

Emerging Pharmacy Trends Assessment: Summary of Secondary Research Findings

Prepared for AMCPF and Pfizer

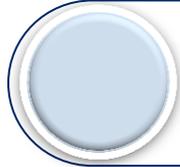
May 26, 2014



Agenda



Project background and objectives



Secondary research methods



Emerging themes from secondary research



Summary of secondary research findings

The overall project goal is to create an evidence-based, validated report on managed care pharmacy trends and response strategies

Overall project goal

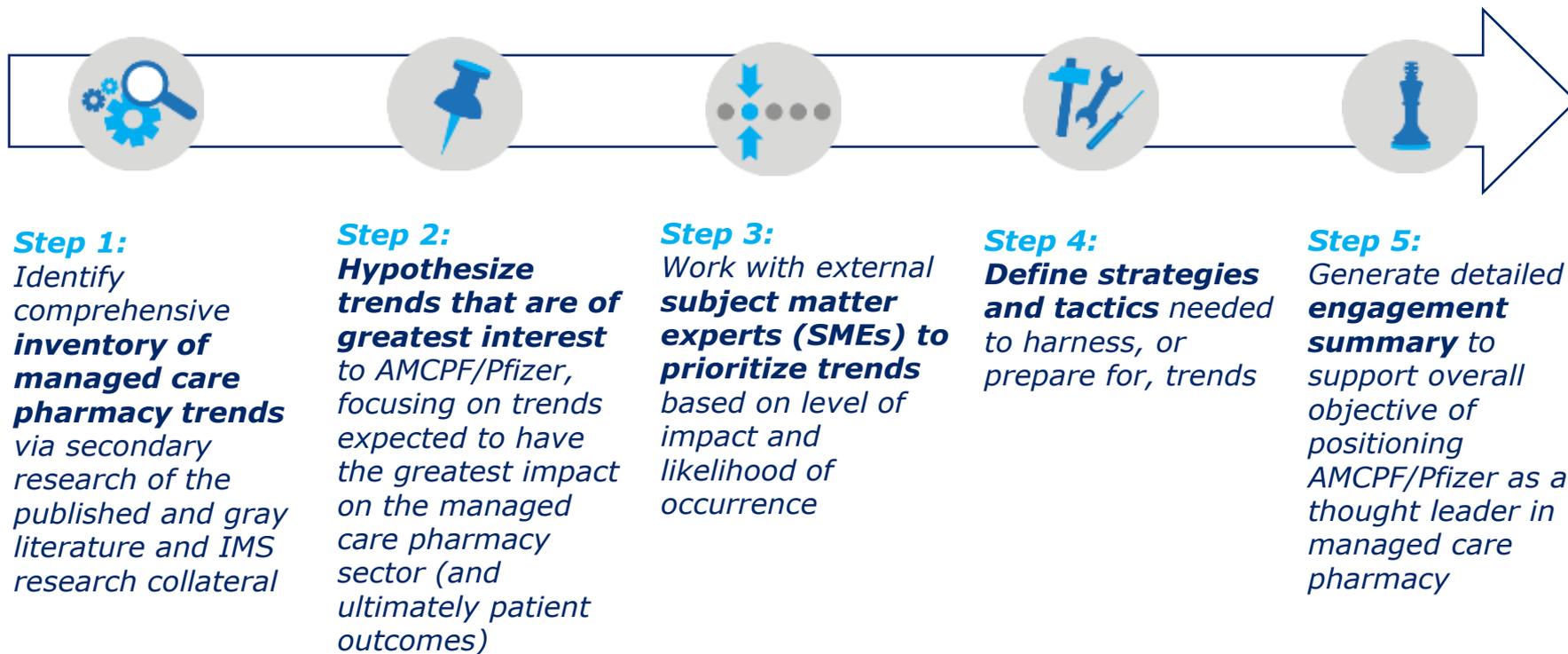
To identify emerging managed care pharmacy trends and to generate recommended strategies for healthcare payers and providers to harness upcoming trends and/or mitigate any potential negative impacts

Additional project objectives

- Develop an approach for trends assessment that is industry focused, practical, credible and reproducible
 - Leverage secondary research and IMS resources to evaluate how previously identified pharmacy trends have evolved, inform future trends and pinpoint potential solutions for harnessing these trends
 - Facilitate a live workshop with key managed care pharmacy and academic experts to process, evaluate and rank literature-based trend analysis and refine action plan
 - Generate a comprehensive resource, and accompanying streamlined presentation for use with managed care provider organizations and pharmacists, health care payers, policy makers, researchers, educators, media and other related stakeholders
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To meet these objectives, IMS proposed secondary research to inform trends and collaboration with thought leaders to validate findings

TREND HYPOTHESIS AND VALIDATION APPROACH



Across the engagement, a combination of evidence-based and expert opinion-based approaches will be used to identify and rank trends



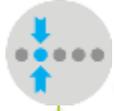
Identify Trends

Synthesis ●

Expert opinion-based ●

Evidence-based ●

- 1 **AMCPF /Pfizer hypotheses:** Begin with initial list of potential trends *Focus of today's presentation*
- 2 **Look back:** Focus on key data-driven trends based on historical information (*emphasis on peer-reviewed sources*)
- 3 **Evaluate emerging trends:** Focus on emerging/new trends distinct from historical trends (*emphasis on gray/informal sources*)
- 4 **Draft synthesis:** Conduct comparative analysis of compiled trends in draft task deliverable (*non-ranked*)
 - AMCPF/Pfizer to review preliminary findings and provide feedback



Refine/Process Trends

- 1 **SME signal detection:** Elicit information on individual SME-hypotheses for trends in a vacuum
- 2 **Stakeholder validation/refinement:** AMCPF/Pfizer and SMEs to review IMS deliverables to identify any gaps, provide support collateral or flag trends for removal
- 3 **Finalize synthesis:** Incorporate findings from SME signal detection and AMCPF/Pfizer feedback on draft deliverable to create final content that will be leveraged to generate workshop content



Rank Trends & Map Solutions

- 1 **Live workshop:** Engage SMEs to discuss, rank and map trends to solutions
- 2 **Develop results collateral:** Final report to outline methods, results and solutions
- 3 **Stakeholder review:** AMCPF/Pfizer and SMEs review to validate final conclusions

The content in today's draft secondary research presentation will be revised iteratively based on AMCPF/Pfizer feedback and SME input

**Draft
Deliverable
Presentation
Focus**

Step 1: Ensure we have a robust list of top emerging trends based on secondary sources

- Utilize search strategy (based on initial AMCPF/Pfizer trends) to conduct a targeted assessment of evidence on recent/emerging trends in the public domain
 - Synthesize evidence to identify top trends based on evidence-based findings and expert opinions reported in the public domain
 - Develop MS PPT presentation outlining secondary research methods and summary of prevalent trends expected to impact managed care pharmacy in the near future
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**AMCPF/
Pfizer
Review**

Step 2: Utilize internal review to validate and refine trends

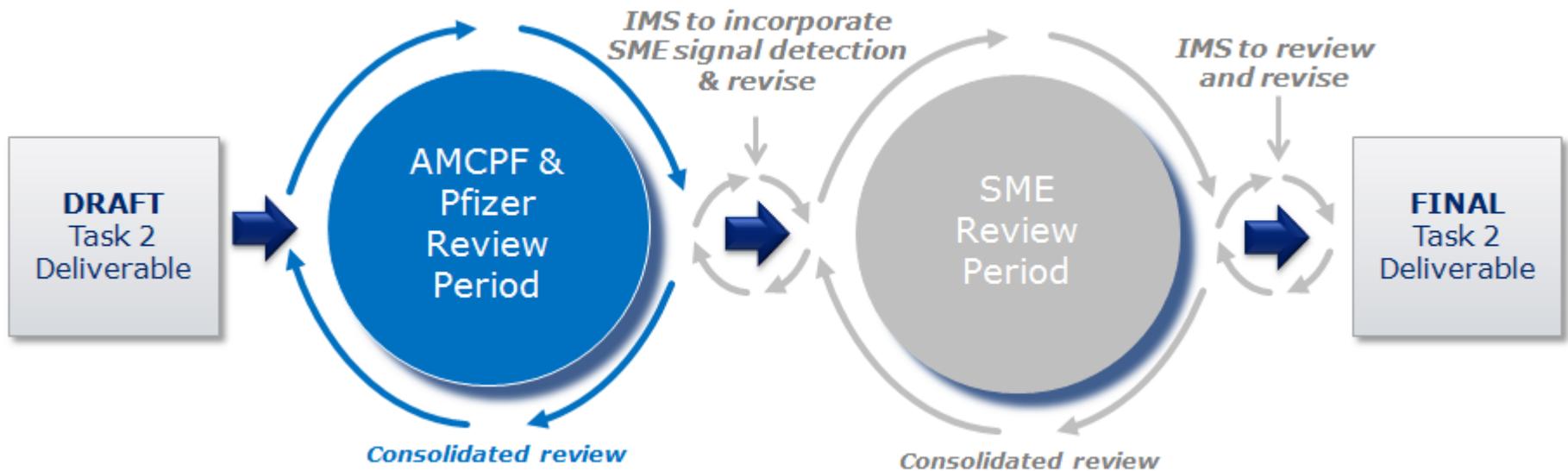
- Review the draft synthesis of the task 2 deliverable to flag questions, identify any gaps, provide support collateral or flag trends for removal
 - IMS to incorporate AMCPF/Pfizer feedback into the draft task deliverable
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**Incorporate
SME signal
detection**

Step 3: External feedback to validate trends and inform workshop collateral

- Elicit information on individual SME-hypotheses for trends in a vacuum as a first step post recruitment
- Summarize SME trends to generate a shortened list of emerging trends for discussion during the live workshop and identify potential data gaps to be filled via additional desk research
- Share a copy of the updated MS PPT presentation, complete with summary of SME signal detection, to gather additional feedback
 - This updated presentation will be leveraged to generate support collateral for the live workshop

After today's presentation, AMCPF/Pfizer will have a review period to process the information on the slides and provide feedback to IMS



- The AMCPF/Pfizer review should focus on high-level alignment, including:
 - Flagging any trends for removal (based on competing interests or stakeholder preferences)
 - Providing feedback on top priority trends from your organizations perspective
 - Outlining any questions for IMS feedback
 - *Note that detailed feedback on phrasing/naming/scoping is not required for this interim deliverable but will be important for the final project report (after the live workshop)*
- After the AMCPF/Pfizer review period, the deck will be updated to incorporate the results of SME signal detection (i.e., top trends based on SMEs) before sharing the content with SMEs for any high level feedback

Agenda



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Secondary research methods



Emerging themes from secondary research



Summary of secondary research findings

A targeted, structured review was conducted to gather information on evidence-based, or historical trends in managed care pharmacy

Search Limits: English, 2011-present (published articles); 2012-present (gray literature)

- Databases/engines for the peer-reviewed literature: **PubMed** and **Google Scholar**:
 - Base terms: “managed care” or “managed care pharmacy” (title/abstract); combined with key words related to:
 - Cost OR economic OR utilization
 - Data OR informatics
 - Specialty pharmacy
 - Patient outcomes OR patient adherence OR quality of care
- Gray literature sources (focusing on reports related to managed care pharmacy):
 - Government organizations (CBO, CMS, GAO, MedPac)
 - Managed care or pharmacy associations (AMCP, NAMCP, AAMCN, ASHP, AHIP)
 - Managed care organizations/specialty groups (Kaiser, Express Script, EMD Serono, AHA, VA, Robert Wood Johnson Foundation, NEHI, Brookings Institution)
 - Broader pharmacy/pharmaceutical related groups (PCMA, PhRMA)
 - Independent thought leaders (IMS institute, Deloitte Center for Health Solutions)
- Ancestral searches were also conducted to identify any additional studies of relevance or importance

Web searches were also conducted to gauge the pulse of public opinions on current trends and identify emerging trends

Search Limits: English, 2012-present, US-focused

- Given the project focus on emerging trends, it was important to identify themes with growing importance that may not have historical data or formal publications
- Therefore, web searches in Google were used to capture a variety of opinion-based publications, including news stories, editorials and special interest pieces
- Search terms included:
 - Managed care pharmacy
 - Managed care specialty pharmacy
 - Top trends in managed care pharmacy
 - Managed care pharmacy trends
 - Managed care pharmacy forecast
 - Managed care pharmacy AND cost
 - Managed care pharmacy AND utilization
 - Managed care pharmacy AND patient outcomes
 - Managed care pharmacy AND healthcare mega-trend

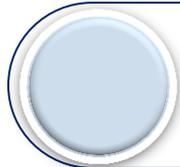
After filtering via abstract and paper screening, 120 sources were deemed relevant for inclusion in the secondary literature synthesis

| | PubMed | Stakeholder Reports | Google | Ancestral |
|-------------------------|-----------|---------------------|-----------|-----------|
| Search Results | 767 | - | - | - |
| Abstracts Screened | 115 | - | - | - |
| Papers Screened | 40 | 47 | - | - |
| Sources Included | 33 | 42 | 16 | 29 |

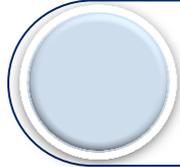
*Information from **120 sources** was reviewed and synthesized*

- Given the project emphasis on emerging trends, a large number of included sources were based on stakeholder reports and other gray literature documents (as opposed to peer-reviewed articles)
- The majority of sources focused on 'recent' or 'current' trends and evidence on emerging trends was more limited
- The most common method for identifying trends was interviews/web polling among members (associations, managed care plans) or a sample/random sample of affected stakeholders
- Empirical analyses of real world evidence (e.g., administrative claims) were used to identify current/recent trends but did not typically include forecasts or data-driven projections of emerging trends
- Generally, methods for identifying emerging trends were informal, including mostly high level discussions of possible trends/uncertainties based on the insights of a singular expert or sponsoring organization
 - The ASHP pharmacy forecast used one of the most formal methods for identifying appropriate specialists, quantifying information on projections and mapping issues to solutions

Agenda



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Secondary research methods



Emerging themes from secondary research



Summary of secondary research findings

Before reviewing the top themes from the public domain, let's outline some of the challenges in generating evidence-based findings

- Emerging themes in the public domain are generally nebulously defined, with limited consistency in phrasing, buzz words or mappings to topic areas
- Given the interconnected nature of the healthcare system, most trends are not mutually exclusive and may cover several concepts or interact with other trends
- Most identified trends were not mapped to the likely impact on managed care pharmacy but were instead discussed at a higher level in terms of their impact on health system dynamics, costs or patient outcomes
 - Note that SMEs will play a key role in connecting the most important trends to pivotal implications for managed care pharmacy for this engagement
- Very few publications focused on solutions for managed care and any solutions identified were commonly proposed as options for multiple emerging trends
- The level of focus of trends was high variable, with some reports discussing mega-trends, others focusing on a key event (ACA) and many covering a single internal/micro-level issue

Given the lack of uniformity in identifying, defining, categorizing and discussing themes in the public domain, a key objective of the final project report will be to establish an easy-to-understand framework for positioning our top themes

Most trends are interconnected and impact many parts of the healthcare system but we can organize them by main area of impact

- Healthcare reform and increased participation in 340B programs
- Moving from FFS to bundled payments
- Expanded use of value based benefit design models
- Healthcare reform and Medicaid expansion

Payments & Government



Pharmaceuticals & Manufacturers



- Spending/utilization for specialty pharmaceuticals
- Performance and market impact of biosimilars
- Growth in pharmaceutical innovation
- Growth of personalized medicine
- Use of big data for innovation and decision-making

- Consolidation/integration of healthcare stakeholders
- Changing role of employers in US healthcare
- Expansion of PCMHs
- Physician shortages and evolving care roles
- Growth and performance of ACOs
- Managing high cost, complex diseases
- Application of big data in patient care



Care Provision & Providers



Patients & Patient Outcomes

- Shifting financial risk to patients
- Growth of consumerism
- Role of technology in patient engagement

Please note that this mapping is presented to understand similarities and differences between concepts and is not a formal, validated framework **imshealth**



Spending/utilization for specialty pharmaceuticals

Current trends in increased utilization and spending for specialty medicines are expected to continue, contributing to increasing fiscal pressures for providing pharmaceutical care

- Recent data, empirical projections and industry experts agree that spending and utilization of specialty drugs are expected to grow over the next five years, comprising an increasing share of the total drug spend in the US
- The influence of healthcare reform (i.e., increased spend) and utilization management practices (i.e., reduce spend) introduce uncertainty into the future dynamics of the specialty care space

- Forecasts project that specialty drug spend will increase by about 17-20% annually and will consume 50% (or more) of the drug budget by 2018, surpassing the spend on traditional non-specialty medicines^{1,2}
- To date economic concerns have shown little impact on specialty utilization and use is expected to increase given the rush in specialty drug launches in 2013 (more than 40 estimated launches)³
- In a survey of forecast panelists, approximately 70% experts predicted that the number of drugs available only through specialty pharmacies will increase by 75% over the next 5 years⁴
- The “specialty by retail” model will continue to take shape as larger chains enter the specialty pharmacy marketplace⁵
- Cost drivers that contribute to the rising specialty drug spend within the managed care infrastructure may include: drug mix, the degree of provider reimbursement, member benefit design, distribution channel, the extent of utilization management, and the degree of operational effectiveness in paying claims correctly⁶
- Healthcare reform (driven by the ACA) may contribute to further increases in specialty drug spending, as health insurance coverage is expanded to new populations⁵

Key data gaps/uncertainties: The impact of healthcare reform on utilization of specialty medicines and performance of utilization management tools to control increasing costs/utilization

Expert opinion-based ●

Evidence-based ●



Performance and market impact of biosimilars

Biologic patent expiries are paving the way for biosimilars in the US and creating potential opportunities to reduce pharmaceutical spending from discounted biosimilar products

- Given looming patent expiries and the success of biosimilars in Europe, US stakeholders are anticipating biosimilars to impact spending (lower pricing) and prescribing practices in the US
- However, the lack of formalized regulatory guidance, uncertainty over procedures for evaluating/recommending use and the continued emergence of innovative treatment options may dampen the overall impact in the US market

- Between 2009 and 2019, nearly 21 biologics (estimated market value >\$50B) will go off-patent in the US¹
- Biosimilars are gaining use in Europe but the lack of final regulatory framework in the US has hindered growth by failing to address uncertainties around manufacturing, safety and reimbursement of these products¹
- However, it is generally assumed among experts that the US will have a developed biosimilar market by 2020²
- Surveyed pharmacy experts predicted that at least 25% of orders for expensive biologics will be filled with biosimilar products in the next 5 years³
 - Also, 90% of those surveyed predicted that P&T committees in at least 50% of hospitals within the next 5 years will have a formal process for evaluating biosimilars³
- Experts expect a 20% pricing discount from originator biologics, but the difference between CBO-recommended discounts (40%) and market discounts seen in Europe (10-15%) suggest uncertainty around likely US trends^{1,4}
- Further, the role of biosimilars in the US market may be limited if new patent-protected innovative products continue to displace older off-patent products²

Key data gaps/uncertainties: Final US regulatory framework on market access, impact of new innovative product entry and procedures for evaluating/using biosimilars in practice

Expert opinion-based ●

Evidence-based ●



Growth in pharmaceutical innovation

Recent – and projected- growth in pharmaceutical innovation is expected to escalate cost pressures for the US pharmaceutical market and increase complexity of care

- Pharmaceutical innovation is at an all-time high with record approvals and a robust clinical development pipeline focused on high cost diseases, biologic therapies and first in class treatments for new populations/indications
- However, the impact of most potential innovations will remain uncertain until late stage clinical development (reducing the ability for stakeholders to prepare for future challenges)

- Record numbers of FDA approvals in recent years signaled a boom in innovation that is expected to continue in the near future given the 6,200+ number of active products in the clinical development pipeline¹
- Innovation is heavily focused on products aimed at treating high cost diseases (approximately 2000 oncology products) as well as expensive biologics (more than 900 biologics in development)^{1,2}
- Given regulatory advances, drug development strategy is shifting from the historic “me-too” strategy to a “me-first” approach, with an increasing emphasis on orphan drugs, targeted treatments and new indications
 - Around 70% of products across the innovation pipeline are potential first-in-class medicines, representing new pathways or steps in care²
 - About 60% of ongoing pivotal trials for oncology agents are being conducted in indications with a target population of fewer than 12,500 patients³
- Given the current innovation pipeline, experts expect to see a shift from blockbusters in primary care to specialty and/or targeted blockbuster therapies³

Key data gaps/uncertainties: Successful transition of products in development from clinical programs to approved medicines with demonstrated health benefits

Expert opinion-based ●

Evidence-based ●



Growth of personalized medicine

Scientific advancements (including those in genomic testing and diagnostics) are supporting new approaches in drug development and the potential for more effective prevention, diagnosis and treatment through personalized medicine

- Pharmaceutical investment in personalized medicine, the declining cost of decoding genomes and expert opinions suggest increasing utilization of personalized medicine in the near future
- However, potential privacy issues as well as data gaps on the value of personalized medicine in a fiscally constrained system may mitigate use

- Between 2005-2010 pharmaceutical companies increased their personalized medicine investment by roughly 75% and investment is projected to increase by an additional 53% by 2015¹
- The majority of pharmaceutical manufacturers (est. 94%) are investing in personalized medicine research and 12% to 50% of the products in their pipelines are personalized medicines¹
- As the cost of decoding a person's genome falls in the coming years (projected to fall from range of \$10,000 - \$25,000 to approximately \$1000) additional opportunities to expand/build on personalized medicine will emerge²
- A majority of pharmacy experts predict that 20% or more of new molecular entities marketed each year will have an accompanying diagnostic test to support optimal patient selection and dosing³
- About half of pharmacy experts anticipate that the use of diagnostics will impact medication use, safety and efficacy in the next 5 years³

Key data gaps/uncertainties: considerations of the cost/benefit of genomics/diagnostics in practice (value for money), privacy concerns with personal data

Expert opinion-based ●

Evidence-based ●



Use of big data in innovation and decision-making

The use and availability of big data is growing in the pharmaceutical sector, creating novel opportunities for supporting innovation and enhanced use of evidence-based medicine in care decisions

- Data assets are growing rapidly and increasing integration and development of HIT infrastructure will present new opportunities to leverage data
- However, the availability of relevant, high quality data metrics is still low, which hinders use

- Given the rise in technology and increasing expansion of healthcare information technology (HIT), the potential for big data to support future care decisions is growing rapidly¹
- During the innovation phase, new forms of data including consumer-generated data, registries and administrative claims may present new approaches to clinical trials that allow for empirical conclusions on performance and safety without the significant cost investment from conventional approaches²
- The move from health data in paper records to large-scale digital data warehouses is permitting population-level analyses of changes in disease patterns, which will help in identification of target populations and in the evaluation of long term efficacy and safety with real-world evidence³
- Pharmacy experts anticipate the use of diagnostic or prescriptive analytics to effect medication use, safety and efficacy in the next 5 years and a quarter of them predict that a single standard source of drug information will be used to ensure data quality and consistency across all applications in the next 5 years⁴
- Also, many stakeholders have increased their expectations for launch product outcomes data over the past few years to focus not only on the level of data but the relevancy and quality of metrics, as exemplified by recent ASCO recommendations for meaningful clinical trial outcomes⁵
- Increases in available, relevant big data assets in healthcare are also expected to increase the use and performance of evidence-based decision tools (including CER) in optimizing patient care decisions⁶

Key data gaps/uncertainties: Health infrastructure to support data expansion, proprietary nature of healthcare data assets, impact of big data on healthcare decisions and delivery

Expert opinion-based ●

Evidence-based ●



Healthcare reform and Medicaid expansion

Medicaid expansion (triggered by health reform) will create business opportunities for managed care plans to increase coverage under managed Medicaid but increasing cost pressures will require tactics to improve efficiency while maintaining quality metrics

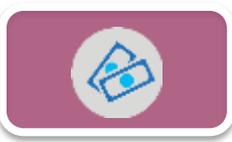
- Medicaid enrollment is projected to increase by over 18 million by 2021 and managed care plans are preparing to increase coverage (via managed Medicaid) by implementing new care models and cost containment policies to improve efficiency
- The ability of managed care to control costs while meeting quality metrics will be dependent on many new care models/reimbursement practices that have uncertain long-term performance

- Healthcare reform and the expansion of healthcare insurance (via health insurance exchanges, or HIX) is projected to increase Medicaid enrollment by about 8.7 million people in 2014 and by 18.3 million by 2021^{1,2}
- Most Medicaid plans use commercial payers to manage their members and administer benefits and, therefore Medicaid expansion presents a business opportunity for managed care payers to cover new patients³
- However Medicaid expansion is creating new burdens for State and Federal budgets that are already fiscally constrained, thereby increasing the focus on cost containment for Medicaid services and providers (including the CMS star rating system)⁴
- In an attempt to contain spending, an increasing number of States are implementing accountable care models for their Medicaid programs through patient-centered medical homes, episode-based payments, and patient-level accountable care payment reforms⁵
- Therefore, cost reduction and care efficiency are expected to be high-priority goals for Medicaid HMOs as they operate in a system that increasing expects more for less (improved outcomes with lower reimbursements)¹
- Managed care companies are already positioning themselves to participate in the large new markets by undertaking initiatives to reduce costs and improve efficiency in preparation lower payments⁶

Key data gaps/uncertainties: Impact of managed care on Medicaid spending; performance of cost-control activities on total spending and patient outcomes

Expert opinion-based ●

Evidence-based ●



Healthcare reform and increased participation in 340B

The expansion of 340B discounts to hospitals is driving a shift in site of care for cancer treatment/specialty care from community practices to hospitals, impacting pharmaceutical reimbursements and total cost of care

- Recent legislation and a more favorable reimbursement environment are driving increased participation in 340B programs and shifting care to hospitals
- The amount of future participation in the 340B program is uncertain given competing influences of administrative/regulatory burden and increasing consolidation

- Because of approximate 51% discount to AWP, eligible hospitals are encouraged to pull drug administration services into the more costly outpatient hospital setting, driving up total care costs^{1,2}
- The 340B program is expected to be heavily used by hospitals for managing specialty products as well, which may put pressure on manufacturers (discounts) and payers (higher reimbursement rates for services)^{3,4}
- A recent survey of experts in the pharmacy field predicted that there will be at least a 25% increase in the number of hospitals providing outpatient pharmacy services⁵
- However, this shift in care delivery may not be ubiquitous, as the program's complexity makes it hard for small facilities to participate unless they are part of a larger health system⁵
- Given this, 61% of recently polled experts concluded that participation in the 340B drug pricing program would decline by at least 25% in the next 5 years⁵
- However, increased consolidation of oncology practices with hospitals, via joint ventures and purchase agreements, may increase the number of large groups with the means to meet administrative/regulatory requirements, thereby contributing to greater shifts in care patterns⁶

Key data gaps/uncertainties: Level of participation in 340B program, payer/manufacturer responses to shifting care trends

Expert opinion-based ●

Evidence-based ●



Migration from FFS to bundled payments

Increased consolidation and cost pressures (including ACA) have driven the movement away from FFS models to bundled payments with the intention of creating better care alignment and incentives that minimize costs while maintaining high quality patient care

- Despite limited information on long-term performance, pilot initiatives for extended bundled payments are underway and use of bundled payments is expected to increase in coming years
- Information on the optimal design and long-term performance of bundled payments is unknown

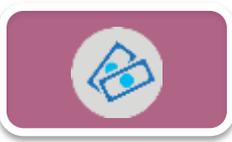
- Almost without exception, experts have recommended discarding the current fee for service (FFS) model in favor of having providers share risk for the cost and quality of services¹
- Research has shown that bundled payments can align incentives for hospital, post-acute care providers, doctors and other practitioners to partner closely across all settings that a patient may encounter to increase efficiency and reduce overall spending²
- The use of bundled payments is increasing and more than 500 hospitals are participating in a Medicare bundled payment initiative¹
- A recent poll of pharmacy experts revealed that nearly 85% of hospital pharmacists believe that most hospitals will be involved in at least one form/type of bundled payment by 2018³
- Payers representing more than half of covered lives in 2012 have begun to explore pilot programs that look at bundled payments for services with large, in-network oncology groups (>30% increase over the last year)⁴
- The optimal application of bundled payments in practice is uncertain, and advocacy groups recommend that payers should work with other stakeholders to jointly develop and test payments that balance cost containment while ensuring patients receive the best, evidence-based care²

Key data gaps/uncertainties: Long term performance of bundled payments in controlling costs while mainlining health outcomes, optimal design for bundled payments

Expert opinion-based ●

Evidence-based ●

1. Blumenthal 2013; 2. RWJF 2013; 3. Zellmer 2013; 4. Magellan Pharmacy Solutions 2012



Expanded use of value-based benefit design models

In the wake of consolidation, health reform and fiscal strain, value-based benefit design is emerging as a new – and potentially improved – approach to balancing care quality and cost by incentivizing use of optimal services

- Expected improvements in balancing cost containment with optimal patient/provider incentives have increased the popularity of value-based benefit design models
- However, the optimal design of such systems is unknown and preliminary research suggests that financial incentives may be inadequate to fundamentally shift care trends/patient behaviors

- Value-based benefit design is expected to provide a different lever on pharmacy management which will allow for the appropriate drug to be channeled to the appropriate patient¹
- Value-based benefit design has the potential to serve as an engagement tool across stakeholders. Using both direct and indirect data through health information technologies, communications and services, payers can invest in incentives that change behaviors to improve health, productivity, quality and financial trends²
- Earliest users of value-based reimbursement were forward-thinking employer groups who motivated patients to make healthy lifestyle choices through the use of incentives but more recently disincentives have become the norm, as payers have begun to penalize patients for poor health choices³
- With the implementation of value-based pricing for hospitals by CMS, pharmacists will play a key role in sharing medication-related measures of performance, resolving access issues, and ensuring continuation of drug therapy⁴
- However, in the community pharmacy arena, a model with financial incentives that emphasizes/rewards pharmacist information services will impact staffing levels and the amount of pharmacist time available for consultations⁵
- Though expert opinion suggests favorable predictions for performance, information on the optimal design of programs is uncertain and some early studies suggest that changing payment levels may not be sufficient to incentive care improvements (i.e., zero dollar copays do not improve adherence)⁵

Key data gaps/uncertainties: Optimal design of value-based benefit programs, long-term performance of value-based benefit design and impact on access, patient outcomes (adherence) and costs

Expert opinion-based ●

Evidence-based ●

1. Mahoney 2008; 2. Tzeel 2013; 3. Cruickshank 2012; 4. Zellmer 2013; 5. Owen 2014



Consolidation/integration of healthcare stakeholders

Cost pressures and healthcare reform are increasing consolidation across healthcare stakeholders, changing the balance of negotiating power across players and centralizing decisions on patient care

- The majority of experts expect consolidation (hospitals, insurers, and PBMs) to continue and to translate into improved patient management (via HIT, increased resources) while reducing costs from more favorable reimbursement and increased efficiency
- However, the advantages of consolidation (administrative efficiency, HIT gains) will need to be balanced against potential impacts on patient choice (and subsequent health outcomes)

- Oncology practices are increasingly consolidating and joining hospitals due to lower Medicare reimbursement rates, and recent legislation making it easier for hospitals to qualify for increased 340B drug discounts¹
- Healthcare experts are predicting that 20% of the nation's hospitals will seek to merge in the next 5 to 7 years, driven by increasing pressures to lower costs, increase efficiency and improve quality²
- Hospital conglomerates are purchasing medical practices and individual physician practices, potentially increasing costs to payers while reducing patient choices³
- Similarly, PBM consolidations are rising and are expected to continue, with independent specialty pharmacies and smaller PBMs being purchased by larger players⁴
- These larger PBMs will have more negotiating power with pharmacies/managed care/insurance exchanges and may start to centralize decisions (e.g., drug coverage) that impact patient management⁴
- Advantages of consolidation may include improved administrative efficiency and an increased ability to invest in, and increase, the use of health information technology and integrated data assets²
- Opponents of consolidation warn that potential monopolies may form and subordinate the individual (consumer) in the value chain and hamper or remove the patient's freedom to choose³

Key data gaps/uncertainties: Impact/interplay of consolidation on administrative efficiency, negotiation power across stakeholders, patient choice and HIT

Expert opinion-based ●

Evidence-based ●

1. Genentech 2012; 2. Enders 2014; 3. Brooks 2012; 4. Hernandez 2013



Changing role of employers in US healthcare

The role of employers in the health system is shifting from “defined benefits” to “employer activism” that includes dropping benefits or taking an active role in cost control and encouragement of health lifestyles

- Employers are increasingly moving employees to health insurance exchanges and actively seeking strategies to reduce costs for covered employees, especially for high cost diseases such as oncology
- The impact of increasing employer-spurred shifts to HIX and employer-sponsored cost control tactics on patient outcomes and overall healthcare spending remains uncertain

- Surveyed employers cite that their main goals are to contain costs, encourage healthily lifestyles (i.e., wellness programs and incentives), and improve quality of life¹
- Employers are increasingly requesting that payers provide cost-control initiative programs for oncology that ensure appropriate use, access and methods to provide more benefit with less cost²
- More than half of surveyed employers (N=101) have purchased (or plan to purchase) stop-loss coverage to manage the risk of high-cost cancer care that includes drug therapy costs, which was identified as the most significant driver of the overall costs of cancer care³
- Innovative employers are using approaches including contracting with single provider, establishing direct-to-employer primary care services at clinics located in or near the employer, shared financial responsibility with employees, and focused efforts in employee wellness and prevention^{4,5}
- Healthcare reform is expected to cause the employer-sponsored insurance market to shrink⁶
 - Current evidence suggests that companies are increasingly sending retirees and active employees to online marketplaces to reduce administrative burdens while providing employees more choices⁷

Key data gaps/uncertainties: Impact of changing employer role on patient, magnitude of impact of HIX on employer role/coverage

Expert opinion-based ●

Evidence-based ●



Expansion of patient-centered medical homes

Patient-centered medical homes (PCMH) are an evolving, emerging model of care that is projected to produce improved fiscal and health outcomes through efficient, coordinated care and the use of EBM

- Proponents of PCMHs believe the integrated, patient-centered approach to care is optimally design to ensure care efficiency across the changing treatment/financial landscape
- However, evidence from pilot programs is not consistent and the long-term performance of PCMHs is uncertain, especially under changing reimbursement conditions

- PCMHs are an emerging care model that focuses on care coordination and evidence-based medicine with the hope of achieving both cost containment and improved patient outcomes in the midst of increasing treatment complexity and shifting reimbursement models¹
- Proponents of PCMHs suggest that this care approach will be essential in the future to ensure that care delivery adapts to trends in patient/family involvement in care decisions (consumerism), integrates EBM into routine practice, and increases use of HIT/EMRs in tracking/evaluating care¹
- The use of PCMH is expanding and most states have some form of a PCMH in place with similar components, such incentives to reach or exceed agreed-upon quality benchmarks²
- Evidence on the performance of PCMHs is predominantly based on pilot studies, with early trends commonly suggesting cost savings and quality improvements²
- However, some early pilots in oncology suggest uncertainty in performance, with some evidence showing that PCMHs support optimal alignment between payment incentives and a patient-centered care approach while others report that changes/improvements in care behavior were not reported^{3,4}

Key data gaps/uncertainties: Impact of future reimbursement/financial changes on care delivery in PCMHs, long term performance of PCMHs in controlling cost and improving care quality

Expert opinion-based ●

Evidence-based ●



Physician shortages and evolving care roles

Physician shortages and the changing US healthcare landscape are contributing to fundamental shifts in roles for physicians and non-physicians in providing care

- Physicians are taking on new roles in care coordination for complex diseases while non-physicians are increasing their roles in primary care and less complex diseases to mitigate the impact of physician shortages and the changing healthcare landscape
- However, the long-term impact of these changing care roles on healthcare costs and patient outcomes is uncertain and future changes in the US healthcare system will be a continuing complexity

- Current utilization patterns suggest that by 2020 there will be a shortage of 91,500 physicians, including 45,400 primary care physicians and 46,100 subspecialists¹
- Given increases in newly insured persons (under ACA) and a growing emphasis on care coordination, the demand for physicians and other clinicians will only continue to grow and exacerbate shortages²
- Further, physicians are being asked to take on new roles. In a recent national survey of case managers, 63% of physicians reported that more than half of their day is dedicated to performing coordination activities but 80% reported being “not at all knowledgeable” or only “somewhat knowledgeable” about the new care coordination provisions under the ACA³
- Other healthcare stakeholders including nurse practitioners (74% of HMOs license NP for primary care), pharmacists, medical assistants, and community health workers are gaining/will continue to gain a greater role in patient care and case management to overcome physician shortage⁴⁻⁹
- Continued shortages, rising costs, standardization of practices and increased technology is projected to spur dramatic changes in who treats who – with physicians taking on coordination activities currently performed by specialists and non-physicians taking on less complex care and drug management activities^{4,10}

Key data gaps/uncertainties: Impact of changing care roles on healthcare spending and patient outcomes, ability for care delivery to keep pace with changing healthcare landscape

Expert opinion-based ●

Evidence-based ●



Growth and performance of ACOs

The accountable care organization (ACO) model is expanding in the US under the expectation that their design and focus on care coordination can provide the right care to the right person at the right time

- Preliminary information from pilot trends and expert opinion suggest that ACOs are likely to have a positive effect on health and fiscal outcomes
- However, ACOs are still in nascent states and uncertainty exists around the projected level of uptake in the US, the optimal design of systems and the full impact of ACOs on quality, outcomes and cost over time

- ACOs are expanding across the country and more than 400 were in place as of January 2013, with ACOs sponsored by physician groups and hospital systems seeing the fastest growth¹
- The goal of the ACO is to incentivize doctors, hospitals and other providers to coordinate care within a system that can leverage integration to promote administrative efficiency, evidence-based medicine and utilization of HIT^{2,3,4}
- Preliminary data from private-sector ACO models and Medicare ACOs suggest a strong start, demonstrating initial quality improvements alongside net savings per patient, but no single ACO model has emerged as most successful^{5,6,7}
- Government stakeholders (CMS) promoted ACOs given expected savings and recent surveys of pharmacy/medical directors suggest that experts share predictions of savings, with 76% of respondents projecting savings of 1-30% and 4% expecting savings of 40% or more^{8,9}
 - Proposed savings drivers include greater adherence to evidence-based treatments, improvement in coordination of care, integration/use of HIT and greater use of low-cost alternative treatment options⁸
- However, experts question whether savings can be realized from improvements in conventional quality metrics alone, citing concerns over a lack of focus on efficiency and incomplete quality of care measures (e.g., lack of focus on adherence)⁹

Key data gaps/uncertainties: Final uptake of ACOs in the US, overall impact on cost, quality and patient outcomes

Expert opinion-based ●

Evidence-based ●



Managing high cost, complex diseases

Robust innovation has increased treatment complexity and pharmaceutical spending in a number of disease areas, requiring solutions to manage cost pressures and address shifting treatment paradigms

- Spending trends indicate that pharmaceutical costs are highest for a small number of complex diseases and trends are expected to increase in time with continued innovation
- Providers are taking action to address rising costs and complexity but the impact of external factors (payment reform) and the long-term performance of proposed solutions is unknown

- Total spend in specialty pharmaceuticals is clustered within a small number of treatment areas, with the top four classes (inflammatory, MS, cancer, HIV) representing around 75% of total spend in recent years^{1,2}
- Inflammatory conditions and MS were historically high cost areas but oncology is becoming a leading area of cost increases that is forecasted to be the number one therapeutic area for spending in developed nations by 2017³
- Robust innovation is driving cost pressures and increasing treatment complexity, with many therapies focusing on new indications, new combination approaches, new populations and personalized treatments³
- Improved care coordination through new care models (PCMH, ACO), increased use of evidence-based medicine (including comparative effectiveness research, clinical guidelines/algorithms and big data) and care coordination are touted as potential solutions for providers to address rising costs and treatment complexity^{4,5}
- In a recent survey of pharmacy experts, panelists predicted that at least 75% of hospital pharmacists will devote the majority of their time as team members to manage complex medication use⁶
- Similarly, specialty pharmacy providers (SPPs) expect more plans to mandate the use of SPPs for all types of oncology agents) to ensure optimal use of medicines and restrict inefficient use⁷

Key data gaps/uncertainties: Result of interplay between rising costs/treatment complexity and provider approaches to managing diseases, impact of fiscal pressures on patient access in high cost diseases, impact of robust innovation pipeline

Expert opinion-based ●

Evidence-based ●



Application of big data in patient care

The increasing role of health information technology (HIT) in patient care has the potential increase the use of evidence-based care and support novel insights through predictive analytics

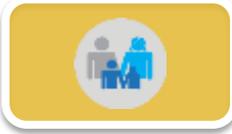
- Use of EMRs is increasing rapidly and many experts predict that this newly acquired data will be translated into action via integrated data assets and predictive analytics in the near future
- However, the adoption of fully functional HIT systems has been limited given the resources and organizational commitment required to establish the technology architecture

- Healthcare organizations are leveraging big data to get more complete patient insights, support care coordination, design outcomes-based reimbursement models, and facilitate population health management^{1,2}
- The use of EMRs and electronic data is growing, with recent surveys showing increasing trends in use across providers and high levels of use (more than 75%) in oncology^{3,4,5}
- Forward looking discussions are focusing on the application of data from electronic records in care provision, with a recent poll of pharmacy experts revealing that more than half of those surveyed anticipate the use of diagnostic or prescriptive analytics to effect medication use, safety and efficacy in the next 5 years⁴
- Further, 25% of respondents predicted that a single standard source of drug information will be used to ensure data quality and consistency across all applications in the next 5 years (which assumes that pharmacy will resolve current data issues)⁴
- A recent survey of physicians indicated that more than half believe that at least some progress is being made in using HIT to ensure patient safety, improve patient care and advance evidence-based medicine⁵
- However, the anticipated productivity gains of health IT are being hindered by the sluggish pace of adoption, the reluctance of many clinicians to invest the considerable time and effort required gain competency, and the failure of many health care systems to implement the process changes to fully realize health IT's potential^{6,7}

Key data gaps/uncertainties: Ability to leverage/link electronic data to gain insights, level of organizational commitment to establish data architecture to support robust HIT

Expert opinion-based ●

Evidence-based ●



Shifting financial risk to patients

Employers and managed care plans are shifting financial risk to patients in an effort to curtail costs and incentive patient involvement in care but potential gains from increasing patient cost share come with implications for adherence, preventive care and access

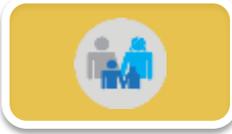
- Employers (HDHP) and managed care plans (increased co-pay/co-insurance) are increasingly shifting costs to patients to achieve reductions in overall costs
- However, new/improved solutions are needed to address the negative outcomes associated with increased patient cost-sharing (e.g., adherence, access, preventive care)

- High-deductible health plans (HDHP) are now the primary benefit offering for 13% of US employers (~20% of Americans with employer-sponsored coverage) and recent polling suggests that more than 40% of employers are considering offering only HDHPs in the future^{1,2,3}
- Further, many plans have implemented a pharmacy benefit that shifts a greater proportion of drug costs to the patient through the use of higher co-payments (especially in high cost areas like oncology)^{4,5}
- Trend reports based on administrative claims indicate that co-insurances increased from 20% to 26% and average copayments increased from \$46 to \$75 in recent years, and cost sharing can be exponentially higher for specialty medicines⁶
- Increased patient cost sharing has been associated with reductions in care costs, with most estimates of first year savings showing reductions of 12-50%⁷
- However, cost sharing may impact access, as the typical plan deductible exceeds the average family's savings³
- Increased patient cost-sharing has been associated with reduced patient adherence, increased treatment abandonment, reductions in preventative care (even when free) and reductions in necessary services for vulnerable populations (chronic illnesses, low incomes)^{1,3,4,8}

Key data gaps/uncertainties: Impact of HIX on uptake of HDHP, patient access under increased cost sharing, performance of solutions to address access/adherence issues

Expert opinion-based ●

Evidence-based ●



Growth of consumerism

Increased availability of healthcare information and shifting costs are increasing consumer engagement and creating an era of consumerism where the patient role in care decision-making is enhanced

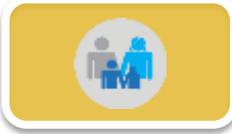
- The documented growth in available, transparent healthcare information via technology and surveys of patients indicate that individuals are becoming more engaged in care decisions
- However, potential information overload and uncertainty around health literacy in the US may hinder the ability of patients to become informed consumers who can make optimal care decisions

- Increased patient engagement could significantly improve outcomes and reduce costs, as more than 75% of spending results from many chronic diseases that are manageable/preventable through the right behaviors¹
- Price-sensitive consumers are distinguishing high-quality care from high-cost care. Recent polling surveys report that a majority of consumers (66%) believe that expensive medical treatment does not equate to better quality and more than 60% indicated that the effectiveness of a treatment was very important when making decisions about care²
- Consumer satisfaction/preferences will play an increasingly important role as patients take on greater cost sharing and have options to move between care providers, hospitals and even managed care plans^{3,4}
- Health plans are already working to shift their business models to serve cost-conscious consumers, recognizing that many will be willing to accept narrower networks and limited formularies in exchange for lower costs⁵
- Looking ahead, experts believe that it is at least somewhat likely that 50% of consumers will use quality of care data on the internet in selecting providers⁶
- Increased provider cost and quality transparency could prompt consumers to change treatment decisions, especially as the "information everywhere" phenomenon increases with smartphones and other technologies^{3,4}

Key data gaps/uncertainties: Level of health literacy among patients, quality of data to inform patient-decision making

Expert opinion-based ●

Evidence-based ●



Role of technology in patient engagement

The rise of technology in healthcare is creating opportunities for increased patient engagement

- Consumers, mainly younger patients, are increasingly using mobile health technologies to engage in managing their health and providers are increasing use of technology to increase patient engagement
- The long-term success of technology in engaging patients and improving care may be impacted by privacy concerns, health literacy and health infrastructure for IT

- Consumers are increasingly adopting mobile health technologies to assist in their care planning and decision-making and over one-quarter of consumers (N=1,000) indicated that they use mobile apps to schedule healthcare appointments¹
- However, early evidence shows that demographics such as age play a large role in use of mobile technologies. Older patients use medical services more frequently but younger patients (25-44 years) utilize mobile technology to communicate with providers almost twice as much as older patients¹
- Nearly 60% of physicians and insurers believe that widespread adoption of mobile health applications will be a key future trend impacting care delivery¹
- Technological innovations are being encouraged by providers to increase the participation of patients in their own healthcare. For example, communication technologies (texts and emails) are also part of the outreach strategies that effectively extend the patient-provider relationship beyond the clinic and into patients homes²
- In a survey of 21 specialty pharmacy providers, more than 65% reported using smartphone and tablet applications to engage the patient with medication and dose reminders, proactive messaging to improve adherence, and patient education regarding treatment plans and disease information³
- However, long-term success of technology integration in healthcare will be impacted by privacy regulations, sufficient infrastructure/analytics to support HIT and health literacy among patients⁴

Key data gaps/uncertainties: Patient privacy, health literacy, technological integration into delivery and outcomes tracking

Expert opinion-based ●

Evidence-based ●

1. PwC Health Research Institute 2013a ; 2. Cruickshank 2012; 3. Genentech 2012; 4. Enders 2014

The preceding slides outlined emerging themes prevalent in the public domain, however several wildcard themes may also be relevant for further consideration

Note that aspects of several wildcard trends were highlighted in the preceding slides (as relevant)

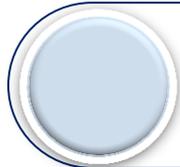
- **Healthcare everywhere:** Experts anticipate that over the next decade, as much as 50% of services will move from hospitals and clinics to homes and communities. New tools (smartphones, remote sensors/monitoring) will empower consumers with more information and control over their healthcare decisions¹
- **Health literacy and HIX:** Transparency of health information in HIX will need to be balanced against patient health literacy. Previously, many consumers could rely on their employers to make key decisions on coverage options. However, patients now must play an active role in making decisions on their own healthcare. Optimal decisions will be dependent on a sufficient level of health literacy across consumers participating in the new “retail” purchasing environment under HIX²
- **E-Prescribing:** E-prescribing may increase efficiency and could also assist with risk evaluation mitigation strategies that are needed for many specialty medicines³
- **CMS Medicare Star Rating:** Reimbursement in Medicare plans will be driven by CMS star ratings^{4,5}
- **Value for Money:** Patients/providers/payers are demanding value for money for healthcare, increasing their awareness of costs and consequences of decisions⁶
- **Focus on the whole patient:** The increasing use of value-based reimbursement and quality-based payments are requiring that many providers move beyond current roles to promote health outside of their care setting (e.g., hospital pharmacists focusing on drug maintenance after discharge)⁷
- **Defining “value”:** Unlike several European systems, the US lacks formal metrics for defining “value” in care (like a QALY in the UK), which may present barriers to effectively creating value-based reimbursement/care models⁸

Very few publications focused on solutions for managed care and any solutions identified were commonly proposed as options for multiple emerging trends

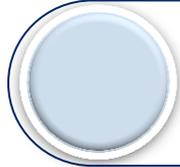
The identification of recommended, actionable solutions will be a key focus of the live workshop, as the choice of solutions will be informed by expert opinions on top solutions and likely implications for managed care pharmacy

- **Comparative Effectiveness Research (CER):** CER is a “sharp tool” for guiding change towards enhanced health in the population by delivering comparative, precise information on optimal options. Differences in coverage/formulary decisions across plans suggest that managed care may not be doing all it can to utilize this effective tool¹
- **Patient-centered programs:** Health plans are working closely with patients on programs that help increase medication compliance, promote rewards for seeking health appraisals and meeting personal goals, and provide low-cost or no-cost coverage for certain preventive and other high-value benefits³
- **Generics utilization:** Maximizing use of generics can help contain drug costs⁴
- **Utilization management tools:** Creating the optimal mix of utilization management practices for high cost treatments and complex disease areas can support efficient use of available treatments²
- **Changes in benefit design:** Specialty pharmacy management goals will include improving adherence, increasing rebates, and reducing variability between pharmacy and medical benefit cost share (commercial and Medicare) and managing medical benefit drugs (Medicaid)⁵
- **Disease/population health management:** Wellness programs, disease management, mental/behavioral health support systems, real-time decision-support, case management, customer segmentation, and tailored protocol/rules based on disease etiology can improve efficiency in care while supporting improved patient outcomes⁶
- **Trends as solutions/leveraging emerging trends:** Several trends outlined in the preceding slides were cited as potential solutions to emerging issues, including but not limited to: patient centered medical homes, accountable care organization, bundled (or global) payment approaches, value based benefit design, increased use of big data/health information technology

Agenda



Project background and objectives



Secondary research methods



Emerging themes from secondary research



Summary of secondary research findings

Moving forward, internal (AMCPF/Pfizer) and external (SME) input will be used to validate, refine and eventually rank top trends

- Healthcare reform and increased participation in 340B programs
- Moving from FFS to bundled payments
- Expanded use of value based benefit design models
- Healthcare reform and Medicaid expansion



- Spending/utilization for specialty pharmaceuticals
- Performance and market impact of biosimilars
- Growth in pharmaceutical innovation
- Use of big data for innovation and decision-making
- Growth of personalized medicine



- Consolidation/integration of healthcare stakeholders
- Changing role of employers in US healthcare
- Expansion of PCMHs
- Physician shortages and evolving care roles
- Growth and performance of ACOs
- Managing high cost, complex diseases
- Application of big data in patient care



- Shifting financial risk to patients
- Growth of consumerism
- Role of technology in patient engagement



- Healthcare everywhere
- Health literacy and HIX
- E-prescribing
- CMS Medicare star rating
- Value of money
- Focus on the whole patient
- Defining value

Wildcard Trends

Note: A summary of SME signal detection will be added to the deck after SMEs are recruited to identify the most important trends for the live workshop

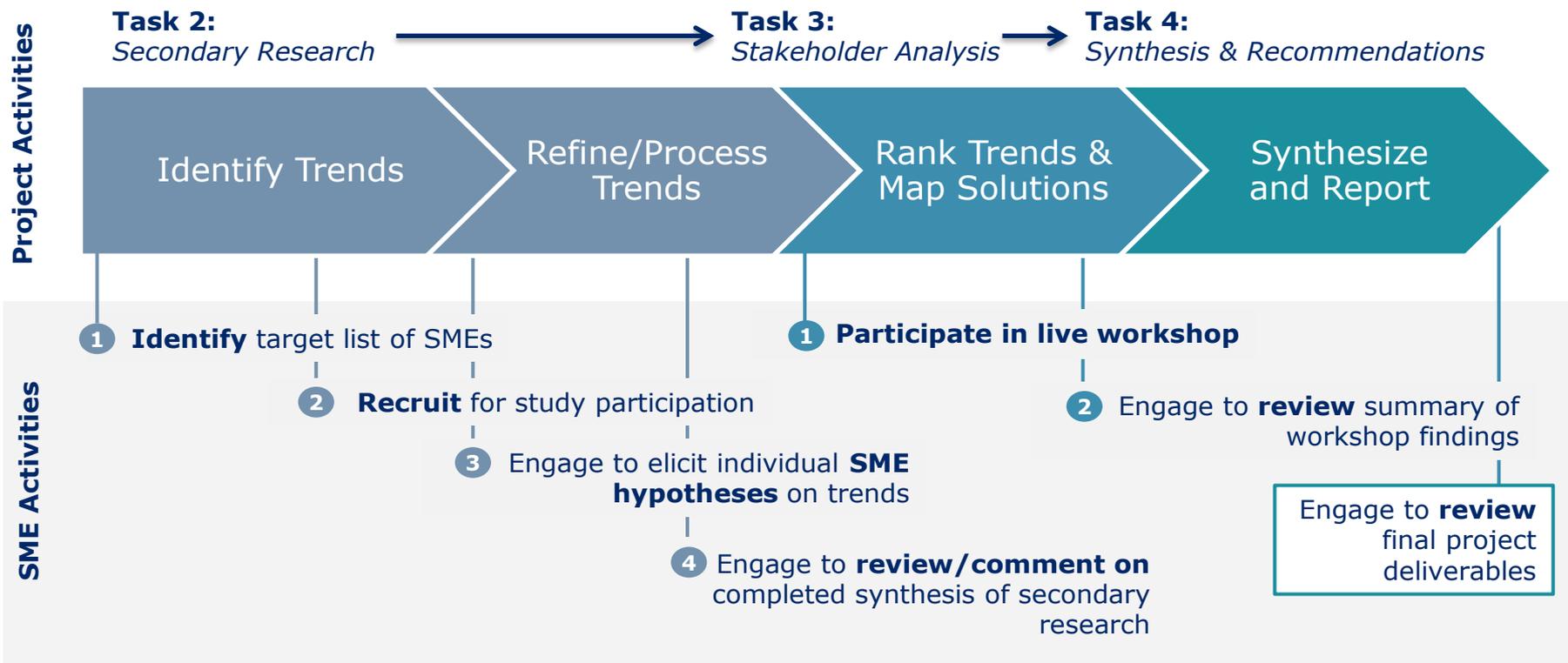
Appendix

Overview of SME activities

Bibliography of cited sources



SMEs will be identified and recruited early in the engagement to enable their participation across the project continuum



Identifying SMEs

- Recommendations for AMCPF board members
- Insight from internal IMS experts
- Recommendations from AMCPF/Pfizer
- Names emerging from secondary research

Screening/Qualifying Appropriateness

- Develop matrix to map SMEs across stakeholder groups and emerging themes
- Where relevant, review publications/work by target SMEs to ascertain perspectives (strategic, academic)
- Recruit to achieve optimal mix of academic and managed care SMEs

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