exportation of pharmaceutical products by target countries has also been gathered through library and the Internet researches. RESULTS: The result of study regarding rate of export showed an increasing rate (each year growth) of 20%, (from 1348 to 2881 million $), 18% (from 1978 to 3777 million $), 10% (from 193 to 293 million $) for India, China and Jordan respectively as developing countries during 2005. 44% (from 2415, 672 million $), 40% (from 1450 to 3483 million $) for Spain and Canada in the same period of time as developed countries. Iran's pharmaceutical export reached to 6.4 from 3.5 million $ in the same period. CONCLUSIONS: While Iran based on a successful reporting situation at the same period of time. India, Jordan, Spain and Canada have taken successful steps in the field of exportation during recent years by implementing desirable exports expanding policies; it seems that Iran has not experienced a successful exporting situation at the same period of time so via either model. Each has unique implications for Medicare reimbursement, programs appropriately within the context of their facility's mission and hospital operations and beneficiary financial responsibility. With informed knowledge of the options, hospital decision-makers are better prepared to position infusion programs appropriately within the context of their facility's mission and capabilities.

PHP53

APPROPRIATE CLASSIFICATION OF HOSPITAL INFUSION SERVICES: MEDICARE REIMBURSEMENT CONSIDERATIONS

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OBJECTIVES: The appropriate and accurate classification of outpatient infusion services is a strategic hospital responsibility having widespread operational impact. Site of care designation, specifically whether a service setting is provider-based or non-provider-based, determines the mechanism of Medicare payment and dictates the program structure required for operational compliance. This project was designed to review models of hospital outpatient drug administration services; discuss the Medicare reimbursement implications, and illustrate options for hospital planning.

METHODS: The history and evolution of provider-based criteria was arrayed along a timeline and the relevant regulations and legislation cited. The provider-based definitions and criteria were described and the concept of “incident-to the physician’s services” was explored as a Medicare requirement. Provider-based and non-provider-based models were compared and contrasted for the following characteristics: functional appearance and processes; Medicare billing and payment, and patient financial responsibilities. Hospital strategic choices were reviewed. RESULTS: There are two primary model options for hospital outpatient infusion service delivery: provider-based and non-provider-based. The provider-based model allows infusion services to operate as a hospital department and to bill and receive payment from Medicare under the outpatient prospective payment system, as long as the regulatory definitions and criteria are met. Non-provider-based infusion services operate as a medical practice model, allowing the hospital to bill and receive payment from Medicare under the physician fee schedule. CONCLUSIONS: Hospitals choosing to offer infusion services may do so via either model. Each has unique implications for Medicare reimbursement, hospital operations and beneficiary financial responsibility. With informed knowledge of the options, hospital decision-makers are better prepared to position infusion programs appropriately within the context of their facility's mission and capabilities.

PHP54

RECOMMENDATIONS FOR ORPHAN DRUGS IN TWO EU MEMBER STATES—A FOCUS ON THE UNDERLYING PHARMACOECONOMIC EVALUATIONS

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OBJECTIVES: In the Netherlands, orphan drug developers can be exempted from providing a full pharmacoeconomic evaluation when applying for reimbursement, whereas in Scotland no such exceptions can be made. METHODS: All orphan drug reimbursement reports from the Dutch reimbursement institution (CFH) and guidance issued by the Scottish Medicines Consortium (SMC) were collected. RESULTS: 38 orphan drugs were submitted to the CFH, 37 to the SMC. Only one CFH submission included a full pharmacoeconomic evaluation, while almost all SMC submissions did. The CFH gave positive recommendations for reimbursement for 36 submissions (95%). In contrast, of the 37 SMC submissions, 19 (51%) received a positive recommendation for use. Half of the SMC submissions reported an unfavourable cost-effectiveness outcome; almost all of these received a negative recommendation. CONCLUSIONS: Differences in policies and requirements for submissions for orphan drugs can explain discrepancies in reimbursement and guidance for use decisions between Scotland and the Netherlands.

PHP55

THE ROLE OF PHARMACOECONOMICS IN DRUG REIMBURSEMENT DECISION-MAKING IN THE NETHERLANDS

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OBJECTIVES: Since 2005 it is obligatory in the Netherlands to submit pharmaco-economic evidence for innovative drugs. The aim of our study is to describe the role of pharmacoeconomics in decision-making in the Dutch reimbursement system. METHODS: We used the analytical ‘fourth-hurdle’ framework for assessing ‘fourth-hurdle’ decisions in the Dutch reimbursement system. We examined policy documents, explored literature and conducted interviews with policy makers and representatives of the pharmaceutical industry. RESULTS: Different schemes exist for inpatient and outpatient drugs. Expensive hospital drugs obtain positive decisions without extensive pharmaco-economic evidence. After a period of three years, it is required to submit evidence on real-world cost-effectiveness. However, the first reassessments are yet to be conducted. In contrast, innovative outpatient drugs are only reimbursed after an assessment of the pharmaco-economic evidence. The Dutch Health Care Insurance Board and the Pharmaceutical Advisory Committee advise the minister on the robustness of the cost-effectiveness evidence, whereas the latter takes the role of the ‘fourth hurdle’. Once recently, assessment and appraisal have become two separate phases in decision-making. The impact of the appraisal committee is still unclear. The near future will show if they take the lead on advising on value for money. No party has taken up this role until now, only the Council for Public Health and Healthcare suggested a threshold range. The industry, however, anticipates that the new committee just adds another hurdle. CONCLUSIONS: The importance of pharmaco-economics has increased in Dutch drug reimbursement decision-making, but plays an uncertain role. It seems that the ‘fourth-hurdle’ system is more lenient towards expensive inpatient and orphan drugs.

PHP56

GLOBAL PRICING AND REIMBURSEMENT (P & R) TRENDS: FURTHER OPPORTUNITIES IN SUPPLY AND DEMAND SIDE CONTROLS FOR MEDICINES

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OBJECTIVES: The mature health economies as exemplified by the G7 Countries have developed collectively a plethora of supply and demand side controls to control access to medicines. Health Policy makers, Payers and Health insurance bodies are expected to utilize new P & R tools to ensure value for money. A survey was undertaken amongst health policy experts to understand trends in P & R. METHODS: Over 2008-2009 23 health policy experts were interviewed from 7 health economies. Specific examples of new and emerging policy reforms were sought with insights requested into how the market access landscape is likely to be transformed over the next decade. P & R tools were classified using the well recognized taxonomy of supply and demand side controls. RESULTS: There is harmonization of thinking amongst health policy leads that unregulated access to medicines is not a sustainable option. The EU has a long established group of P & R policy tools to choose from. New initiatives such as flexible pricing and innovative patient access schemes are becoming more prevalent. In the US an absence of supply side initiatives at a Government level leave individual States to negotiate on Medicare programmes. New policy initiatives emerging include a focus on cost-effectiveness and health economics to prioritize drug spend. CONCLUSIONS: The EU markets have to date led the way in developing innovative P & R tools, but even within these markets, tools have had various degree of success in terms of overall cost containment. However, the US demonstrated to be the most dynamic health care system likely to undergo policy reforms in the near future led by the American Rescue and Recovery Act (ARRA). Although there are clear differences, the recently announced changes may result in a closer resemblance between the US and EU P & R markets.

PHP57

MEDIACRE DRUG PAYMENT AND PHARMACY HANDLING COSTS: HOW FAR HAVE WE COME?

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OBJECTIVES: A fundamental assumption of Medicare’s rate setting methodology for Specified Covered Outpatient Drugs (SCODs) is that pharmacy overhead and handling costs are included by hospitals in their drug charges. Provider reported data does not consistently support that assumption. This study explores the history and current status of this debate and presents additional evidence of the continued variability in hospital drug charge composition and reporting. METHODS: Preparation input included review of legislation and Medicare regulations relevant to outpatient drug payment and pharmacy overhead. Historic discussions of pharmacy costs and charges were identified and accumulated in an indexed database. Data regarding the nature of hospital drug charges were collected from a 2008 hospital survey (n = 356). RESULTS: Historic analyses of Medicare’s rate setting methodology for SCODs support the hypothesis that hospitals may be underpaid for these products, due in part to underestimation of the related costs for pharmacy handling and services. Medicare’s methodology relies upon hospital reported charges submitted on the cost report. The hospital survey revealed that 40% of the respondents do not include in their drug charges amounts for anything beyond drug acquisition cost. CONCLUSIONS: Medicare’s outpatient drug payment rates continue to be derived from hospital charges which have demonstrated wide variability in recognizing pharmacy overhead costs. Although there have been recurring recommendations to Medicare for rate setting methodologies that can adequately address drug handling as well as acquisition costs, outpatient hospital drug reimbursement has now declined for two consecutive years. Failure to resolve this issue may threaten the ability of hospital providers to continue to offer outpatient drug services.