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A Current Look at Value-Based Insurance Design (V-BID) – What do we know today about V-BID’s ability to control health plan costs and improve the quality of health care

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A Current Look at Value- Based Insurance Design (V-BID) – What do we know today about V-BID’s ability to control health plan costs and improve the quality of health care.

Capstone

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11/30/2018

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Section 1: Introduction and Background for Capstone

This report is for the Capstone requirement to complete a Masters in Health Care Policy and Management from Muskie School of Public Service at University of Southern Maine. The subject of this Capstone resulted from the coursework completed at the University, employment in the insurance industry working in the area of health care benefit development and implementation as well as quality measurement and improvement, and a strong interest in developing new ways to improve health care quality and contain the cost of health care in the United States.

In the 1960s into the 1970s, cost and quality of health care in the United States became a major concern. The Nixon administration responded to this concern through a landmark law, the HMO ACT, to encourage the growth of Health Maintenance Organizations. This HMO Act is based on an assumption that appropriately designed health care benefit plans could lower health care plan costs and improve health care quality. This Act helped foster the growth of HMOs in terms of enrollment and for profit HMOs with backing by the stock market. By 1999, over 80 million had enrolled in an HMO (Markovich, M., 2003), approximately 30% of the total U.S. population at that time.

Several HMOs did succeed in controlling costs and improving quality through their design and management. However, this was not sufficient and quality problems and rising health care costs persisted into the 1990s. A literature review for this project searching for the subject of “health care quality” found 47,932 articles published between the years of 1990 and 1999 concerned with some aspect of health care quality. In 1999, the Institute of Medicine (IOM) issued a report *To Err is Human* which stated “a growing body of rigorous research has documented serious and widespread quality

problems in American medicine.” A 1993 article in the New England Journal of Medicine which focused on reducing health care expenses stated the United States spent more than 14 percent of its gross domestic product on health care more than any other nation yet more than 30 million remained uninsured attributed primarily to the high cost of health care premiums (Fries, J.F., et al, 1993). Nonetheless, the health insurance market which now included HMOs continued to believe that benefit design could solve these problems. Health plan designers only needed to find the right benefit plan design(s).

Designing a health benefit plan requires the designer to make determinations on several important components of a health plan. The major components are listed below.

- (1) The medical services the plan will cover/pay for.
- (2) The medical services the plan will not cover/not pay for.
- (3) How the plan will cover medical services, e.g. where and type of provider.
- (4) The amount payable to providers for a covered service.
- (5) The amount payable by plan participants for a covered service, i.e., “cost sharing.”
- (6) If and how the plan will manage health plan members’ health care services, e.g., require utilization review prior to receipt by plan participants.
- (7) The premium to charge plan purchasers (plan members and/or plan sponsors).

One component used by most health plans to control cost and improve quality is cost sharing. Types of cost sharing include:

- (1) Up-front deductibles
- (2) Coinsurance - a percentage based on the plan's cost for a health care service
- (3) Copayments - a set dollar amount for each health service
- (4) Limits on the number of health care services or expenses above which participants pays
- (5) Exclusions for certain health care services - participants pay entire cost

A health plan determines cost sharing amounts to apply to a health plan based primarily on the plan's need to control the expenditures paid by the plan. Expenditures include payments for medical care rendered to the health plan's participants and administrative costs. Administrative costs include monies to administer the health plan (employee salaries, rent, etc.) and profit, dependent on the health plan's financial structure e.g. for-profit or not-for-profit¹. Health plan expenditures are paid by the health plan's premiums collected from participants². Health plans can reduce their expenditures by applying cost sharing which individual health plan participant's pay when they receive a covered service. In addition, total expenditures (payments by both the plan and participants) may be reduced through cost sharing. "It is widely accepted, based on considerable evidence accumulated over decades of study, that higher cost sharing will lead to reduced healthcare expenditures" (Chernew, M. E. and Newhouse, J. P., 2008, p 412). While cost sharing is expected to help control a health plan's total

¹ Health plan premiums also include an amount set aside (required by regulation) for unforeseen expenses.

² Participants in this reference include the health plan's sponsor, e.g. employer and individual participants.

expenditures, cost sharing is also expected to improve the quality of health care that health plan participants receive.

Cost sharing's positive effect on cost and quality improvement on healthcare is based partly on economic theory about how consumers purchase goods. As stated previously, health plans with cost sharing require their plan participants to pay a share of the health care services they receive. Economic theory posits that consumers act rationally and prudently when they purchase products including services with their own funds. Applied to health care, the theory suggests consumers will only buy health care services they need, that are essential and beneficial to their health and well-being, forgoing health care products and services that aren't essential or beneficial to their health and well-being. Effectively, such rational and prudent buying positively effects health plan expenditures by increasing or stabilizing the use of essential/ beneficial health care services and decreasing use of non-essential/beneficial services. Increasing use of beneficial health care services and decreasing non-essential or non-beneficial services is further expected to improve quality. Rational and prudent buying that prevents consumer purchases of unnecessary health care should also decrease health care spending.

As stated previously, several HMOs did control their costs and improve the quality of health care rendered to their plan participants, however, cost and quality continued as issues to the health care marketplace. Starting in the early 1990's the health care market responded to the continued health care issues with costs and quality by introducing new health plan designs which included Exclusive Provider Organizations (EPO), Point-Of-Service (POS), Preferred Provider Organizations (PPO).

These health plans continue to exist today. In contrast to HMOs that had little or no deductibles and most often used copayments (often low) and not coinsurance, these newer plans applied cost sharing to more health care services with higher dollar amounts.

EPOs, while similar in concept to HMOs, did not require participants to choose a primary care provider to direct and manage care. HMOs developed POS plans in response to consumer backlash against the HMO model that required plan participants to only receive medical care authorized by their primary care provider and only from an HMO provider. POS plans usually require participants to choose a primary care provider to direct and manage care, but do allow participants to choose and receive care outside the HMO network without authorization to which higher cost sharing applies. Insurance companies (non-HMOs) developed PPOs which are similar in concept to a POS. PPOs don't require participants to have a primary care provider and allowed participants to choose care from a contracted (aka preferred) provider or a non-contracted (aka non-preferred) provider with lower out-of-pocket costs for former.

The newer concept plans of POSs, EPOs and PPOs, were developed and offered with the expectation they would through their design curb the rising cost of health care and improve health care quality. A primary component of the plan design is cost sharing often high for certain types of services. These new PPOs and POS plans as well as traditional fee for service comprehensive health plans designs may include features other than cost sharing to help control costs and improve quality such as medical review and approval and prescription drug formularies. However, these plans

also continued to rely on cost sharing as one of their primary methods to control costs and secondary to improve quality.

While the newer health plan designs introduced in the 1990s did help control costs, rising health care costs continued throughout the 1990s. Quality also remained an issue. Starting in the early 2000s High-Deductible Health Plans (HDHPs) and Consumer Directed Health Plans (CDHPs) emerged as better health plan designs to control health care costs and improve health care quality. These “new” health benefit plans offered plans similar to PPOs because they used in-network and out-of-network providers, did not require a primary care provider manager, used deductibles and coinsurances, and used other common health plan management methodologies such as utilization review. The main differences between POS and PPO plans and these new CDHPs and HDHPs are the dollar amount of the upfront deductibles, coinsurance amounts, and out-of-pocket maximums. HDHPs and CDHPs have deductibles of at least \$1,350 rising up to \$5,000 and sometimes to \$10,000 per participant. Deductibles require the plan participant to pay the entire cost of a medical service (no payment made by the health plan.) Similar to PPOs after meeting the deductible, the health plan pays a share of a health care costs and participants pay a share. Such cost sharing continues until the plan participant meets their out-of-pocket maximum, e.g. \$6,650 or higher, a point at which the health plan assumes payment for the entire cost for a covered health care service.

Under a HDHP or CDHP co-insurance amounts are often higher than the traditional 20 percent for PPOs reaching 30 to 50 percent of a health services costs. Similar to PPOs, different and separate deductibles and coinsurance amounts as well

as out-of-pocket maximums usually apply to in-network and out-of-network benefits for HDHPs and CDHPs. HDHPs and CDHPs are very similar in concept because their basic feature is high cost sharing by health plan participants. However, CDHPs include a health savings account (HSA) or a flexible spending account (FSA) which plan participants fund³ (although a company sponsor may fund these accounts as well). Participants with either, HSA or FSA, can use these accounts to pay their deductible, copayments, and/or coinsurance. Primary difference between an HSA and FSA is HSAs can accumulate year after year and FSA terminate at year's end requiring plan participant to use all monies in the FSA by year's end. The other primary difference between an HDHP and CDHP is CDHP provide "tools"⁴ for plan participants to help participants determine the best health care service choice for their particular needs. Tools include on-line (1) services to find appropriate services and costs before receipt of a service; (2) services to help participants lead a healthy lifestyle; (3) to track health care services received and costs as well as others. The inclusion of such tools helps supports the use of economic theory for consumer purchases. The inclusion of such tools is an acknowledgement by developers that consumers need reliable and accurate information in order to make the right decision with respect to their health care purchases and that cost alone is insufficient to make a decision.

The development and marketing of HDHP and CDHP designs continued the expectation that finding and implementing the right health plan design would improve quality and control costs. However, as stated previously these "new" HDHP and CDHP plans differ from "traditional" PPO plans primarily because they use higher upfront

³ Funds have income tax advantages by lowering gross income to which tax applies.

⁴ HDHPs may have tools as well, but CDHPs have been marketed with the "tool" concept.

deductibles, higher coinsurance, and higher out-of-pocket expenses payable by plan participants. They use the same cost sharing methodology used by PPOs to control costs and other cost control and quality improvement methods used by both HMOs and PPOs such as medical management. Thus, these newer health plans rely on the same economic concept used by traditional PPOs that consumers will purchase health care wisely and prudently when using their own funds.

There is one significant difference between CDHPs and traditional cost sharing health plans and HDHPS. CDHP's have been promoted with tools for use by participants to make informed decisions for their health care. Some of the tools provided to plan participants include consumer website for health information, consumer guides regarding pricing of health care services, and disease management programs. A report by McKinsey and Company cited by Bond et al (2007) did find that CDHP participants were more value conscious than other health plan participants and CDHP participants exhibited positive attributes with 50% more likely to inquire about the cost of care prior to receiving the care, 30% more likely to obtain an annual physical and 25% more likely to engage in positive health behaviors. These positive attributes that may affect health care costs and quality are assumed to result from participants having to pay a substantial portion of their medical care because of cost sharing and possibly the tools provided to participants with CDHPs. However, whether participants use these tools or whether these tools actually help participants make an informed decision is questionable. No study was found that measured use of these tools or their effect on quality and health care costs.

The other reason to apply high deductibles and coinsurance is their effect on premiums. Similar to other types of insurance, the higher the deductible and other cost sharing paid by health plan participants, the lower the premium to be paid by the individual and/or the health plan sponsor. Lowered premiums have some advantages. Lowering premiums may provide cost relief to an employer's portion of the premium and allows individuals who could not otherwise afford higher premiums to have health insurance coverage. Lower premiums may prevent a health plan sponsor from ending a sponsored plan. However, it should be pointed out that lowering premiums through cost sharing may not reduce a health plan's total health care expenditures as expected. While cost sharing that reduces a premium may also reduce total health plan expenditures, health care expenditures may more often be transferred from the health plan's liability to the plan participants' liability through higher cost sharing paid by the plan participants.

While lower premiums may not directly improve quality; affordable premiums may indirectly help improve health care quality because having access to a health plan does provide advantages compared to individuals without a health care plan. These advantages include access to a provider network that limits charges for health care service costs by providers and thus lowers costs for participants, preventive care services to which the deductible does not apply, and other services provided to participants by the health plan without out-of-pocket costs to the participants. In addition as an insured participant of a health plan, the health plan will cover health care expenses after participants reach their out-of-pocket maximum thus protecting individuals from high catastrophic illness costs. Moreover, providing more affordable

premiums may attract participants with little known or current health care needs but who would buy health insurance to protect from unforeseen health care needs.

Since their introduction in 2003, Consumer Directed Health Plan (CDHPs) have gained significant market share. Between 2006 and 2014, CDHPs grew rapidly from 4 to 20 percent of covered workers in the employer group health plan market (Bundorf, M., Kate, 2016). A 2012 Health Affairs article stated CDHPs could save the American health care system 57.1 billion dollars if 50% of the non-elderly population enrolled in a CDHP (Haviland, A.M., Marquis, S., McDevitt R.D., Sood, N, 2012.)

The positive effects of cost sharing to control health plan costs have been noted. One criticism of cost sharing is it does not control costs but merely transfers the burden of health plan costs to plan participants. Baicker K. and Goldman D. (2011) state cost sharing is a powerful but blunt tool used by most health plans to reduce utilization and save the health plan monies. Baicker and Goldman's research also found that cost sharing for both private and public health plans decreased as a percentage from 1996 to 2008 but participant out-of-pocket expenses increased due to the escalating cost of health care. There is significant criticism regarding the effect of cost sharing on health care quality. Several researchers claim traditional cost sharing negatively impacts health care quality in general and negatively impacts some individuals more than others (Mathew, F. et al, 2012; Choudhry, N.K, et al, 2010; Chernew, M., and Gibson T. B., 2008, Geyman, J.P., 2012; Lee, T.H. and Zapert, K., 2005, Wojcik, J., 2008). Some researchers also contend the relationships between cost sharing and quality are not well understood. Hussey, P., Wertheimar, S., Mehrota A., (2013) conducted a systematic literature review seeking information on the association between cost of

health care and quality of health care and determined that the association is not well understood and requires much more research. Their review found inconsistent evidence on both the direction and the magnitude of the association between health care costs and quality. Although their research concerned the relationship between health care cost and quality, their finding has an implication regarding cost sharing. Absent any other information other than the cost of care, participants in a cost sharing health plan will most likely face difficulty with determining what health care offers the best quality care for their needs.

Although controversy exists about cost sharing's ability to improve quality, the need by health plans to stabilize or lower health plan premiums often takes precedence over suppositions that cost sharing reduces quality. In addition, there is intuitive appeal that everyone should pay even a little for a product or service they receive. All the health plans created by the Affordable Care Act offered plans with cost-sharing from 10% to 40%. Without any other viable methodology to help control costs in the current health care system, health plan designers have little choice but to continue using cost sharing as a primary design feature. Thus as a plan design tool, cost sharing is here to stay. The question is whether a better method exists to determine and apply cost sharing that will help control costs and improve health care quality. Some advocate Value-Based Insurance Design or V-BID is that method that can improve the quality of health care with the improvements leading to lower health care costs.

V-BID is a relatively new approach to health plan design whereby cost sharing varies dependent on the clinical value of a health care service to a patient. In 2003, faculty at the University of Michigan conceptualized V-BID. The University continues to operate a

Center for Value Based Insurance Design that provides consultation and information about V-BID. In addition, Dr. Chernew, PhD and Dr. Mark Fendrick, MD, principle V-BID developers at the University, operate a separate consulting company known as Value Based Insurance Design Health providing consulting and analytical products focused on V-BID.

V-BID differs from existing traditional cost sharing methodologies. Traditional cost sharing (PPOs, HDHPs, CDHPs, etc.) applies the same cost sharing amounts to all health care services regardless of the clinical value to the patient. Clinical efficacy means the care achieves the desired positive medical outcome for a patient. Clinical efficacy is based on the efficacy of the service, i.e., does the service produce positive health results to the patient. Using a V-BID approach, plan developers use scientific evidence about the clinical efficacy of a medical service to determine if that service has high or a low clinical efficacy (clinical value). Clinical services that are deemed low clinical value are assigned higher cost sharing compared to clinical services deemed high clinical value. The health plan designer may use the price/cost of a health care service to set the cost sharing amount, but cost is not a factor in determining the clinical efficacy/value of a service. For example two treatments for the same disease exist, one deemed low clinical value and the other deemed high clinical value, the participant will pay a higher cost share for the low clinical value service compared to the service deemed high clinical value. For some services clinical efficacy also depends on the provider or provider type who will render the service. A service may have high clinical efficacy but only if rendered by a provider who has performed the service numerous times. For some clinical services the clinical efficacy of the provider is not a highly

relevant factor whereas for other services it may be very significant. For some services although the charges by the more experienced proficient provider may be greater than other providers, the cost sharing for the participant would be lower because of clinical efficacy. And, a health care service with equally high clinical value and equal provider efficiency may have different cost sharing dependent on the providers' charge for the care. The health care provider with lower charges would be assigned no or low cost sharing and the higher charging provider would be assigned a high cost sharing relative to the other provider's cost sharing. The chart below illustrates on a high level the potential cost sharing assignments using V-BID approach to cost sharing. The process to assign cost sharing to a health care service has two primary steps (1) establish the clinical value of a service⁵ and (2) determine the cost to provide the service.

Assigned Cost Sharing	Factors to Determine Cost Sharing
Lowest or no cost sharing	High clinical value and low cost
Low cost sharing	High clinical value and high cost
Higher cost sharing	Low clinical value and low cost
Highest cost sharing or not covered at all	Low clinical value and high cost

There are several difficulties with creating a V-BID health plan including determining what services are low clinical value. In *Setting Priorities in Medical Care Through Benefit Design and Medical Management* (2004) Jill Yegian emphasizes the latter, "classifying some therapies as being of low value, [is] an exercise not for the faint of

⁵ Establishing the clinical value of a health care service takes into consideration the absolute value of a health care service, i.e. does it produce the expected health benefit and may take into the account the patient who will receive the service as well as the provider who renders the service.

heart.” Nonetheless, the negative impact of low value services to the health care system is acknowledged with estimates of as much as \$200 billion being spent every year on healthcare services that provide little value to patients (Castellucci, M., 2017).

V-BID proponents believe using a V-BID approach to cost sharing could positively affect the American health care system, by stabilizing costs and producing a higher quality health care system provided a significant number of health plans adopt it. (Aon Hewitt, 2011; Chernew, M.E., Rosen, A.B.; Fendrick, A.M., 2007; Chordas, L., 2007; NCHC Plan for Health and Fiscal Policy, 2012; Rosenthal, M.B., 2009; Yegian, J.M., 2004).

Section 2: Research Question: What do we know today about the ability of Value-Based Insurance Design to control health plan costs and improve the quality of health care rendered to plan participants?

Section 3: Methodology:

Literature Review: Searched scholarly peer-reviewed journals seeking information about the use and results of Value-Based Insurance Design. Search time frame: January 1, 2010 to December 31, 2017. Key words: “Value-Based Insurance Design.” Search Venue: EBSCOhost Research Databases for Academia.

Interview key informants: Selected five key informants with expertise with health care benefit design in the Maine health care delivery. A letter of introduction with request to participate in the project was sent to each key informant. If no response from letter, a follow-up phone call was made to schedule a date and time for interview. In order to conduct interviews, materials for interview were submitted to University of

Southern Maine's Office of Research Integrity and Outreach (ORIO) for review and approval of interviews. ORIO approved materials on March 22, 2018. The following five key informants listed by general position within the health care delivery industry agreed to participate in this project. (1) CEO of a major health insurance plan in Maine; (2) Medical Director of a major health insurance plan in Maine; (3) Independent Consultant for Health Care Delivery System in Maine; (4) Director of Provider Relations for a major health insurance plan in Maine; (5) President of a major health care purchaser for multiple plans in Maine.

Interviews were conducted between April 1st and May 7th 2018 by phone or in person. Participants were provided a copy of the Consent for Participation in Research at the start of the interview. Interviews were open ended. Interviewees were provided an overview of the project and the research question. They were asked to provide their opinion and thoughts about the value of V-BID to control costs and improve quality. Prompting questions were asked when needed.

Section 4: Results of Literature Review:

The literature review search cited a number of documents using the search term "Value-Based Insurance Design." A review of the abstracts or the full text of these initially cited documents eliminated several documents because they were not significantly relative to this study. Forty-two documents were retained to reference in answering this study's research question.

The literature review also cited a significant number of commentaries, essays, or position papers about V-BID or a V-BID concept (46 documents). This study's focus

was finding primary and secondary research that evaluated V-BID programs' or V-BID concepts' with respect to V-BID's ability to control costs and improve quality. Because these forty-six "commentary" documents were generally found to be either pro or critical opinions about V-BID, authors thoughts and insights about V-BID, or a high level but not a statistical evaluation about a V-BID program, most weren't included in this study's analysis with respect to the study question. In addition, although this type of documentation, i.e., commentaries, does further the conversation about V-BID, these documents don't provide the type of evaluation using quasi-experimental design of V-BID programs which some believe is necessary to prove the value of V-BID to help control costs and improve health care quality. If, however, a commentary or an opinion document found through this study's literature review provided relevant information or insight about V-BID, those documents were retained for citation in this report.

In preparation for the Capstone, a preliminary review of the literature sought information on the number and type of health plans that had implemented a V-BID program between the years of 2003 and 2010. This preliminary research identified a few employer health plans. These employer health plans included (1) Pitney Bowes, (2) the State of Maine Employee Health Plan; (3) City of Ashville, North Carolina; (4) BCBS of North Carolina for a group of employer health plans; (5) Marriot International, Inc.; (6) Procter and Gamble Co; (7) Eastman Chemical Company; (8) University of Michigan health care system. The V-BID programs for these identified health plans were limited in scope because all had applied V-BID only to prescription drugs which they further limited to chronic diseases as follows (1) diabetes, (2) coronary artery disease, (3) high blood pressure, (4) hyperlipidemia, and (5) asthma. A few of these identified V-BID

programs also limited their programs to only one chronic disease with diabetes being most prominent. Furthermore, the V-BID programs provided by these employer groups consisted primarily of low or zero dollar copayments for generic prescription drugs with a few applying low copayments to brand name drugs.

The type of V-BID program provided by the employer health plans cited above is indicative of a V-BID program that only applies low or no cost sharing to high clinical value services. These V-BID programs don't apply high cost sharing to low clinical value services. As early as 2010, researchers wrote that applying V-BID concepts only to high clinical value services may not have the intended outcome to help reduce or control costs and improve quality (Fendrick A.M., Smith, D.G., Chernew M.E. (2010); Robinson J.C. (2010) Neuman et al (2010)). Marjorie Ginsburg (2010), the director of Center for Healthcare Decisions writing about V-BID programs stated many health care policy makers believe health plan must use intervention programs to discourage costly and marginally effective medical care in order to control costs. A V-BID program that applies higher cost sharing to costly and marginally effective medical care is such an intervention that could discourage the use of costly and marginally effective medical care. However, as of 2010, no V-BID programs had attempted to apply higher cost sharing to discourage specific types of care or low value clinical services. The reasons included among others; (1) difficulty in determining low clinical value services, (2) difficulty in determining what amount of cost sharing would optimize choosing high value care or low value care, and (3) fear of health plan participants' reaction to cost sharing being applied to low clinical value care.

Although not found by this study's preliminary literature review, more health plans than mentioned above may have implemented a V-BID program prior to 2010. Choudhry et al. (2010) using 2007 survey data from the consulting company Mercer estimated fewer than 20% of large employers had implemented a V-BID program. This percentage albeit small implies a greater number than the eight found by this study. The Choudhry study also cited a growing interest in V-BID particularly for large employer health plans and stated as many as 81% of large employers expected to implement a V-BID program in the future indicating a significant growth in V-BID programs post 2010. Choudhry et al (2010) did conduct a literature review seeking studies that evaluated the impact of V-BID programs on health care cost and quality and found a general lack of studies that supported V-BID programs to control costs and improve quality.

The findings cited in the Choudhry report provided guidance regarding the documentation about V-BID programs to seek to answer this Capstone's research question. Therefore this Capstone study sought documentation that provided information about the number of health plans that implemented new V-BID programs as well as the type of V-BID program, e.g. prescription drugs for chronic disease or other, implemented between January 2010 and December 2017.

The literature review searched for documents published between 2010 and December 2017 and did not find any documentation quantifying the number of health plans that implemented a new V-BID program between this timeframe. A search of the University of Michigan's Center for V-BID website seeking information about the number of health plans (absolute or percentage of all health plans) or names of health plans

currently using V-BID programs and implementation dates failed to find any definitive information. An email inquiry to this Center sent (2018) for a number or percentage of health plans that have implemented a V-BID program since 2010 was responded to with the comment the Center doesn't have this type of information. A search for a newer, i.e. 2017 or 2018 Mercer report similar to the one cited by Choudhry et al (2010) to estimate the number of large employer health plans with V-BID programs implemented after 2010 failed to find any newer data from this source. A call to Mercer for a new report or updated information about use of V-BID by employer groups was not returned. Mercer did issue a "Mercer National Survey of Employer Sponsored Health Plans"⁶ report in the Spring of 2018. Due to the expense, this Mercer report was not obtained for this Capstone but an available overview of the report stated that providing incentives for employees to seek value-based care as the next cost management tool. It is not clear Mercer's reference to providing employees with incentives to seek value based care means employers will use value-based insurance design. Incentives can also mean providing employees with a monetary gift card if they receive a "high value" service or care from a "high value" provider.

This study's literature review found several published studies that allude to, in their introductory section or results/conclusions section, that since 2010 many employers have adopted V-BID concepts or programs into their health plans or that employers are interested in using V-BID. But, these studies did not provide definitive information as to the number of health plans nor the type of V-BID programs implemented since 2010.

⁶ Accessed on-line 9/24/2018 <https://www.mercer.us/what-we-do/health-and-benefits/strategy-and-transformation/mercerc-national-survey-benefit-trends.html>?

The lack of definitive information about health plans that have implemented a V-BID program since 2010 doesn't necessarily mean health plans haven't implemented a new V-BID program. Some CO-OPs authorized by and developed because of the Patient Protection and Affordable Care Act (PPACA) did incorporate V-BID concepts into their health plans (e.g. Community Health Options in Maine and New Mexico's Health Connections) by lower cost sharing for prescription drugs and services related to chronic diseases. Moreover, this Capstone sought V-BID programs that were evaluated and published in peer reviewed journals which has limitations when looking for health plan information implemented by employers or insurers. The type of evaluation for V-BID programs sought by this Capstone's study can be difficult, time consuming as well as costly to perform, factors which may also contribute to a limited number of evaluations found by the Capstone's literature review. In addition, employer health plans and insurers often conduct pilot projects to test a concept such as a new V-BID program but keep results private. Although the results of such pilot projects of implemented V-BID programs may have appeared in trade journals, this Capstone's literature review did not include such trade journals. In conclusion and based on the limited documentation found through this study's literature review, it can't be stated with certainty that a significant number of health plans have implemented V-BID programs or that health plan have implemented V-BID programs other than prescription drug benefits or the preventive care benefits as required by the PPACA (this required V-BID benefit is discussed in the next paragraph) between the years of 2010 and 2018.

While there is limited information about the number and type of health plans implementing V-BID programs, starting in 2010 changes at the federal level occurred to

promote the use of V-BID programs by health plans. One change was the enactment of The Patient Protection and Affordable Care Act (“PPACA”) in 2010 which required health plans to cover 100 preventive care services without cost sharing. Applying no cost sharing to preventive care (high clinical value services) is considered a V-BID “type” program.

Applying no or low cost sharing for preventive care services is expected to remove the financial barriers that prevent individuals from seeking early detection of undiagnosed or untreated conditions and diseases. Detecting disease early is further expected to lessen the need for invasive or complex treatments which should result in lower expenditures and improved quality. In addition, creating financial incentives for individuals to seek and obtain preventive care services is expected to contribute to behavioral changes that may improve health with improved health reducing the overall need for health care services in turn reducing costs.

The PPACA required Health and Human Services to develop guidelines for health plans to implement Value Based Insurance Programs. Because the requirement to develop guidelines via Rule was in Section 2713 “Coverage of Preventive Care Services,” the PPACA narrowly focused on preventive care, i.e., high clinical value services only. The authors of the PPACA did not include a separate section of the law for the Secretary to create a framework or guidelines for health plans to develop and implement V-BID programs that applied to health care services to other than preventive care and in particular to low clinical value health care services. The PPACA does not appear to prohibit health plans from designating a covered service high or low clinical value service nor does it appear to prohibit applying higher cost sharing to low clinical

value services. However the lack of specificity in the PPACA for V-BID programs other than preventive care and the lack of guidance by Rule may have hindered the development V-BID programs that apply variable cost sharing based on the clinical value of a health care service other than preventive care or prescription drug services. In addition, there is some sentiment that the Affordable Care Act specifically excludes charging higher cost sharing to low clinical value services.

The rationale for the PPACA's focus on high clinical value services and more narrowly defined as 100 preventive care services is not known but probably includes the difficulty in determining or defining low clinical value services, difficulty in codifying low clinical value services, and the backlash from providers and consumers.

The preventive care "V-BID" benefit program required by the PPACA and implemented in health plans starting January 2014 was initiated with the expectation that preventive care can improve the quality of care overall and eventually lead to lower health care costs. This study's literature review didn't find any studies that evaluated the impact on cost and quality of health care due to the PPACA's requirement to cover preventive care services without cost sharing. This lack of "information" may have occurred because this study's search was limited to "Value-Based Insurance Design" which is not a term normally used to describe the required PPACA preventive care benefits. However, the lack of studies on the impact of this new preventive care requirement is more likely because it's too early (2017/2018) to conduct valid studies on the impact of these required benefits.

In addition to the PPACA of 2010, Medicare for its Medicare Advantage Health Plans (MAHPs) initiated a V-BID demonstration project in 2017 in seven states and added three more states to the project for 2018. The results of this demonstration project, however, will not be known for a few more years; therefore no information about the impact of V-BID on MAHPs was found through this study's literature review. This study's literature review did find information about how MAHPs could utilize V-BID concepts in their designs as stated by the Centers for Medicare and Medicaid Services – Innovation Center. According to this Center, MAHPs can lower the cost sharing for enrollees to treat enrollees with diabetes, congestive heart failure, past stroke, hypertension, coronary artery disease, mood disorders, dementia, rheumatoid arthritis, and chronic pulmonary obstructive disease. The V-BID program for MAHPs is disease specific whereby the health plan may reduce cost sharing or offer additional services to participants with a specific chronic disease. MAHPs in the V-BID pilot can't reduce benefits or charge high cost sharing for other services to offset costs for lower cost sharing. Similar to the PPACA, the federal law that supports testing V-BID programs for Medicare Advantage Plans for a positive effect on cost and quality failed to address the need for these health plans to use negative incentives to discourage use of low value clinical services. Ubel P.A. (2016) wrote in a commentary for the Journal of the American Medical Association that health care costs will go up because the Medicare Advantage plans can only lower co-payments on high value services but can't increase co-payments for low value services.

In addition to the MAHPs pilot program for V-BID, in 2017 the federal government authorized TRICARE to include a demonstration program using V-BID principles.

TRICARE is a health plan for active military and their families. The Conference Report of the National Defense Authorization Act (F/Y 2017) authorized a TRICARE pilot program to demonstrate and assess the feasibility of incorporating a value-based health care methodology by reducing copayments or cost shares for targeted populations for high-value medications and services and the use of high-value providers.⁷ The TRICARE V-BID program affected only prescription drugs and allows TRICARE to treat non-generics as a generic for purposes of cost sharing. The program also allows TRICARE to exclude pharmaceutical agents determined to provide very little or no clinical effectiveness from its pharmacy program. Because the effective date for this pilot was January 1, 2018 there are no reports on its impact by this study's literature review

According to University of Michigan's Center for V-BID ("Center"), various state Medicaid programs have also implemented V-BID programs into its health plan designs. The details for the V-BID programs implemented by federally funded health care programs (Medicare, Medicaid and Tricare) were not obtained because these programs were not the focus of this study. However, these government authorized V-BID programs appear to be primarily prescription drug for chronic diseases V-BID programs that reduce cost sharing paid by plan participants for limited types of medications. Moreover, this study's literature review did not find any studies that evaluated the impact on quality and costs from these V-BID programs on any of these government authorized V-BID programs. As stated above, these V-BID programs may not have existed long enough for a study or to determine impact.

⁷ Page 454 Conference Report 2017 for the National Defense Authorization Act accessed on line 9/14/2018 <https://docs.house.gov/billsthis/week/20161128/CRPT-114HRPT-S2943.pdf>

As early as 2010 questions about the effectiveness of V-BID programs to control costs and improve quality began to emerge. These questions stemmed from what researchers saw as a lack of rigorous study using quasi-experimental design as well as V-BID's limited application to prescription drugs which was also limited to drugs for a few chronic disease. Maciejewski et al (2010) stated that "although value-based insurance design has been adopted by many employers and insurers, its benefits haven't been evaluated using rigorous, quasi-experimental study designs" (page 2003). In an attempt to help dispel this inadequacy of study, Maciejewski et al (2010) conducted a quasi-experimental study on a V-BID prescription drug program for four chronic diseases; (1) diabetes (2) hypertension, (3) high cholesterol, and (4) congestive heart failure. The program was implemented by BCBS of North Carolina for its beneficiaries. Their study compared 750,000 participants in the experimental group (with V-BID) to 640,000 participants in a control (without V-BID) group. As a quality measure, these researchers conducted pre and post medication adherence measurements on both groups which however was the only quality measurement. They found participants in the V-BID program improved adherence to drug regimens by 2 to 4 percent dependent on the disease. Their study, however, didn't evaluate the V-BID program's effect on costs although they did state the insurer's medication costs increased significantly. The researchers concluded that more of their type of research on V-BID was needed as well as additional research to determine the optimum copayment levels that would improve adherence and minimizes payer expense.

Zeng et al (2010) also stated skepticism about V-BID's effectiveness was growing even as more health plans implemented a V-BID program because of the

“paucity of evidence” that supported V-BID’s effectiveness. Similar to Maciejewski, Zeng et al (2010) wanted to provide data about V-BID using a rigorous scientific methodology. Zeng et al (2010) studied a V-BID prescription drug program for diabetes comparing a V-BID group to a control group without V-BID (V-BID program implemented 2007). Zeng’s methodology included pre and post measurements using a propensity score weighting method, and a difference in differences approach to estimate the increase in adherence to diabetic drug regimens. They found that participants in the V-BID group increased adherence from 75.3% to 82.6 percent or in other words those with V-BID reduced non-adherence to diabetic medication drug regimens by 30%. Again adherence to a drug’s regimen (diabetic medication only) was the only quality measurement. The study didn’t evaluate the effect of the V-BID program on cost. While the Zeng study concluded their study was rigorous and should be replicated by others, they also noted study problems as follows (1) only looked at changes in adherence and no clinical measurements, (2) small sample; (3) short term data – no long term data; (4) patient clinical inertia⁸ not accounted for.

The researchers Maciejewski et al (2010) and Zeng et al (2010) advocated for more rigorous study similar to their studies with the additions of other study protocols including (1) larger sample sizes, (2) studies over a longer period of time, and (3) studies with more quality and financial measures. They believe better and more study was needed in order to overcome the skepticism about V-BID’s ability to improve quality and control costs.

⁸ clinical inertia is when patients are reluctant to add or continue medication for reasons other than cost of drugs

Using the methodology and criteria suggested by Maciejewski and Zeng as well as other study criteria used to measure the efficacy of V-BID programs this study reviewed the documents found through its literature review for studies that:

1. Included a study group with a V-BID program and a control group without the V-BID program.
2. Included pre and post measurements for both the study group and the control group with appropriate statistical techniques applied.
3. Had study periods of longer duration than 1 or 2 years typical in existing studies up to 2010.
4. Measured more than adherence to a medication regimen as a quality indicator.
5. Included the impact on the costs and savings to a health plan.
6. Applied V-BID concepts to more types of medical services other than prescription drug benefits for chronic diseases and/or preventive care.
7. Applied V-BID to low clinical value services through higher cost sharing in addition to lower cost sharing to high clinical value services.
8. Conducted a statistical analysis on data relevant to a V-BID program

. The following provides a list of documents that met one or more of the eight criteria listed above for studying the efficacy of a V-BID program. (The list includes studies by Maciejewski and Zeng already mentioned above.) The first four studies listed below are studies of V-BID using a mathematical modeling methodology (not empirical) that studied the effect of a V-BID program on cost only. All nineteen studies listed below were studies of a V-BID program for a prescription drug V-BID program for

a chronic disease or several chronic diseases. Most all the studies only measured adherence to a drug regimen as the quality indicator. There were no studies of a V-BID program that applied to both high and low clinical value services. All studied V-BID programs that lowered cost sharing for specific prescription drugs for a chronic disease. A couple of studies' study periods were longer than 2 years but none longer than three years.

1. Meincj and Motheral (2010) Mathematical modeling results showed negative cost savings - no quality measurement;
2. Davidoff et al (2012) Mathematical modeling results showed positive cost savings - no quality measurement;
3. Olchanski et al (2013) Mathematical modeling results showed a mix of positive and negative effects on costs dependent on the drug – no quality measurement;
4. Rael M.B. (2014) Mathematical modeling results showed negative cost savings – no quality measurement.
5. Chernew et al (2010) - cost neutral – no quality measures.
6. Macieweski et al (2010) increased adherence to drug regimen but significantly higher costs to health plan for prescription drugs.
7. Chourdhy et al (2010) modest increase in adherence to drug regimen – no cost analysis.
8. Zeng et al (2010) modest increase in adherence to drug regiment – no cost analysis.

9. Gibson et al (2011) For participants with a V-BID program modest increase in adherence to drug regimen for one chronic disease and small cost savings - no adherence changes to two other chronic diseases and cost neutral.
10. Gibson et al (2011) the study looked at a V-BID program for diabetes with and without a disease management (DM) program citing increases in adherence to drug regimen for those with a DM program as well as increased costs.
11. Kim et al (2011) concluded adherence to drug regimen may increase with a V-BID program that has active counseling – increases in total health plan costs.
12. Farley et al (2012) increases in adherence to the drug's regimen – cost impact not studied.
13. Frank et al (2012) reduction in copayments for selected statin medications should improve adherence – no cost analysis.
14. Eliot et al (2013) participants self-reported small increases in adherence to diabetic medication – no changes in clinical measures e.g. glycemic control - total pharmacy costs increased – total medical costs decreased insignificantly.
15. Maciejewski et al (2014) – increases in adherence to drug regimens – higher medication costs \$6.4 million – lower non medication costs \$5.7 million (not cost neutral).
16. Chourdhy et al (2014) increases in adherence to drug regimen for V-BID programs that were more generous, targeted high risk patients, offered a

wellness program, did not offer a disease management program and offered V-BID through a mail order program.

17. Musich et al (2015) Increases in adherence rates for two studied diseases (diabetes and hypertension) – decreases in medical costs not significant to offset increase in costs for drugs.
18. Maeng et al (2016) No quality measures studied – study concluded that a V-BID program implemented within a wider wellness program targeting the appropriate population can lead to positive cost savings.
19. Reed et al (2017) Control group with no V-BID had a modest decrease in drug regimen adherence, the group with V-BID had an insignificant increase in adherence – cost impact not evaluated.

Four exceptions to studies of implemented V-BID programs for prescription drugs for chronic disease were found through the extended review and analysis. However, these study exceptions to RX only V-BID programs had a prescription drug(s) as a major component of the V-BID program. These four studies met one of the eight criteria listed above. The V-BID program study exceptions to prescription drugs for chronic diseases only are as follows with findings (brief synopsis).

(1) A study using mathematical modeling to determine the impact of applying V-BID programs to prescription drugs as well as all types of health care benefits that concluded : (1) V-BID applied to high value pharmaceuticals only increased life expectancy but also increased overall costs; (2) no change in overall costs if higher cost sharing applied to low value pharmaceuticals along with lower cost sharing for high value pharmaceuticals; and (3) V-BID applied only to high value clinical services

increased costs but cost neutral if V-BID applied to both high value clinical services through low cost sharing and low clinical value services through higher cost sharing, (Braithwaite et al, 2010).

(2) Using the results of thirty-two studies of osteoporosis treatment to prevent hip fractures, researchers estimated the effects of a V-BID program that lowered cost sharing for the most effective treatments cited in the studies. They determined that hip fractures could be reduced by 8.5% and total plan costs could be reduced by 9.0% through a V-BID program that incentivized high clinical value services. The V-BID program was for high clinical value prescription drug treatments for osteoporosis not the typical chronic disease for most other V-BID programs. (Chambers et al, 2014⁹).

(3) A study evaluating the impact of a V-BID program consisting of two cost sharing schemes for physical therapy for back pain; (1) a bundled cost sharing paid once at start of treatment (study or intervention group) and (2) cost sharing payment paid at each session (control group). The one-time copayment was substantially lower in total dollars than the co-payments paid per session. The measurements used by the researchers were a self-reported patient satisfaction survey by both the study and control group and self-reported functional status survey by the study group only. Researchers found the study group reported higher satisfaction with the care they received than the control group. The researchers stated there was a correlation between higher care satisfaction and improvements in functional status. These

⁹ A study published in 2013 by the same researchers/authors under a different title in a different journal was not sufficiently different enough to constitute a different study.

researchers noted several limitations in their study design that they believe may have impacted their results. (Maeng et al, 2015);

(4) A study that looked at changes to utilization and health plan spending for a V-BID program that reduced office visit co-payments for chronic disease and preventive care as well as prescription drugs for chronic care diseases. The study group was enrollees in the State of Connecticut employee health plan (HEP) The researchers stated the claims data for the study group (enrollees in HEP) showed increases in adherence to drug regimens as well as increases in visits for preventive care and chronic diseases care compared to the control (comparison) group. Although the authors stated cost impact was inconclusive, the average cost for HEP enrollees was \$7,913.60 compared to the control group of \$4,375.27. (Hirth et al, 2016)

For all the studies, whether a V-BID prescription drug program or other types of health care, very few evaluated the effect of V-BID on costs to the health plan or insurer. The studies that showed positive cost results i.e., lower costs to the health plan, also issued cautions in their conclusions about V-BID's ability to control costs and improve quality in the long term or their study's results could apply to health care services other than the services covered by the V-BID program of which prescription drugs for chronic care predominated.

In addition to experimentally or quasi-experimental designed studies cited above, a few studies used a literature review methodology to determine the impact of V-BID programs to control costs and improve quality. Those studies are as follows.

These literature review studies would have included one or more of the experimental experimentally designed studies listed above.

- (1) Lee et al (2013) used a literature review methodology to find peer reviewed studies published prior to 2012 that evaluated the effects of a V-BID on medication adherence, medication expenditures, and total health care expenditures. These researchers found thirteen study results that met their study criteria. They attributed this low number to the nascent nature of V-BID. They did conclude that the thirteen studies had conducted well designed studies with all showing medication adherence increases due to the V-BID program as well as significant increases in prescription drug costs. Only four of the thirteen studied a V-BID program's impact on overall cost citing no significant increase in overall costs. Based on their literature review findings, Lee et al (2013) concluded that V-BID programs may not decrease health care costs significantly.
- (2) Buttorff et al (2013) conducted a literature review to find information about V-BID programs to provide to state exchanges to help the exchanges develop V-BID programs. They found limited information about the value of V-BID programs but did conclude that long term cost savings could only be achieved if higher cost sharing applied to low clinical value services.
- (3) Krack, L.G. (2017) conducted a systematic literature review to identify studies that empirically analyzed the effect of V-BID programs on

health plans' and participants' costs. He concluded that V-BID was advantageous for participants and cost neutral for both health plan and participants. Differences in effect of the V-BID programs were partly explained by V-BID incentives and severity of disease.

- (4) A systematic literature review conducted by Agarwal et al (2018) sought peer reviewed studies published from 2008 to 2017 that studied medication adherence changes and other outcomes due to a prescription drug V-BID program. They found twenty-one unique studies, eight of which had not been included in previous written reviews. They stated V-BID programs cited in published studies showed “moderate-quality evidence” of improvements in medication adherence in the range of 0.1 to 14.3 percent due to a V-BID program. They also found only nine of the twenty-one studies evaluated health care cost spending with two showing decreases in spending and seven showing no significantly spending differences attributed to the V-BID program.

Section 5: Discussion of Literature Review Findings

While this Capstone study found published studies that presented positive results from a V-BID program, the studies didn't sufficiently overcome the problems cited by Maciejewski et al (2010) and Zeng et al (2010) about the lack of rigorous studies and limitations of V-BID programs to other than prescription drugs for chronic diseases or meet more than one or two of the seven criteria listed above. The issues

that continue to affect V-BID's ability to show it can control costs and improve quality are:

- (1) The number of rigorous studies of V-BID programs that included a study group and a control with pre and post measurements decreased over time (2010-2018);
- (2) Study periods continue to be short, most for 1 or 2 years;
- (3) The studied V-BID programs were primarily prescription drug programs indicating that the use of V-BID programs to other than prescription drugs has not occurred.
- (4) The studied prescription drug V-BID programs were primarily for four chronic diseases of diabetes, asthma, hypertension, and heart disease. This limitation to chronic diseases and only for prescription drugs further indicates the limited application of V-BID programs in the health care system.
- (5) The primary measurement to determine improvement in the quality of health care due to V-BID was the change in prescription drug adherence rates for the drugs included in the V-BID programs. Most studies didn't evaluate the effect of the V-BID program on other quality indicators such as clinical health care outcomes attributable to prescription drugs. If a study did use another quality indicator, most studies did so on a very limited basis such as measuring the change to participant A1C levels because of a V-BID program focused on diabetic drugs.
- (6) A limited number of studies evaluated the effect of the V-BID prescription drug program on emergency room visits, hospitalization and office visit.

- (7) The lack of evaluation on other than prescription drug regimen adherence quality indicators is a direct result of V-BID programs not being applied to other than prescription drugs for chronic diseases as well as the difficulty in obtaining data for use in other measurable events.
- (8) Many studies either didn't evaluate the effect of the V-BID program on health plan costs or if studied, the results were inconclusive or showed the V-BID program was cost neutral to the health plan.
- (9) This study did not find any study of a V-BID program that applied to both high and low clinical value services through differential cost sharing or the application of higher cost sharing to low clinical value services.
- (10) The studies found by this study evaluated the impact of V-BID programs applied to high clinical value services only and mostly V-BID programs consisting only of prescription drugs considered high clinical value.

Several researchers wrote about their concern about V-BID's ability to reach its goal to control costs and improve quality because of V-BID's limited studies application. As stated above these researchers spoke about the issue that V-BID has and continues to apply only to high clinical value services through lower cost sharing and ignores the need to apply higher cost sharing to lower clinical value services. Many researchers, even the developers and the promoters of V-BID, believe that V-BID can't achieve its goal of controlling costs or improving quality if V-BID only applies lower cost sharing to high clinical value services. Fendrick, A.M., Smith D.G., Chernew, M.E., (2010) stated there are controlled studies showing V-BID programs that only apply lower cost sharing to high value services are unlikely to finance the investment needed to fund a V-BID

program. This is an acknowledgement that the cost of lowering cost sharing for high clinical services must be funded by applying higher cost sharing for services for low clinical value services.

Developing a V-BID program that applies to low and high clinical value services has many problems to overcome. A major inhibitor to applying low clinical value services to a health plan is how to determine low clinical value services and how and what amount to apply cost sharing to low clinical value services. Neuman et al (2010) started their research with a premise that V-BID programs must apply to both high and low clinical value services. They conducted a literature review seeking papers published since 2000 that provided information about designating a service as low clinical value. From their research, they concluded that determining low value clinical services had challenges including the controversy of determining a service low clinical value. Devries et al (2016) conducted a literature review seeking studies for use in developing a comprehensive and sound list of low clinical value care measurements for use in monitoring low value care utilization. Based on their research they questioned the validity of the measurements they did find and concluded more attention was needed to develop such measures.

Moreover and in general, limited research is available on the effect on health care cost and quality due to V-BID programs that apply higher cost sharing to low clinical value services simply because most if not all V-BID programs applied higher cost sharing to low clinical value services or cites it as such. As stated previously, this Capstone's research did not find any studies that involved V-BID programs that applied differential cost sharing applied to both high and low clinical value services, only high

clinical value services. As found through this study's literature review, much of the written advocacy to apply V-BID programs to both high clinical value services through lower cost sharing and low clinical value services through higher cost sharing derives from commentaries and position papers as well as studies based on economic theory regarding cost sharing. A few statistical studies found by this Capstone's literature review did evaluate the impact of cost sharing differentials but not because of a specific V-BID program. The Capstone found these references through its literature review because the studies concluded that their results may apply to V-BID design. These studies and those like them could provide valuable information useful to define low clinical value services and develop cost sharing for low clinical value services in a V-BID program and include those by (1) Zhang et al, 2017; (2) Stuart et al, 2017; (3) Ellis et al, 2017; (4) Abbass et al, 2017; (5) Anupam et al, 2017.

While help to create better V-BID programs including applying V-BID to both high and low clinical value services can be obtained from studies of cost sharing other than V-BID programs, development and study of V-BID programs that apply to more than high clinical value services and more than prescription drugs are essential.

Unfortunately, the V-BID programs authorized by the federal government for Medicare Advantage plans and TRICARE do not allow higher cost sharing for lower clinical value services and such federally sanctioned V-BID programs predominately cover prescription drugs considered high clinical value. Although the PPACA did not preclude the application of variable cost sharing to both high and low clinical value services to qualified health plans, the lack of regulatory guidance may have hindered such application. Moreover, state and other federal laws that affect health plans may prevent

the application of adequate differential cost sharing to high and low clinical value services. For example, Maine law requires that a non-preferred provider (e.g. low clinical value provider) receive reimbursement not less than 20% from preferred provider (high clinical value provider). Fendrick, A.M. and Soonavala, R., (2017) state in a commentary in the American Journal of Managed Care that the movement towards High Deductible Health Plans didn't reduce spending on healthcare services that provide unclear or no clinical benefit. As a solution they argue that federal laws governing Health Savings Accounts (HSAs) need to change so participants can use their HSAs to purchase high clinical value services for existing health conditions which current laws governing HSAs prevent.

In addition to the lack of studies on V-BID programs for more than prescription drugs, a few issues exist regarding the methods used to evaluate V-BID programs. The process used to calculate adherence changes to drug regimens brought criticism by some researchers. The predominant criticism was most studies used changes in participants' medication adherence regimens observed through claims data as the sole measure for quality. Buono et al (2017) criticized the methodology most V-BID programs researchers used to measure adherence regimen changes because they relied on claims data to calculate a medication possession rate (MPR) from refill data as a proxy for rate of adherence. Buono et al (2017) believe using MPR via claims data results in inaccurate measurement because adherence changes result from patient-level interventions which can't be detected through claims data. Another issue already cited in this report is the lack of other quality measurements other than adherence to medication regimens.

Another issue noted by this study, was an issue of not separating the impact of a V-BID program from another existing or simultaneously implemented health plan program that could have affected regimen adherence or other health care changes more than the V-BID program. For example, a few V-BID prescription drug programs required participation in a disease management program or a wellness program. Musich et al (2015) and Kim et al (2011) did note the positive results of the V-BID program they studied may have also been affected by a disease management program or wellness program in place along with the V-BID program but did not separate each program's impact. Gibson et al (2011) concluded that a V-BID prescription drug program with a disease management program was more powerful to improve adherence rates than one without a disease management program. In contrast to the Gibson study's findings, Choudhry et al (2014) found that V-BID without a disease management program had better adherence outcomes. A study by Voils et al (2014) looking into the reasons why nonadherence occurred and found reasons other than cost sharing such as personal issues of "I forgot" or "I was travelling" as rationale given for nonadherence with cost sharing being not a reason for many.

The cost to implement and maintain a V-BID program was a missing element in studies found by this study's literature review. However, most studies concluded that because the health plan absorbed the participants' reduced cost sharing, the health plan's costs must have increased. Most studies stated the health plans that implemented a V-BID program did so with the expectation of savings from lower hospitalizations, fewer emergency room visits, lower physician visits because of better chronic disease control that would offset their absorption of participants' cost sharing.

But most studies did not conduct the type of analysis to determine this offset. Almost all studies did not provide any information about the cost to a health plan to implement a V-BID prescription drug program which is a separate cost from the cost of providing health care to participants. In general, evaluating a reduction in total health plan costs was not within the scope of many studies. If total health plan cost evaluation was within the scope of the study the results were inconclusive or the savings from reduced medical expenditures did not outweigh the expense to the plan for high prescription drug costs.

Other issues with current V-BID program studies included the lack of adequate control groups in most studies. The control groups consisted of individuals without a V-BID program and thus they paid higher cost sharing for prescription drugs determined “high value services.” Studies of payment differentials for the same high value services are not the same as studying the impact of differential cost sharing between high value services and low value services and thus produce incomplete results. In addition, many of the V-BID programs for prescription drugs lowered participants’ cost sharing for generic drugs for which cost sharing was already fairly low e.g., \$5 to \$0. This small change as well as the significantly low beginning cost sharing amounts paid by participants raises issues whether the V-BID programs for prescription drugs could have any impact on quality and costs.

Section 6: Interviews With Key Informants:

The interviews with the selected key informants corroborated many of the findings discovered through the literature review. Two interviewees had direct experience with a V-BID program for prescription drugs and physician visits for chronic

care. The other interviewees had limited direct experience with V-BID programs.

Specific comments provided by interviewees are as follows:

- V-BID is a good idea in theory but how to implement it across a plan is difficult.
- V-BID doesn't appear to have saved health plans any money.
- Undertaking evaluation of V-BID is difficult –uncertainty with respect to what to measure and how to measure.
- Educating consumers about V-BID including clinical value differences is very important.
- The price of health care is the major issue regardless of who pays for it – health plan participants or the health plan.
- Current V-BID programs appear to shift costs from participants to the health plan and not change practice patterns
- In Maine, establishing V-BID programs other than for prescription drugs is limited due to the number, location, and type of providers to engage in a V-BID program.
- V-BID programs can help vulnerable participants who have difficulty paying their cost share.
- Current delivery system is resistant to change making such programs as V-BID difficult to successfully implement.
- There are many challenges to implement a V-BID program for low clinical value services.
- Assigning value to a health care service is a contentious endeavor.

All interviewees stated they thought V-BID and V-BID concepts had the potential to provide help in lowering costs and improving quality. However, all believed that V-BID is just one of the tools or methods that should be used to improve quality and control health care costs.

Section 7: Conclusions and Suggestions to Improve V-BID:

Based on a literature review and discussions with key informants, there remains intuitive appeal to apply V-BID to help control costs and improve the quality of health care in the United States. However, many of the V-BID studies have been limited in scope and insufficient to provide conclusive results that V-BID controls costs and improves quality.

Despite the limitation of evidence that V-BID works to control costs and improve quality benefit designers should not abandon V-BID concepts. The current studies and analysis thereof do provide suggestions to improve V-BID programs to help bring about the promised change of controlling costs and improving quality as well as suggested methods to study V-BID programs to provide evidence of the impact of V-BID programs. The suggestions are as follows.

- (1) Many researchers now conclude that V-BID must apply to low clinical value services to achieve quality and savings in the long term (Buttorff et al, 2013; Maciejewski et al, 2014; Lewry et al, 2015; Chernew and Fendrick, 2016).
- (2) The problems cited that prevent V-BID programs from applying low value services that must be overcome include: (a) regulatory restrictions that prevent increasing cost sharing for low clinical values ; (b) the difficulty in defining low clinical value

services; (c) non-acceptance by providers as well as consumers that a service provides low clinical value; and (d) health care service patterns that are difficult to change. Overcoming these problems will require changes and efforts by all involved in health care system including regulators, providers, insurers, and consumers.

- (3) Although Medicare through the Medicare Advantage Plans as well as some Medicaid plans have adopted V-BID, many employer group health plans have not. As one researcher stated, employer health plans need real evidence that V-BID will save money in the long term, in addition to improving the quality of health care they cover.
- (4) There is a need for more and better comprehensive studies to determine high and low value services as well as how to direct patients to the high value services. Chandra et al (2011) wrote that comparative effectiveness analysis although expensive could provide needed information to determine high value health care and low value health care. Chambers et al (2014) also advocated for more comparative effectiveness research for use to develop better V-BID programs.
- (5) Starting in 2015 the concept of “clinical nuance,” became more prevalent in most writings about V-BID. Please see Appendix 1 for a more detailed explanation for the term “clinical nuance.” The University of Michigan’s Center (UMC) for V-BID which is one of the strongest proponents of Value-Based Insurance Design promotes the use of clinical nuance to create V-BID programs. In summary per UMC’s website, Clinical nuance means medical services differ in the health they produce but the health they produce may also depends on (1) the patient receiving

the service, (2) the provider rendering the service and (3) where the service is provided.

Conceptually, it is easy to understand that different medical services produce different health results and those health results may also depend on the additional components of who receives the service, who renders the service, and where the service is rendered. However, benefit designers may find it difficult to use clinical nuance to develop a V-BID program. For example, designers would have to distinguish between high and low value drugs, high and low value providers, and high and low value uses of the same drug, and possibly between different patients (Robinson, J.C., 2010). In addition, designers may find it difficult to use clinical nuance to develop an explainable cost sharing V-BID program where cost sharing for the same diagnostic service or visit to a physician differs based on the person, the provider, the place as well as why someone will have the service or visit. The ability to provide adequate information about a V-BID program to participants is essential to the success of a V-BID program. Henrikson et al (2014) concluded that participants had incomplete knowledge of benefits soon after a V-BID rollout which they stated has impact on participants' health care use.

(6) A few researchers suggested V-BID programs would be most effective if they targeted different groups such as:

- (1) high risk populations within a chronic disease population
- (2) populations who use specialty pharmaceuticals
- (3) high utilizers of specific types of low value services
- (4) high risk populations for specific diseases, e.g. colon cancer

(7) Although a somewhat new concept to apply to health insurance and very limited in studies, the concept of how behavioral hazard impacts compliance with medication regimens and other health care services could help develop newer and better V-BID programs. Behavioral hazard basically expands on the concept of moral hazard to which cost sharing has been the primary solution. Behavioral hazard takes into account personal behaviors that may affect a person's health or decisions about health care to apply cost sharing. For example, while charging consumers less for what is determined a high value services makes sense intuitively, this may have unintended consequences. Dong, Y (2013) suggests that insureds with little or no cost sharing for prescription drugs for a chronic disease are more likely to rely on medication instead of behavioral changes. This may explain why some studies found decreases in adherence rates for individuals without V-BID because they made behavioral changes and ended their reliance on prescription drugs. More information and use of behavioral hazard when developing and using cost sharing appears needed. Other researchers (Baicker K., Mullainathan, S., Schwartzstein, J., (2015) also promote the inclusion of behavioral hazard theories to develop V-BID programs.

(8) The need to find the right method to encourage patients to learn and engage in high value health care services in opposition to low value services was written in many essays and commentaries. They espouse more needs to be done such as better information that will engage consumers to choose high value health care services beyond what V-BID currently provides through cost sharing differentials. This Capstone study did not look at how consumers use information about high or low

value health care services or if they even use such information. The Choosing Wisely Campaign developed on-line information for consumer use when contemplating a health service. A study looking at the use of the Choosing Wisely Campaign information may provide valuable insight for developing V-BID programs

(9) More research is needed to determine the optimum cost differentials between low and high value services to support high value services. Is the difference between \$0 co-payment and a \$20 or \$30 co-payment significant enough to change someone's behavior or use a different provider or service? Also, as stated above there is a need to look at the behavioral impact of low cost sharing on health care that can improve due to changes in lifestyle or behavior.

(10) Benefits attributed to V-BID cost sharing differential to choose high value services may lessen once an insured meets their out-of-pocket maximum. At that point, if not cost sharing what incentives would work to ensure use of high value services when they need expensive surgery? One potential incentive learned through the interviews was to give patients in need of surgery a \$500 gift card if they chose what the insurer termed high value service (high value service defined by cost and provider).

(11) It is commonly understood or at least thought that low-income individuals and families need help paying for their cost sharing particularly when costs are high and medical needs high. However, did the Affordable Care Act's (ACA) Cost Sharing Reduction (CSR) where 5.9 million exchange enrollees received reductions or complete elimination of their cost sharing negate the impact of wise consumer

choices through cost sharing? Could the CSR been structured differently to apply the CSR only to high value services?

(12) A common theme observed in writings and discussions about the United States health care system is the high price for health care services. Some interviewees stated applying V-BID concepts of differential cost sharing for a high value service based on high cost providers and low cost providers of equal provider value could result in lower prices.

(13) There is value in reading and analyzing an entire study and not rely on the abstract to make determinations about whether to implement something new into a benefit plan design.

Section 8: Limitations:

The literature review for this study was limited to scholarly peer reviewed journal articles using databases available thru ECHOhost using the search term “value-based insurance design.” The citations for documents from this search would have had to have the term V-BID somewhere within the document. If this term was not in the document, even if the study evaluated a key V-BID concept such as the effect of applying copayment differentials to low and high value services, the document would not have appeared in the citation listing. In addition, citations of documents that concerned Value-Based Insurance from databases not included in ECHOhost such as CINAHL would not have appeared in the results. While it is not known how many documents were missed because of these issues, a substantial number of documents

did result from the search using ECHOhost with the search term “Value-Based Insurance Design.” However, despite these limitations, it was determined that the findings from the literature review along with the findings from the interviews provided sufficient documentation to make conclusions and suggestions cited in Section 7 of this report.

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Appendix 1

The University of Michigan's Value Based Insurance Design Center states "clinical nuance" is a key innovation implemented using Value-Based Insurance Design to determine cost sharing for a medical service.

The Center provides additional information including examples to help understand "clinical nuance" as a concept. According to the Center "clinical nuance" incorporates two facts about medical care.

The first fact is clinical services differ in the amount of health produced, i.e., clinical benefit. The health care produced by a clinical service determines the "value" of the clinical service as either (1) high value or (2) low value. The Center provides a couple of examples of this first fact, one of which is shown below.

An office visit with a cardiologist post heart attack has higher value. i.e., produces a higher amount of health compared to an office visit with a dermatologist for mild acne, i.e. produces a lower amount of health.

But, according to the Center, a specific clinical service is never always high or low value

The second fact states the clinical benefit from a clinical service also depends on (1) who receives it, (2) who delivers it and (3) where delivered. The example given for this second fact is screening colonoscopy. The Center states that a screening colonoscopy produces:

- (1) Exceptional value to a person who is 1st degree relative of colon cancer sufferer;
- (2) High value for a person with average risk who is 50 years old or older;
- (3) Low value for a person who is 30 years old with no family history of colon cancer

The clinical value based on the person receiving the colonoscopy can be further refined based on the provider that renders the colonoscopy or where the colonoscopy is delivered.

A “certified” high performance provider will provide a higher value service compared to a provider with poor performance

Finally the value of the service but not necessarily the clinical value can be assessed by where the service is provided. The Center states an ambulatory care center will provide the colonoscopy for less cost than a service provided by a hospital.

Using clinical nuance as described by the Center, a person regardless of age who has a 1st degree relative with colon cancer would pay lower cost sharing for a screening colonoscopy compared to any aged person with average risk for colon cancer. If the person with a 1st degree relative with colon cancer also receives care from a high performing provider, the cost sharing would be lower and lowered again if they received the care at an ambulatory facility instead of a hospital. The person who has average risk would pay higher cost sharing compared to the person with a 1st degree relative with cancer, but their cost sharing could be mitigated if they receive care from a high performer and if they receive care at an ambulatory care facility.

According to the Center, value-based design sets cost sharing to encourage use of high value services and providers and discourage use of low value care and uses the term “clinical nuance” to describe the process to set cost sharing.

The above information was derived from the University of Michigan’s Value Based Insurance Design at <http://vbidcenter.org/initiatives/v-bid-clinical-nuance/Understanding> and Implementing Clinical Nuance