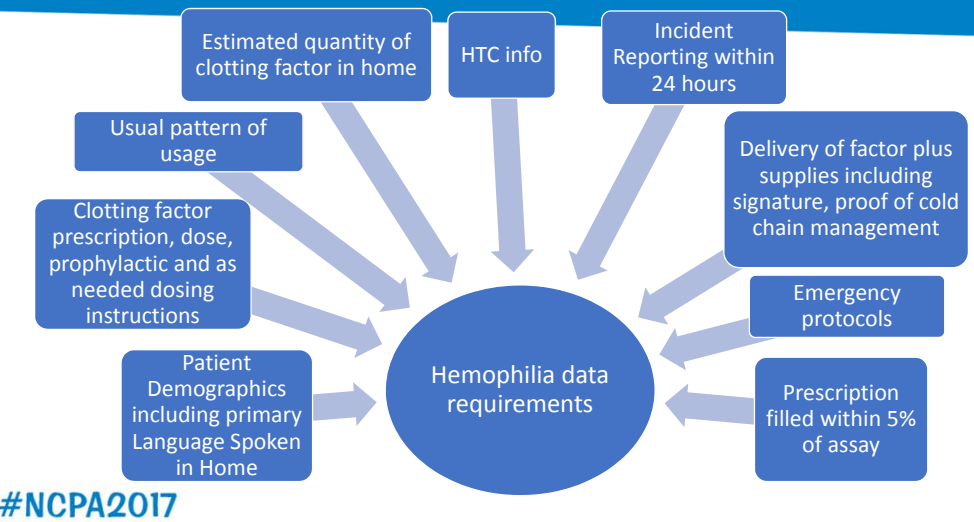
What Data is the Payor Requiring?

- Top 5 questions from Payers
  - Is the treatment working and is the patient adherent to therapy? – Clinical Outcomes
  - How long has the patient been on therapy?
  - Is the patient receiving high quality services?
  - Were prior authorization steps taken?
  - How many patients will be receiving therapy?

- Patient surveys
- Time on Therapy
- Disease Specific analysis
- Summary Utilization
- Reauthorization
- Time-to-fill
- Patient Abandonment and Rejection Rate
- Patient Assistance
- Patient status (PA, Shipment, Hold, etc.)

Inclusion in Payor Network



No data

Unhappy Drug Rep and HUB

No prescriptions

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HUB Vendors

COVANCE | SonexusHealth | McKESSON Empowering Healthcare | Lash Group AmerisourceBergen Consulting Services

CareMetx | trialcard Access. Acquisition. Adherence. | TripleFin | Rx Crossroads

CCAM Health Services | arx AssistRx | UBC An Express Scripts Company | ENVOYHEALTH A Diplomat Company

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How Network Partners Are Chosen

Channel Access To Drug → Level of Control

Open	Preferred	Limited	Exclusive
• > 100k patients • Low control • Low touch service • No data visibility • No limit on access	• 100k – 20k patients • ⇧ control • Low touch service • ⇧ data visibility • No limit on access; list of preferred partners	• 20k – 5k patients • ⇧ control • Medium touch service • ⇧ data visibility • 1 SPP/$1,000 drug cost • 1 SPP/100 patients/month	• < 5k patients • High control • High touch service • High data visibility • 1 SPP

These networks can vary by drug AND by type of site of care

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Dispensing Entity Decisions

PAYER ALIGNED
Cigna, Aetna, RightSource, AcariaHealth

PBM ALIGNED
accredo, MagellanRx MANAGEMENT, CVSHealth, exactus, briova

RETAIL ALIGNED
Walgreens Specialty Pharmacy, PRIME THERAPEUTICS, Walmart, AXIUM, RITE AID

WHOLESALER ALIGNED
US Bioservices, ACS Advanced Care Scripts, Omnicare, OncoSourceRx, Biologics

INDEPENDENT
Diplomat, Avella, CareMed, Onco360, Orsini, BioPlus, SALVEO, Amber PHARMACY, SenderraRx

HIS / IDN / ACO
GEISINGER, MAYO CLINIC, Henry Ford HEALTH SYSTEM, excelera, FAIRVIEW, PREMIER, COMMCARE

ALIGNMENT AFFECTS OBJECTIVES, BEHAVIOR, and WILLINGNESS TO PARTNER

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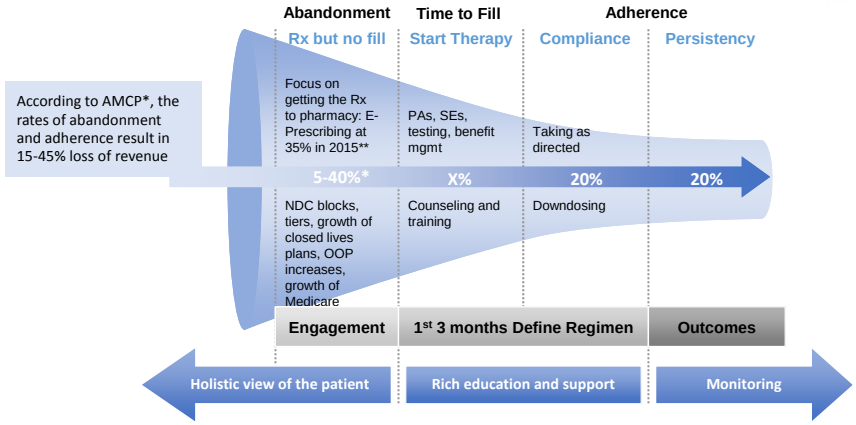
What does the manufacturer want to hear for inclusion into their LDD network?



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* AMCP JMCP 2015 adherence reports
** Surescript article August 2016

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Other LDD Access "folks" to consider

- Medical Science Officer
- Marketing Department
- HUB
- Wholesaler
- Data aggregator

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Types of Manufacturer Contracts

- Manufacturer data contracts
  - Access to product
  - Rebates to the pharmacy
  - Rebates to the payers
  - Fair Market Value service contracts
  - GPO contracts

Legal Issues play a role

- Anti-Kickback Statute
- Stark Law
- Civil Monetary Penalty Law
- HIPAA
- Medicaid Best Price, AMP and ASP price reporting
- Core Services vs. Enhanced Services
  - Establishing FMV and commercial reasonableness
  - Discounts vs. Payments
  - Evidencing Performance of Services

HIPAA plays a role

- Patient level data integration
  - No PHI
    - No chance of data breach and easy legal and compliance review
    - Low quality data. Inaccurate patient counts and length of Tx
  - Partial PHI
    - Only send data for patient with signed HIPAA auth/consent
    - Risk for manufacturer if SP doesn't have proper forms for each state
  - Full PHI
    - Best data set, but need stakeholder alignment
    - Check your POS/switch contracts

Key Contractual Relations

Manufacturer →	Hubs / PA Support / FAPs	Bona Fide Service Fee Agreements
Manufacturer →	3PL	Bona Fide Service Fee Agreements Purchase Discount Agreement
Manufacturer →	Specialty Distributor	Bona Fide Service Fee Agreements Purchase Discount Agreement
Manufacturer →	Specialty Pharmacy	Bona Fide Service Fee Agreements Purchase Discount Agreements Performance Rebate Agreements
Physician →	HUB	Business Associate Agreement
Manufacturer →	Payor (Health Plan / PBM)	Tier Placement Rebate Agreements

BASS BERRY + SIMS

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Bona-Fide Service Fees

- *Per § 414.802, the considerations to be met for a service fee paid by a manufacturer to an entity to be bona fide and excluded from ASP calculation:*

1. Fee paid represents fair market value
2. Fee paid must be for a bona fide, itemized service that is actually performed on behalf of the manufacturer
3. Manufacturer would otherwise perform or contract for the service in the absence of the service arrangement
4. Fee is not passed on in whole or in part to a client or customer of any entity, whether or not the entity takes title to the drug***

****Per CMS, "if the fee paid meets the other elements of the definition of 'bona fide service fee', then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity"* (72 Fed. Reg. 39164 (Jul. 17, 2007))

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What Data is the Manufacturer Requiring?

- Patient Onboarding Data
  - –Referral volume for their drug
  - –Stages of approval:
    - Rx Received – Benefits Investigation - PA? - Deny? - Appeal? - Overturn?
  - –Time between each stage
  - –Overall time from receipt to dispense
  - –Success rate:
    - ?% dispensed by your pharmacy
    - ?% referred out and to whom?

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What Data is the Manufacturer Requiring?

- Patient "Clinical" Data
  - –Adherence and Persistency
- MPR (medication possession ratio)
- PDC (proportion of days covered)
- Pharmacovigilance
- REMS data
- Quality of Life
- Disease progression
- Inventory Levels
- Payors (Insurance, Medicaid, Copay assistance, Copay to member)

Setting Standards for data transmissions

- NCPDP workgroups
- WG7 = Manufacturer and Associated Trading Partner Transaction Standards
- Phone calls every other week
- Quarterly meetings in various locations
- https://www.ncpdp.org/Events/Work-Group-Meetings

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