ABSTRACT

Title of Dissertation: EVALUATING THE QUALITY OF HOME HEALTH CARE FOR INDIVIDUALS WITH COMPLEX MEDICAL NEEDS RECEIVING PRIVATE DUTY NURSING SERVICES IN THE MARYLAND RARE AND EXPENSIVE CASE MANAGEMENT PROGRAM

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Dissertation directed by: Associate Professor, Dr. Lori Simon-Rusinowitz, & Associate Professor, Dr. Jie Chen, Department of Health Policy and Management

OBJECTIVE: To use process and structural measures to evaluate the quality of Private Duty Nursing (PDN) services provided to individuals with complex medical needs in the Rare and Expensive Case Management (REM) program in the state of Maryland. The results will form the basis for recommendations for legislative changes regulating Private Duty Nursing provider agencies.

BACKGROUND: Individuals with defined complex medical needs diagnosed before age 21, may receive skilled nursing level of care at home under the Maryland Medicaid REM program. The REM and similar programs have been shown to be cost effective, providing cost-savings to both state Medicaid programs and private insurance companies as the beneficiaries avoid long stays in short-term and/or long-term care facilities. Unfortunately, the quality of care in the REM program is not consistent. Thus, there is a need to evaluate REM program services to

understand the reasons for these inconsistencies and make recommendations for fixes to the State and PDN provider agencies.

TARGET POPULATION: Individuals with complex medical needs receiving REM program services and PDN provider agencies in the state of Maryland.

DATA: Results of audits of client and personnel records of PDN provider agencies performed by the Division of Nursing services (DONS) in the Maryland Department of Health were reviewed and analyzed.

ANALYTICAL METHOD: This was a mixed methods study, utilizing both qualitative and quantitative methods for data analyses. A descriptive study method with a retrospective analysis was also employed. Frequencies, percentage scores, and means with confidence intervals were generated in Google Sheets and Stata software. Finally, qualitative content analysis was used to analyze the DONS auditors' comments, to find themes from key words or phrases.

RESULTS: The study found major deficiencies in the client and employee records. Out of 99 employee and 30 client records from about 13 PDN provider agencies, 100 % of the records had deficiencies of one kind or the other, the most prevalent being discrepancies between the physician orders and the medication administration records.

CONCLUSION: Study findings indicate that improvements to the quality of nursing services to REM program participants can be implemented at provider agencies as well as the executive and legislative levels of state government.

EVALUATING THE QUALITY OF HOME HEALTH CARE FOR INDIVIDUALS WITH COMPLEX MEDICAL NEEDS RECEIVING PRIVATE DUTY NURSING SERVICES IN THE MARYLAND RARE AND EXPENSIVE CASE MANAGEMENT PROGRAM

By

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Dissertation submitted to the Faculty of the Graduate School of the
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Advisory Committee:

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Preface

The aim of this project was to evaluate the quality of private duty nursing services provided to individuals with complex medical needs in the Rare and Expensive Case Management (REM) program in the state of Maryland and to use the results to inform Private Duty Nursing (PDN) provider agencies on areas needing improvement. The findings will also be shared with the executive and legislative arms of the Maryland State government to influence legislation aimed at improving the quality of services to REM program participants.

Foreword

I am honored to write the foreword to this all-important academic work focused on the quality of nursing (Private Duty Nursing [PDN]) services delivery in the Maryland Medicaid Rare and Expensive Case Management (REM) Program. I have been intimately involved in the administration of the delivery of PDN services in the REM program for more than 15 years, with over 10 years as the Chief of the Division of Nursing Services (DONS), the unit within the Maryland Department of Health (MDH) responsible for administering the authorization of PDN services for participants enrolled in the REM program. The DONS also review and approves the application of Residential Services Agencies (RSA) that require certification to provide PDN services to REM program participants. Based on physician orders and nurse assessments, the DONS determine the level of care needed by REM program participants and authorizes approved PDN provider agencies to render the care for cycles of 60 days at a time. The DONS make recommendations for regulations guiding the provision of nursing services to REM program participants and performs audits of PDN provider agencies following participant complaints or reports of incidences such as recurrent hospitalizations or deaths of participants. This study shines a light on significant challenges with the care of REM program participants that encourages active collaboration between the DONS, the families of REM program participants, and PDN provider agencies to ensure better quality of care for the REM program participants. I welcome the interest of academic institutions such as the University of Maryland on the PDN services available to participants enrolled in the REM program. We at the DONS take the findings reported in this dissertation very seriously, and I am certain that health advocates in the community and within the legislature will do same. This work is a must read for PDN provider agencies.

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Chief, Division of Nursing services (DONS), Maryland Department of Health.

Dedication

This project is dedicated to baby Channing Mathews, who lost her life as a result of poor quality of care and lack of a well-trained nurse. May your soul rest in peace.

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I want to thank my advisers and committee members, Dr. Lori Simon-Rusinowitz (Committee Chair), Dr. Jie Chen (Committee Co-Chair), Dr. Pamela Donohue, Dr. Barbara Resnick and Dr. Luisa Franzini, for their contributions to this work. I also want to thank, members of the Chronic Critical Illness (CCI) Working Group at Johns Hopkins Hospital, the Faculty and staff of the Department of Public Policy & Management at the University of Maryland, College Park, Maryland State Senator Shirley Nathan-Pulliam, Dawnn Williams from the Division of Nursing Services (DONS) at the Maryland Department of Health, Dawn Seek at the Maryland National Capital Home Care Association (MNCHA), Shannon Gahs - Director of Government Affairs at BAYADA Home Health Care, and the Staff and management at Optimal Health Care Inc. for their immense support and feedback.

I also want to acknowledge all the people in my life who have contributed to raising me up to the woman I am today. To my mom and dad for their endless sacrifices to ensure I had a better life. To my siblings, for always being there and doing their best to guide and lead me. To my aunties and uncles, for all their efforts to ensure that they were part of the village that raised me. To my friends who have always been there to cheer me on. To my co-workers and classmates, who have been there to walk this journey with me. To my children who have given me reason to work hard and want to be better. To my husband - the Man, the Myth, and the Legend - for always believing in me and helping me to believe in myself. To my heavenly mother Mary, for giving me the graces to fulfill my calling in life. And to my Lord and my God, for the privilege to be a child of God.

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List of Abbreviations

ACA	-	Affordable Care Act
CCI	-	Chronic Critical Illness
CNA	-	Certified Nursing Assistant
COMAR	-	Code of Maryland Regulations
CY	-	Calendar Years
DONS	-	Division of Nursing Services
FFS	-	Fee-For-Service
HHA	-	Home Health Aide
HMO	-	Health Maintenance Organizations
LPN	-	Licensed Practical Nurse
MAC	-	Maryland's Access to Cares
MAR	-	Medication Administration Record
MCO	-	Managed Care Organizations
MDH	-	Maryland Department of Health
MNCHA	-	Maryland National Capital Home Care Association
MT	-	Medication Technician
N-G	-	Nasogastric
OHCQ	-	Office of Health Care Quality
PDN	-	Private Duty Nursing
PII	-	Personal Identifiable Information
POC	-	Plan of Care
PRN	-	As Needed
REM	-	Rare and Expensive Case Management
RN	-	Registered Nurses
RSA	-	Residential Service Agencies

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

INTRODUCTION

Private Duty Nursing (PDN) services are skilled nursing services provided to individuals with complex medical needs in their homes. PDN services are vital in ensuring the safety and wellbeing of the recipients and to help relieve the immediate family members. However, PDN services must meet some basic standards of quality to be both lifesaving and cost effective. Evaluating the quality of PDN services is an important way to ensure that high quality care is provided to the recipients of these services.

There are three primary ways to evaluate the quality of PDN services.[1] The first is to utilize outcome measures that result from the care of the clients. The second is by evaluating the process measures that go into providing the care. The third is by evaluating the structure that is needed to provide the care. For this project, process and structural measures were used to evaluate the quality of care provided to individuals in the Rare and Expensive Case Management (REM) program.

PROBLEM STATEMENT

In the State of Maryland, individuals diagnosed with complex clinical conditions may receive PDN services under the REM program. Individuals with complex medical needs are most often children with a broad range of medical conditions that require them to be dependent upon medical technology to survive at home. These complex conditions may include but are not limited to requiring a tracheostomy tube or mechanical ventilator to breath, and/or needing a gastrostomy tube or a nasogastric tube to maintain adequate nutrition. These individuals are

[1] Avedis Donabedian, *Explorations in Quality Assessment and Monitoring* (Ann Arbor, MI, MI: Health Administration Press, 1980).

cared for at home by Registered Nurses (RN) or Licensed Practical Nurses (LPN) working for licensed PDN provider agencies. The PDN services included in the REM program are administered by the Division of Nursing Services (DONS) at the Maryland Department of Health (MDH). The REM program makes it possible for these individuals to be relocated from costly short-term and long-term care facilities to their homes where they are taken care of by their families and licensed nurses. The REM and similar programs in other states have been shown to be very cost effective, providing cost-savings to both state Medicaid programs and private insurance companies.[2] [3] [4] Unfortunately, despite the potential cost-savings, the standard and quality of care in the REM program is not consistent for every individual receiving this service in the state of Maryland.

JUSTIFICATION OF CURRENT STUDY

Most PDN provider agencies lack the resources and capacity to make the necessary changes that would positively impact the quality of care provided to individuals with complex medical needs and their families. These agencies are set up as small business enterprises and most of them do not have the infrastructure to meet all the demands of the clients, clients' families, REM program requirements and state regulations. In addition, given that the PDN provider agencies serve a large number of individuals who receive Medicaid benefits, the low Maryland Medicaid reimbursement rate makes it even more difficult for these agencies to

[2] E. Cohen et al., "Children with Medical Complexity: An Emerging Population for Clinical and Research Initiatives," *Pediatrics* 127, no. 3 (2011): pp. 529-538, https://doi.org/10.1542/peds.2010-0910.

[3] E. R. Elias and N. A. Murphy, "Home Care of Children and Youth with Complex Health Care Needs and Technology Dependencies," *Pediatrics* 129, no. 5 (2012): pp. 996-1005, https://doi.org/10.1542/peds.2012-0606.

[4] Alan I. Fields, "Home Care Cost-Effectiveness for Respiratory Technology—Dependent Children," *Archives of Pediatrics & Adolescent Medicine* 145, no. 7 (January 1991): p. 727, https://doi.org/10.1001/archpedi.1991.02160070025016.

establish and maintain good quality of care for these clients. The low Medicaid reimbursement rate makes it hard for the agencies to offer competitive pay and benefits packages that could attract qualified experienced nurses.[5] These agencies also do not have the resources needed to set up and implement the type of training programs that will provide the necessary knowledge for the nurses.

In 2018, the Maryland General Assembly and the governor created a task force to study the impact of the Medicaid reimbursement rate on access to care and the quality of care for individuals receiving PDN services under the REM program. [6] After an extensive review, the task force found that about 17% to 29% of approved PDN service hours were not provided to individuals approved for LPN level of care. The task force also found that the Maryland state Medicaid reimbursement rate for home health services at the LPN level of care was much lower than that of three neighboring states, as well as the District of Columbia (Washington DC). These findings are in line with anecdotal evidence from REM program participants and PDN provider agencies suggesting that the low Medicaid reimbursement rate is negatively impacting recruitment and retention of qualified experienced nurses in home care in the state of Maryland. In addition, the task force found that there is an urgent need for a standardized training program to improve the knowledge level of home care nurses, which is essential to meeting the goal of achieving good quality of care for REM program participants.

In 2019, a bill was proposed to increase the Maryland Medicaid reimbursement rate for LPN level of care for REM program participants to $45 per hour. This bill also called for the

[5] Andrea K. McDaniels, "Maryland Families Struggle to Find in-Home Nurses, Who Make More Money in Neighboring States," baltimoresun.com, September 13, 2018, https://www.baltimoresun.com/health/bs-hs-home-nurses-20180916-story.html.

[6] Maryland Senate Bill 1041, "Maryland SB1041," TrackBill, accessed March 26, 2020, https://trackbill.com/bill/maryland-senate-bill-1041-public-health-care-of-medically-fragile-individuals-channings-law/1715539/.

institution of a mandatory training program to ensure that home care nurses acquire the skills needed to serve individuals with complex medical needs.[7] Unfortunately, due to the high price tag of the bill, it failed to pass out of the finance committee. Recently, in the 2020 legislative session, the 2019 bill was edited and refiled. The new bill, eliminated the provision for a reimbursement rate increase, but kept the requirement for a training program for home care nurses and included a mandate for the Office of Health Care Quality (OHCQ) in the MDH to design and implement the training program.[8] However, in order to avoid the high price tag, the revised bill proposed passing on the cost for implementing this training program to the PDN provider agencies, by mandating the agencies to pay the state program for the training of the nurses. The passage of such a bill will add more burden to the already under-funded and over-stretched PDN provider agencies struggling to keep up with the current regulatory demands while maintaining the expected standard of care per OHCQ regulations and REM program requirement.

Given the lack of political will to provide the financial (reimbursement rate increase) and technical (paid training program) resources needed by PDN provider agencies, it is apparent that these agencies have to find ways of improving the quality of care for their clients in the context of the current available resources. With this in mind, it is essential to evaluate the PDN services available within the REM program in order to fully understand the deficiencies that currently exist within the system and put forward recommendations on how to fix them. Hence, the goal of

[7] Maryland House Bill 1696, "Maryland HB1696," TrackBill, 2018, https://trackbill.com/bill/maryland-house-bill-1696-task-force-to-study-access-to-home-health-care-for-children-and-adults-with-medical-disabilities-and-report-on-home-and-community-based-services/1557215/.

[8] Maryland Senate Bill 733, "Maryland SB733," TrackBill, accessed March 26, 2020, https://trackbill.com/bill/maryland-senate-bill-733-public-health-care-of-medically-fragile-individuals-channings-law/1883571/.

this study was to review and analyze data from the audit of client and staff records of PDN provider agencies performed by the DONS. The overall objective was to utilize the finding improve the quality of care for this individuals. The results will be shared with PDN provider agencies with evidence-based suggestions on changes that could be made to improve the quality of care for REM program participants. This information may also help PDN provider agencies avoid financial losses due to state mandated recovery of funds following DONS audit results that show agencies to be out of compliance with state regulations.

PUBLIC HEALTH IMPLICATIONS

The lack of consistent, good quality of care for REM program participants not only affects individuals, it also impacts their families, the PDN provider agencies, and the Maryland state health care system in general. The immediate consequences of poor quality of care are felt by the REM program participants who may not have the right quality of services needed to keep them at home. The lack of well-trained skilled home care nurses results in serious negative health consequences for these individuals, with frequent episodes of (re)hospitalizations, emergency room visits, preventable complex medical procedures and even death.[9] In addition, inconsistencies in the quality of care provided often lead to disruptions in their family routines and the routines of the primary caregivers. These disruptions negatively affect the livelihood of the primary caregivers as they are forced to take time off from paid work and as a result cannot provide for the financial needs of the rest of their families.[10]

[9] Savithri Nageswaran and Shannon L. Golden, "Improving the Quality of Home Health Care for Children with Medical Complexity," *Academic Pediatrics* 17, no. 6 (2017): pp. 665-671, https://doi.org/10.1016/j.acap.2017.04.019.

[10] John D Lantos, "Ethical Aspects of Pediatric Home Care," *Pediatrics* 89, no. 5 (May 1992): pp. 920-924.

The lack of consistent good quality care for REM program participants also has a negative financial impact on the Maryland health care system in particular and the Maryland economy as a whole. When these individuals get sick or develop complications due in part to substandard care, they often end up in the emergency room, or worse have extended stays in intensive care units. Hospital stays are significantly more expensive than home-based care.[4] With clients in the hospital, home care nurses are out of work and struggle to provide for their own families. Furthermore, the primary caregivers for these individuals are also unable to work because they must be in the hospital with their family members. All of these factors have a negative impact on the overall economy of the state.

LITERATURE REVIEW

To give some context to the problem of quality of care for individuals with complex medical needs, it is important to understand the Maryland State Medicaid system and its implication for client care. Therefore, some background information on the Maryland State Medicaid system in general and the REM program in particular, is reviewed in this section.

HISTORY OF MARYLAND MEDICAID

The Maryland State Medicaid program started with passage of the Social Security Act amendment in 1965 by President Lyndon Baines Johnson. [11] Though implementation of the law did not take effect immediately in Maryland, the framework was available. Prior to the mid-1970s, Medicaid services were provided solely on a Fee-For-Service (FFS) basis. In the 1970s, Health Maintenance Organizations (HMOs) were formed which continued to function on the FFS model for about 20 years. In 1991, in addition to the HMO and FFS, the state formed a

[11] Debbie I. Chang et al., "Honesty as Good Policy: Evaluating Maryland's Medicaid Managed Care Program," *The Milbank Quarterly* 81, no. 3 (2003): pp. 389-414, https://doi.org/10.1111/1468-0009.t01-1-00061.

central program known as Maryland's Access to Care (MAC) targeted at individuals who had not joined any HMO. In 1997 the state switched to the Health Choice (HC) program where it used Managed Care Organizations (MCOs) as medical homes for all eligible Medicaid recipients.[11]

Maryland Medicaid provides payment for primary care visits, prescriptions, reproductive and behavioral health care, early childhood intervention services and nursing facility care for low-income individuals. As of 2001, 440,000 individuals had enrolled under an MCO.[12] This number has increased significantly over the last decades due to the expansion of Medicaid coverage following passage of the Affordable Care Act (ACA) enacted in 2010. Currently, enrollment in the Maryland state Medicaid program stands at approximately 1.3 million individuals.[13] The healthcare system in Maryland has gradually undergone a lot of structural changes to accommodate more beneficiaries and control costs. Currently, Maryland Medicaid FFS providers, MCOs, and administrative services organizations (Carve-out program) partner to administer Medicaid services.

HEALTH CHOICE PROGRAM

The Health Choice (HC) program enrolls individuals into MCOs. Multiple providers participate in the HC initiatives to offer care to eligible individuals. Currently, the state contracts with eight MCOs to provide Medicaid covered services to eligible Medicaid recipients in Maryland. These MCOs are Amerigroup, Kaiser Permanente, United Healthcare, Maryland Physicians Care, MedStar Family Choice, Jai Medical Systems, Priority Partners, and Riverside Health of Maryland. The program covers approximately 75% of all Maryland residents who

[12] Maryland Medicaid, "Maryland Medicaid and You: Measuring Medicaid Impact," Maryland Department of Health, 2016, https://mmcp.health.maryland.gov/docs/Medicaid_and_You_2016_e.pdf.

[13] Kristin Allen, "Medicaid Managed Care Enrollment Update – Q4 2019," Health Management Associates, February 27, 2020, https://www.healthmanagement.com/blog/medicaid-managed-care-enrollment-update-q4-2019/.

qualify for Medicaid.[12] The HC program is a prepaid system where the MCOs are paid to provide benefit packages that cover the services that are offered to the patients. If any services are not covered by the package, a recipient can still obtain the services through one of the waiver programs or carve out programs.

MARYLAND MEDICAID CARVE-OUT PROGRAMS

The State of Maryland created carve-out programs that compensate for services using the FFS reimbursement model as an additional way to control costs. The carve-out programs are managed outside the bigger Medicaid plans. This is because the state appreciates the high cost of offering care to patients with rare disorders and the accompanying high cost of treatment that follows them. About 33% of services covered under HC are carved-out and available on an FFS basis.[11] Some of the commonly carved out services include; dental care, substance abuse rehabilitation, the Model Waiver program and the REM program.

THE RARE AND EXPENSIVE CASE MANAGEMENT PROGRAM

The REM program is an initiative that was introduced as part of HC. The program was implemented in 1997 as a population carve-out program. The program was carved out of the managed care system because of the potential that the cost of healthcare for this population would be too high to maintain. In addition, the REM program was introduced as a carve-out because of the specialized care that each REM program participant requires. The MCOs could not be expected to have all of the needed specialists within their networks. As a result, the REM program was designed to ensure that certain medically fragile individuals were provided access

to timely, high quality, medically appropriate services across the entire continuum of health services.[14]

The REM program coordinates care for individuals who have rare and expensive medical conditions. In order to qualify for the REM program, an applicant must be diagnosed with a condition that is rare, expensive to treat and is listed on the REM program diagnosis list (See appendix 2). All REM program participants are managed through an FFS reimbursement system that seeks to reimburse for specific services offered by approved providers. The program pays for a range of services, such as: medical, dental, vision, PDN, occupational therapy, and home medical equipment and supplies.

The DONS at the MDH is currently responsible for administering the PDN services provided within the REM program, and DONS staff are responsible for approving individuals for services. They also screen and enroll PDN and Home Health agencies to provide care to these medically fragile individuals. The DONS is responsible for ensuring that these agencies are providing care in compliance with REM program requirements and Maryland state regulations.

PRIVATE DUTY NURSING SERVICES

PDN services refer to skilled nursing care provided to a patient on a one-on-one basis by licensed nurses in the home setting. PDN is an alternative to institutional care and is designed to help clients who are managing complex medical conditions, and is available in shifts of 2 up to 24 hours a day, 7 days a week. Some of the most common PDN services provided to eligible recipients are; tracheostomy care, ventilator care, respiratory treatments, catheter and ostomy care, gastrostomy (feeding tube) care, Nasogastric (N-G) tube care, medication, and injection

[14] Sanjay K. Pandey et al., "An Assessment of Maryland Medicaid's Rare and Expensive Case Management Program," *Evaluation & the Health Professions* 23, no. 4 (2000): pp. 457-479, https://doi.org/10.1177/01632780022034723.

administration. In the state of Maryland, REM program services are provided by LPNs or RNs employed by PDN provider agencies. Occasionally, non-licensed staff (Home Health Aide (HHA), Certified Nursing Assistant (CNA), and Certified Medication Technician (CMT)) may be utilized to provide nursing services under the delegation and supervision of an RN.

PRIVATE DUTY NURSING AGENCIES

Most home health agencies who provide PDN services in the state of Maryland are licensed as Residential Service Agencies (RSA) by the OHCQ under the MDH. These agencies go through a rigorous application process to be approved/licensed to provide PDN services for REM program participants. In addition to the licensure process, these agencies are also required to go through a credentialing process with the DONS before they are permitted to start receiving referrals. Currently there are a total of 59 agencies that are approved to provide PDN services in the REM program.[15]

When a client is referred for PDN services, the agency sends a registered nurse to do an initial assessment to determine the client's level of need. The supervisory nurse is also responsible for creating a Plan of Care (POC) in collaboration with the client's primary physician. When the level of need is determined, the agency is responsible for recruiting, and placing nurses who can provide direct care to the client. In all instances, the agency must make sure the direct care nurse is adequately trained and oriented to the house to ensure good patient outcomes. This is a very lengthy and important process that is needed to ensure the quality of care for the individuals being served.

[15] "Need Help with Fact Check," *Need Help with Fact Check*, April 6, 2020.

INDIVIDUALS WITH COMPLEX MEDICAL NEEDS

As of June 2019, 4,286 individuals were pre-authorized to receive services in the Maryland REM program.[7] Of this number, approximately 583 individuals were receiving PDN services through the Maryland Medicaid program[15], with 74% of these being children under the age of 21.[16] Seventy-one percent (71%) of individuals with complex medical needs are children with a broad range of medical conditions that often involve multiple organ systems.[1] A number of studies have shown that these children constitute a small fraction of all children in the larger population but they contribute a greater proportion of health care utilization and health expenditure for all children.[17] [18] [19] Many of the individuals who receive in-home services are technology-dependent[20] and require care from Registered Nurses (RNs) and Licensed Practical Nurses (LPNs).[21] Home care for these individuals has been shown to be cost-effective as compared to care at inpatient facilities (hospitals or nursing homes).[22] [23] In addition, home-based care has been known to increase the value of health care delivery by providing good-quality care at home and avoiding care in more expensive hospital settings.[4] As a result, the demand for home

[16] Long Term Services and Supports, "REM Presentation for CFC Supports Planners April 2016," Maryland Medicaid Community Programs (MMCP), 2016, https://mmcp.health.maryland.gov/longtermcare/Resource%20Guide/Forms/AllItems.aspx?RootFolder=%2Flongtermcare%2FResource%2BGuide%2FNew%2BSPA%2BTraining&FolderCTID=0x012000EC3A5071C9264542AAA2F6F7FBC9693C&View=%7BD27B28D9-A2B3-4C1B-A997-DAC031628942%7D.

[17] Jay G. Berry et al., "Children with Medical Complexity And Medicaid: Spending And Cost Savings," *Health Affairs* 33, no. 12 (2014): pp. 2199-2206, https://doi.org/10.1377/hlthaff.2014.0828.

[18] E. Cohen et al., "Patterns and Costs of Health Care Use of Children with Medical Complexity," *Pediatrics* 130, no. 6 (2012), https://doi.org/10.1542/peds.2012-0175.

[19] Tamara D Simon et al., "Children with Complex Chronic Conditions in Inpatient Hospital Settings in the United States," *Pediatrics* 127, no. 2 (2010), https://doi.org/10.1542/peds.2009-3266d.

[20] H Zafar and Nash D C. Nash, "Present and Future of Pediatric Home Healthcare," in *Guidelines for Pediatric Home Health Care* (Elk Grove Village, IL.: American Academy of Pediatrics, 2009), pp. 11-36.

[21] Russell C. Libby et al., "Pediatric Home Health Care Providers," in *Guidelines for Pediatric Home Health Care* (Elk Grove Village, IL., IL: American Academy of Pediatrics, 2009), pp. 45-53.

[22] Oscar G Casiro et al., "Earlier Discharge with Community-Based Intervention for Low Birth Weight Infants: a Randomized Trial," *Pediatrics* 92, no. 1 (July 1993): pp. 128-134.

[23] Pamelyn Close et al., *Pediatrics* 95, no. 6 (June 1995): pp. 896-900.

health care for children with complex medical needs has increased significantly in the last decade. [24]

Given the increase in the demand for in-home care for these individuals,[9] the current nursing shortage crisis,[25] [26] the low Medicaid reimbursement and low pay for home care staff in Maryland,[7] finding qualified nurses to care for these children is very challenging. PDN provider agencies are experiencing significant difficulties finding and retaining well-trained and qualified nurses to provide quality care for their clients. Therefore, the quality of care for these individuals is declining. However, the quality of care issue in the REM program is not just a financial issue, it could also be an issue of poor management on the part of the agencies,[27] substandard training provided to nurses,[28] and outdated regulations and program requirements[29] that have all failed to keep up with the times.

Evaluating the quality of home care services is an essential tool needed to obtain crucial data that would inform changes in regulation and public funding of home health care programs. A number of studies have shown that improving the quality of healthcare services would generally lead to a decrease in the cost of healthcare, and an increase in the productivity of health

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[24] Edwin Simpser and Mark L. Hudak, "Financing of Pediatric Home Health Care," *Pediatrics* 118, no. 2 (January 2006): pp. 834-838, https://doi.org/10.1542/peds.2006-1489.

[25] Nadine Genet et al., "Home Care across Europe - Current Structure and Future Challenges," 2012, http://www.euro.who.int/__data/assets/pdf_file/0008/181799/e96757.pdf.

[26] Heather Janiszewski Goodin, "The Nursing Shortage in the United States of America: an Integrative Review of the Literature," *Journal of Advanced Nursing* 43, no. 4 (2003): pp. 335-343, https://doi.org/10.1046/j.1365-2648.2003.02722_1.x.

[27] Winnie T. Maphumulo and Busisiwe R. Bhengu, "Challenges of Quality Improvement in the Healthcare of South Africa Post-Apartheid: A Critical Review," *Curationis* 42, no. 1 (2019), https://doi.org/10.4102/curationis.v42i1.1901.

[28] Institute of Medicine (US) Committee on the Adequacy of Nursing Staff in Hospitals and Nursing Homes, "Staffing and Quality of Care in Nursing Homes," Nursing Staff in Hospitals and Nursing Homes: Is It Adequate? (U.S. National Library of Medicine, January 1, 1996), https://www.ncbi.nlm.nih.gov/books/NBK232673/.

[29] Bo Kyum Yang et al., "State Nurse Practitioner Practice Regulations and U.S. Health Care Delivery Outcomes: A Systematic Review," *Medical Care Research and Review*, 2020, p. 107755871990121, https://doi.org/10.1177/1077558719901216.

care workers and overall better health outcomes for patients. In addition, changes that result in improvements in the quality of health care would lead to enhanced performance of healthcare organizations and create an environment for better working relationships between employees and employers in the healthcare industry.[30] [31] [32] [33]

EARLIER RESEARCH WORK

Prior to the 1980s, most Medically Fragile Children (MFC) were considered too vulnerable to send home at all and many languished for years in a variety of long-term care settings.[34] In the 1980s, a series of national conferences were held in the United States to address the multifaceted issues of children who depend on sophisticated technology for their survival. The reports from these conferences informed the creation of family-centered, community-based, comprehensive care programs for MFC.[34] [35] It also resulted in the recommendation to send MFC home to the most normal environment (integrated community setting) as soon as possible.[36] As

[30] Pui-Mun Lee, Pohwah Khong, and Dhanjoo N. Ghista, "Impact of Deficient Healthcare Service Quality," *The TQM Magazine* 18, no. 6 (2006): pp. 563-571, https://doi.org/10.1108/09544780610707075.

[31] Puay Cheng Lim and Nelson K.h. Tang, "A Study of Patients' Expectations and Satisfaction in Singapore Hospitals," *International Journal of Health Care Quality Assurance* 13, no. 7 (2000): pp. 290-299, https://doi.org/10.1108/09526860010378735.

[32] Joseph A. Maxwell, *Qualitative Research Design: an Interactive Approach* (Thousand Oaks, CA: Sage, 2005).

[33] "Report of the Surgeon General's Workshop on Children with Handicaps and Their Families: Case Example, the Ventilator-Dependent Child.," Clinical Pediatrics 22, no. 8 (1982): pp. 567-571, https://doi.org/10.1177/000992288302200809.

[34] Cindy L. Capen and E. Rosellen Dedlow, "Discharging Ventilator-Dependent Children: A Continuing Challenge," *Journal of Pediatric Nursing* 13, no. 3 (1998): pp. 175-184, https://doi.org/10.1016/s0882-5963(98)80076-6.

[35] ERIC, "Repdrt of the Surgeon General's Workshop on Children with Handicaps and Their Families. Case Example: The Ventlator-Dependent Child.," Institute of Education Sciences, 1982, https://files.eric.ed.gov/fulltext/ED247676.pdf.

[36] J Kaufman and D Hardy-Ribakow, *Journal of Pediatric Nursing* 2, no. 4 (1987): pp. 244-249.

of 2018, a Kaiser Family Foundation Medicaid Benefits Survey found that approximately 25 states offered REM program type PDN services through their Medicaid programs.[37]

There has been extensive research on various aspects of providing PDN services to MFC in the home. In 2002, Harrigan and his colleagues did an integrative review of the care for MFC and made major recommendations for future research in this area.[38] In 2004, Wang and Alan did an extensive review of the literature to summarize the state-of-the-art on the development of pediatrics home care, and its impact on technology-dependent children and their families, and social implications.[39] In 2018, Haken *et al*., did a systematic review on types, trends and experiences with the use of advanced medical technologies in the home setting.[40] Overall, the above three reviews showed that published research work evaluating PDN services could be put into one of the following four categories: a) general analysis of the effectiveness of home care programs, b) a cost evaluation of home care programs, c) an assessment of the treatment protocols and technology used in these home programs and d) the impact of the home care services on quality of life for individuals and their families. Haken *et al*., reviewed about 87 research articles published between 2000 and 2015 and found that the majority of the papers focused on describing the impact of home care programs and services on patients or informal

[37] The Henry J. Kaiser Family Foundation, "Medicaid Benefits: Private Duty Nursing Services," The Henry J. Kaiser Family Foundation, January 18, 2019, https://www.kff.org/medicaid/state-indicator/private-duty-nursing-services/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D.

[38] Rosanne C. Harrigan et al., "Medically Fragile Children: An Integrative Review Of The Literature And Recommendations For Future Research," *Issues in Comprehensive Pediatric Nursing* 25, no. 1 (January 2002): pp. 1-20, https://doi.org/10.1080/014608602753504829.

[39] Kai-Wei Katherine Wang and Alan Barnard, "Technology-Dependent Children and Their Families: a Review," *Journal of Advanced Nursing* 45, no. 1 (2004): pp. 36-46, https://doi.org/10.1046/j.1365-2648.2003.02858.x.

[40] Ingrid Ten Haken, Somaya Ben Allouch, and Wim H. Van Harten, "The Use of Advanced Medical Technologies at Home: a Systematic Review of the Literature," *BMC Public Health* 18, no. 1 (2018), https://doi.org/10.1186/s12889-018-5123-4.

caregivers and the provision of care to these individuals at home.[40] Seven of the articles evaluated the services from the aspect of training and education provided to the nurses/professionals and patients/informal caregivers. Thirteen of the articles evaluated the quality of care and reported on client safety in general. Finally, three articles mainly looked at costs and/or reimbursement.

Of the articles reviewed in the aforementioned literature review papers, two were particularly relevant to the study reported in this dissertation because the authors focused on evaluating services provided by specific state PDN programs. Leonard *et al*., did a program evaluation to determine the impact of Minnesota's Medicaid Model Waiver program.[41] Richardson e*t al*., evaluated the Michigan Department of Public Health Specialized Home Care Program for children with special health needs.[42] Both of these studies found significant deficiencies with the programs that were reviewed. Leonard *et al*., found that of the 96 children who applied for the program, only 24 were able to receive approval. There was a need for funding and for a statewide system of care to prevent frustration and confusion for parents/professionals and to eliminate gaps in the distribution of funding. Richardson *et al*., found that there were some cost savings in the Michigan program but there was a need to evaluate participant satisfaction with the program. Of note, none of the reports reviewed investigated quality of care from the perspective of improving the organizational system of the PDN service providers.

[41] Barbara J Leonard, Janny D Brust, and Thomas Choi, "Providing Access to Home Care for Disabled Children: Minnesota's Medicaid Model Waiver Program," *Public Health Reports* 104, no. 5 (1989): pp. 465-472.

[42] Matthew Richardson et al., "Establishment of a State-Supported, Specialized Home Care Program for Children with Complex Health-Care Needs," *Issues in Comprehensive Pediatric Nursing* 15, no. 2 (1992): pp. 93-122, https://doi.org/10.3109/01460869209078245.

THEORETICAL FRAMEWORK

The Donabedian Framework was the theoretical framework chosen for this project. This model was first published in 1966 and has been modified over the years.[1] [43] The framework initially defined healthcare quality as "the application of medical science and technology in a manner that maximizes its benefit to health without correspondingly increasing the risk". In his work, Donabedian proposed that quality healthcare is a multi-dimensional concept with three distinguished components: technical quality, interpersonal quality, and amenities.

In this model, Donabedian defined these components as follows: Technical quality relates to the effectiveness of care in producing achievable health gain. Interpersonal quality refers to the extent of accommodation of the patient's needs and preferences. The amenities include features such as comfort of physical surroundings and attributes of the organization of service provision. He later proposed the triad structures, processes and outcomes as a framework for assessing quality of care. Structure refers to the attributes of the settings in which care is provided. It includes such elements as resources, staff and equipment. Process covers all aspects of delivering care and is related to interactions within and between practitioners and patients. Outcome focuses on the end-result or the effect of the care provided.[43] The structure, process and outcome framework provide an appropriate model for this project.

Utilizing outcome measures to evaluate the quality of home health care for Maryland Medicaid REM program participants can be effective because these services can affect many facets of an individual's health for which outcome quality measures can be constructed. In addition, home health is intended to enhance or at least maintain the health of the individuals

[43] Avedis Donabedian, "The Quality of Care," *Jama* 260, no. 12 (1988): p. 1743, https://doi.org/10.1001/jama.1988.03410120089033.

who receive the services. Over the years, many studies have emphasized the importance of utilizing outcome measures to evaluate health-care quality.[38] [44] [45] [46] [47] [48]

However, despite the importance of outcome measures, there are two main reasons why it could not be the exclusive method used for evaluation of quality of care for this project. Outcomes for REM participants are influenced by multiple aspects of the client care environment, not just services provided by a PDN provider agency. For example, the physician care, hospital discharge planning, and care provided by family members or other informal caregivers all significantly influence client outcomes. Another problem with utilizing primarily outcome assessment to evaluate quality of care for clients receiving REM program services is that the probability that patient status will improve or be maintained depends on the underlying condition, comorbidity, and the home environment of the client. Even though one can adjust for such differences using multivariate analyses methods, the difficulties in isolating the unknowns makes it impossible to truly judge the progression of an outcome measure.

On the other hand, utilizing process measures helps to explain which aspects of care for these individuals are problematic. Process measures require standards or guidelines to which actual patient care can be compared. These standards or guidelines can be used to measure process quality by collecting uniform data and comparing actual care with standards. As a result,

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[44] Institute of Medicine, *Improving the Quality of Care in Nursing Homes* (Washington, DC: National Academy Press, 1987).

[45] Kathleen N. Lohr, "MEDICARE—Vol. I—A Strategy for Quality Assurance; MEDICARE—Vol. II—A Strategy for Quality Assurance—Sources and Methods," *Journal For Healthcare Quality* 12, no. 5 (1990): p. 31, https://doi.org/10.1097/01445442-199011000-00015.

[46] H. S. Luft, "Evaluating Individual Hospital Quality through Outcome Statistics," *JAMA: The Journal of the American Medical Association* 255, no. 20 (1986): pp. 2780-2784, https://doi.org/10.1001/jama.255.20.2780.

[47] Lynn T. Rinke and Alexis A. Wilson, *Outcome Measures in Home Care* (New York: National League for Nursing, 1987).

[48] Stephen M Shortell and Edward F.X. Hughes, "Effects of Regulation, Competition, and Ownership on Mortality Rates among Hospital Inpatients," *New England Journal of Medicine* 319, no. 20 (1988): pp. 1354-1358, https://doi.org/10.1056/nejm198811173192018.

it is very easy to translate findings from results of projects into recommendations for improving quality. According to Wyszewianski, process outcomes provide a necessary supplement to outcome measures and give one the ability to associate good or bad outcomes with care provided by an agency.[49]

In-home health care standards have been developed by many individual home health agencies, agency associations and accreditation agencies for quality assurance programs.[36] [50] In addition, the Maryland Medicaid REM program and similar programs have developed a set of program requirements for the PDN provider agencies that are intended to ensure the quality of the care for the program participants. These care standards and program requirements relate to key attributes of care that can more easily be linked to specific outcomes. For PDN clients whose outcomes are sometimes difficult to define and difficult to measure, process measures provide another approach to evaluating quality of care. However, reliance on only process measures for the evaluation of quality of care is not adequate because these standards of care are often global and their application requires judgment on the part of a surveyor or reviewer.[31] [51] [52] Thus, these results may be subject to the biases of the surveyor or reviewer, and therefore limited in generalizability.

Structural measures can also be used to evaluate the quality of care provided by PDN provider agencies to individuals on the REM program. Over the years, organizations like the

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[49] Leon Wyszewianski, "Quality of Care: Past Achievements and Future Challenges," *Inquiry* 25, no. 1 (1988): pp. 13-22.

[50] Texas Association of Home Health Agencies, "Home and Community-Based Services Handbook," Texas Health and Human Services, June 1, 2010, https://hhs.texas.gov/laws-regulations/handbooks/home-community-based-services-handbook.

[51] Joint Commission on Accreditation of Healthcare Organization (JCAHO), "JCAHO Publishes 1999–2000 Accreditation Manual for Home Care," *Biomedical Safety & Standards* 29, no. 3 (1999): p. 22, https://doi.org/10.1097/00149078-199902150-00014.

[52] Barbara Stover Gingerich, "Community Health Accreditation Program Millennium Standards Released," *Home Health Care Management & Practice* 15, no. 3 (2003): pp. 251-252, https://doi.org/10.1177/1084822302250692.

National League for Nursing have developed and reviewed structural standards that can be used to evaluate home care agencies. These structural measures include but are not limited to guidelines on agency organizational structure, and staff qualification. They also include provider agency level indicators such as; standards for admitting patients, assuring confidentiality, record keeping, dispensing pharmaceuticals, and maintaining equipment.[51] [53] Although these standards establish the presence of provider agency-level elements necessary to provide adequate care, they do not assure that provider agency capability translates into good patient care. Therefore, structural measures should be used with caution because, although measures such as extensive compliance with documentation can ensure continuity of care for REM program participants, it can also impose a heavy administrative burden that can distract from the provision of care. Furthermore, structural measures do not directly assess quality at the patient level.

For this project, it would have been ideal to consider all three measures of health status as this researcher assess the quality of PDN services provided to individuals in the Maryland Medicaid REM program. However, because of the lack of outcome data such as decrease in hospitalization, improvement in clinical outcome, reduction in complications or deaths, and patient satisfaction, this study focused on process and structural measures. This study utilizes these structural and process measures with the goal of giving PDN provider agencies tangible recommendations for improving quality of care for their clients.

[53] U.S. Department of Health and Human Services (USDHHS), "CMS-3819-F Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies Interpretive Guidelines," Centers for Medicare & Medicaid Services, 2018, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-25-HHA.pdf.

DISSERTATION SUMMARY

STUDY 1: Assessment of quality of private duty nursing agencies providing services to individuals in the Maryland Rare and Expensive Case Management Program – a clinical audit.

In Maryland, agencies that provide Private Duty Nursing (PDN) services to individuals in the Rare and Expensive Case Management (REM) program are required to collect and retain complete and accurate documentation for every hour of service that is billed to the state. This documentation is especially important to facilitate effective care by helping to identify patient needs, ensure continuity of care and most importantly empower nurses to make good clinical decisions. Periodically, the Division of Nursing Services (DONS) in the Maryland Department of Health (MDH) audits PDN provider agency records to ensure that provider agencies are following DONS and state guidelines in the delivery of services to REM program participants. The purpose of this study was to analyze and synthesize the findings of the audits carried out on the clinical and personnel records pertaining to PDN services provided to REM program participants. The research question was: Are there process deficiencies in the delivery of PDN services to individuals on the REM Program? If yes, what are the deficiencies and what are the implications for the quality of client care?

This is a descriptive study with a retrospective analysis of audit results of documentation review of 30 client records from about 13 PDN provider agencies. Google Sheets and Stata software were used to determine the frequencies, percentage scores, and means with confidence intervals for different parameters in the audit. Analyses of the results revealed several deficiencies in the client care that could lead to adverse outcomes for the clients if corrective actions are not taken by the PDN provider agencies. The hope is that improvements to the quality of nursing services can be implemented at provider agencies as well as the executive and legislative levels of state government

STUDY 2: Policy Impact: Effects of Policy Regulation on the quality of private duty nursing services provided to individuals in the Maryland Medicaid Rare and Expensive Case Management program

There is a severe nursing staff shortage experienced by Private Duty Nursing (PDN) agencies providing services to individuals with complex medical needs in the Maryland Medicaid Rare and Expensive Case Management (REM) Program. Therefore, it is a constant struggle for these agencies to meet the staffing levels needed to serve their clients and the clients' families. Several studies have shown that the workforce crisis in the nursing field can be attributed to the nursing shortage, low reimbursement/pay rate, and state policies and regulations. The aim of this paper was to examine the possible impact of one such regulation in the state of Maryland that requires PDN provider agencies to hire nurses with specialized pediatric and clinical experience to provide services to the children in the REM program. The research question was: Are there structural deficiencies in the delivery of PDN Services to individuals on the REM Program? If yes, what are they, and what are the implications for the quality of client care?

To investigate this issue, this researcher did a retrospective analysis of the results of audits of 99 personnel and 30 patient records submitted to the state by PDN provider agencies. The audit was done by the Division of Nursing Services (DONS) in the Maryland Department of Health (MDH), using an audit instrument created specifically for this purpose. The results showed that the majority of PDN provider agencies were unable to comply with the requirements of the program regulations. In addition, there was no evidence that this requirement is translating to better care for the client. On the contrary it seems to be just a bottleneck in the hiring process. As a result, this researcher is proposing for the state to consider eliminating this requirement and replacing it with a mandate that training on specific skills such as tracheostomy care (among others) be provided to nurses before they are assigned to take care of REM program participants.

STUDY 3: Improving the quality of care provided to individuals receiving private duty nursing services through the Maryland Medicaid Rare and Expensive Case Management program

Private Duty Nursing (PDN) services are provided to individuals on the Maryland Medicaid Rare and Expensive Case Management (REM) program by PDN provider agencies that are approved by the Division of Nursing Services (DONS) in the Maryland Department of Health (MDH). These services are vital to ensure the safety and wellbeing of the individuals in their homes. An audit of 99 personnel and 30 patient records submitted to the state by PDN provider agencies showed significant gaps in records keeping and documentation which could point to potential problems with client care. The purpose of this study was to do a review of the comments provided by the DONS program auditor and use the findings to provide PDN provider agencies with best practice and recommendations for improving the quality of documentation and hence nursing service delivery to REM program participants. For this study, the research question was: Are there specific process and structure measures that can be implemented to improve the quality of care for individuals on the REM program?

The results of the study showed that these agencies are not following their own internal policies, completing documentation correctly and following up with the care of clients. These findings suggest that some of these PDN provider agencies lack the infrastructure to support the clients in the REM program. Some suggestions are provided to help improve the quality of services delivered to REM program participants.

CONCLUSIONS

Despite the importance of the Maryland Medicaid REM program in providing care for these individuals and the need to ensure good quality of care for REM program participants, there has been only one evaluation of this program since its inception.[14] This lone study focused

on evaluating the cost savings that resulted from the case management services provided as part of this program. Although this researcher has reason to believe that the DONS program has done audits for their internal use, there is no published work that can be used by PDN provider agencies in this program to improve the quality of the service delivery system. Therefore, in order to help provider agencies to improve the quality of care delivered to REM program participants in the context of the current nursing shortage and low Maryland Medicaid reimbursement rate, this study was carried with the objectives to:

- Assess the current quality of PDN services and identify the key areas of deficiency found in services provided to Maryland REM Program participants.
- Explore the effects of certain program policies and regulations on the quality of care provided by PDN provider agencies to individuals in the Maryland Medicaid REM program.
- Propose some practical evidence-based solutions that can be implemented by PDN provider agencies to improve the quality of care provided to individuals receiving PDN services through the Maryland Medicaid REM program.

The goal is to share the results of this study with PDN provider agencies in the state of Maryland and to advocate/lobby for changes that would improve the quality of care for REM program participants.

CHAPTER 2: STUDY 1: Assessment of quality of private duty nursing agencies providing services to individuals in the Maryland Rare and Expensive Case Management Program – a clinical audit.

INTRODUCTION

Documentation in the nursing field is a vital communication tool for the exchange of information between nurses and other caregivers.[54] A number of studies have shown that quality nursing documentation promotes patient safety, facilitates continuity of care and effective communication between caregivers.[52] [55] In addition, nursing documentation is used for quality assurance, legal purposes, health planning, allocation of resources and nursing development and research.[56] In Maryland, agencies that provide Private Duty Nursing (PDN) services to individuals in the Rare and Expensive Case Management (REM) program are required to collect and retain complete and accurate documentation for every hour of service that is billed to the state. These services are provided to individuals with complex clinical conditions. These are most often children with a broad range of medical conditions that make them dependent on medical technology to survive at home.

To be effective, nursing documentation needs to contain valid and reliable information and comply with established standards for which it was created.[54] [56] [57] Several studies have assessed the quality of nursing documentation using different auditing instruments with different criteria

[54] Christine Urquhart et al., "Nursing Record Systems: Effects on Nursing Practice and Healthcare Outcomes," *Cochrane Database of Systematic Reviews*, 2009, https://doi.org/10.1002/14651858.cd002099.pub2.

[55] C Bjorvell, "Development of an Audit Instrument for Nursing Care Plans in the Patient Record," *Quality in Health Care* 9, no. 1 (January 2000): pp. 6-13, https://doi.org/10.1136/qhc.9.1.6.

[56] Oili Karkkainen and Katie Eriksson, "Evaluation of Patient Records as Part of Developing a Nursing Care Classification," *Journal of Clinical Nursing* 12, no. 2 (2003): pp. 198-205, https://doi.org/10.1046/j.1365-2702.2003.00727.x.

[57] Ewa Idvall and Anna Ehrenberg, "Nursing Documentation of Postoperative Pain Management," *Journal of Clinical Nursing* 11, no. 6 (2002): pp. 734-742, https://doi.org/10.1046/j.1365-2702.2002.00688.x.

reflecting how quality was perceived by the researchers.[58] [59] [60] [61] [62] [63] Of interest is a study by Borcher (1999), which was focused specifically on improving nursing documentation in the PDN setting. They implemented a documentation improvement project in one PDN provider agency. In this project, they focused on revising the documentation system with implementation of a flow record and conducting group nurse education. After the completion of the project, they found significant and sustained improvements in nursing documentation.

Documentation in patient medical records must be complete, comprehensive, use common vocabulary, be legible, and use standardized abbreviations and symbols to be considered of good quality.[64] [65] However, the quality of nursing documentation is evaluated on its completeness, quantity, legibility, patient identification, chronological report of events, comprehensiveness of

[58] Ellen L. Borchers, "Improving Nursing Documentation for Private-Duty Home Health Care," *Journal of Nursing Care Quality* 13, no. 5 (1999): pp. 24-43, https://doi.org/10.1097/00001786-199906000-00005.

[59] Diana Jefferies, Maree Johnson, and Rhonda Griffiths, "A Meta-Study of the Essentials of Quality Nursing Documentation," *International Journal of Nursing Practice* 16, no. 2 (2010): pp. 112-124, https://doi.org/10.1111/j.1440-172x.2009.01815.x.

[60] Maria Müller-Staub et al., "Nursing Diagnoses, Interventions and Outcomes ? Application and Impact on Nursing Practice: Systematic Review," *Journal of Advanced Nursing* 56, no. 5 (2006): pp. 514-531, https://doi.org/10.1111/j.1365-2648.2006.04012.x.

[61] Cristina Oroviogoicoechea, Barbara Elliott, and Roger Watson, "Review: Evaluating Information Systems in Nursing," *Journal of Clinical Nursing* 17, no. 5 (2008): pp. 567-575, https://doi.org/10.1111/j.1365-2702.2007.01985.x.

[62] Wolter Paans et al., "Prevalence of Accurate Nursing Documentation in Patient Records," *Journal of Advanced Nursing* 66, no. 11 (2010): pp. 2481-2489, https://doi.org/10.1111/j.1365-2648.2010.05433.x.

[63] Kaija Saranto and Ulla-Mari Kinnunen, "Evaluating Nursing Documentation - Research Designs and Methods: Systematic Review," *Journal of Advanced Nursing* 65, no. 3 (2009): pp. 464-476, https://doi.org/10.1111/j.1365-2648.2008.04914.x.

[64] Bola Ofi and Olanrewaju Sowunmi, "Nursing Documentation: Experience of the Use of the Nursing Process Model in Selected Hospitals in Ibadan, Oyo State, Nigeria," International Journal of Nursing Practice 18, no. 4 (2012): pp. 354-362, https://doi.org/10.1111/j.1440-172x.2012.02044.x.

[65] Asta Thoroddsen et al., "Accuracy, Completeness and Comprehensiveness of Information on Pressure Ulcers Recorded in the Patient Record," *Scandinavian Journal of Caring Sciences* 27, no. 1 (2012): pp. 84-91, https://doi.org/10.1111/j.1471-6712.2012.01004.x.

description, nursing assessment, objective information, signature, date and timeliness.[66] Nursing documentation is important for facilitating effective care by helping to identify patient needs, and most importantly, to empower nurses to make good clinical decisions.[64] Therefore, incomplete documentation undermines the essential foundation needed to provide good quality care, quality improvement or effective decisions on allocation of resources.[67]

It is well documented that patient safety could be compromised when nurses do not document nursing processes effectively and completely. [62] Two main home health agency accreditation organizations (The Joint Commission on Accreditation of Healthcare Organizations, JCAHO, and Community Health Accreditation Program, CHAP), have identified good documentation as one of the process measures to evaluating quality of care. [51] [68] [69] In addition, it is crucial that nursing assessments, care plans, implementation of interventions, and evaluation of results be systematically and accurately communicated through effective documentation. [70] [71] The purpose of this descriptive project was to analyze and synthesize the findings of the Division of Nursing Services (DONS) program audits carried out on the clinical records of PDN provider

[66] Ning Wang, David Hailey, and Ping Yu, "Quality of Nursing Documentation and Approaches to Its Evaluation: a Mixed-Method Systematic Review," *Journal of Advanced Nursing* 67, no. 9 (June 2011): pp. 1858-1875, https://doi.org/10.1111/j.1365-2648.2011.05634.x.

[67] Magdalena Annersten Gershater, Ewa Pilhammar, and Carin Alm Roijer, "Documentation of Diabetes Care in Home Nursing Service in a Swedish Municipality: a Cross-Sectional Study on Nurses' Documentation," *Scandinavian Journal of Caring Sciences* 25, no. 2 (2010): pp. 220-226, https://doi.org/10.1111/j.1471-6712.2010.00812.x.

[68] CHAP , "Standards of Excellence Private Duty," CHAP Education: CHAP Private Duty Standards of Excellence, 2006, https://education.chaplinq.org/products/private-duty-standards-of-excellence-pdf.

[69] Laura M. Smith et al., "Patient Experience and Process Measures of Quality of Care at Home Health Agencies: Factors Associated with High Performance," *Home Health Care Services Quarterly* 36, no. 1 (February 2017): pp. 29-45, https://doi.org/10.1080/01621424.2017.1320698.

[70] Edith R Gjevjon and Ragnhild Hellesã¸, "The Quality of Home Care Nurses' Documentation in Electronic Patient Records," *Journal of Clinical Nursing* 19, no. 1-2 (2010): pp. 100-108, https://doi.org/10.1111/j.1365-2702.2009.02953.x.

[71] Elisha M. Okaisu et al., "Improving the Quality of Nursing Documentation: An Action Research Project," *Curationis* 37, no. 2 (2014), https://doi.org/10.4102/curationis.v37i2.1251.

agencies serving REM program participants. The objective was to evaluate the current quality of PDN services and identify the key areas of deficiency that could be improved upon. The research question was, are there process deficiencies in the delivery of PDN Service to individuals on the REM Program? If yes, what are the deficiencies and what are the implications for the quality of client care?

The findings of this project highlight areas in need of improvement in the home care nursing clinical practice setting that will result in better quality of care for REM program participants.

METHODS

This retrospective study was a retrospective analysis of audit results of client records from about 29 PDN agencies.[72] The audits, which were carried out by the DONS at the Maryland Department of Health (MDH), were done on client records that were submitted by PDN provider agencies serving REM clients. The reasons for the audit were mostly as a result of client complaints, client deaths, reportable incidents, and review for medical necessities

DATA COLLECTION PROCESS

Generally, records for nursing services rendered to a REM participant are kept in the client's records at the PDN provider agency. PDN provider agencies are required by regulation to make client records available to the MDH at any time upon request. Audits of provider records can be done in person at the agency office (On-Site Audit) or at the MDH office (Desk Audit). In the case of a Desk Audit, the DONS program would send a letter to the PDN provider agency requesting specific records, from a specific time period, with a specific due date to return the information. A representative from the PDN provider agency would put all the records together

[72] "Re: Need Help with Fact Check," *Re: Need Help with Fact Check*, April 10, 2020.

and mail them back to the appropriate address. When the records are received at the MDH, a representative from the state is tasked with reviewing the records and documenting the findings using the "Medical On-site/Desk Audit form". The Medical On-site/Desk Audit form is an audit instrument designed by the DONS staff specifically for auditing records of PDN provider agencies. Upon completion of the review, a letter is sent to the agency with a copy of the audit form, listing the deficiencies that were found and requesting corrective action and/or requesting money back from the PDN provider agency if the services were not rendered in accordance with the program regulations. The client records audited in this study, were examined according to the criteria in the Medical On-site/Desk Audit instrument created by the DONS program.

To gain access to the audit records from the DONS program, this researcher filed a freedom of information request with the MDH (see a copy of the letter in Appendix 1). The MDH granted the request and notified this researcher that she would receive the records. After redacting Personal Identifiable Information (PII) on the audits, MDH emailed the records in PDF format. Upon receipt of the records, this researcher coded the electronic data entries and used the codes to enter the data into a Google spreadsheet for analysis.

CODING PROCESS

The audit instrument was made up of the following 10 sections; 1) General Information, 2) Physician Information, 3) Medication Administration Record (MAR), 4) Plan of Care (POC), 5) Progress Note, 6) Supervision, 7) Program Requirement, 8) Clinical Management Policy, 9) Personnel Records, and 10) Money Recovery. However, in this study the analysis was limited to sections 1 to 8 of the audit instrument. The specific questions in each section guided the response coding. The responses to the questions in sections 2 to 8 were coded as follows. 1)YES, if the state reviewer responded "yes", 2) NO, if the state reviewer responded "NO", 3) N/A, if the

state reviewer responded "N/A", 4) Unknown, if the state reviewer left the space blank, 5) Not Submitted, if the state reviewer commented that it was not submitted (See sample in Appendix 3).

DATA ANALYSIS

For statistical analyses, Google Sheets and Stata software were used. Frequencies and percentage scores with 95% confidence intervals for all the non-compliance parameters in the audit records were calculated. The results of the analyses are shown in the tables below with the values of non-compliance rates greater than 30% depicted with an asterisk. A threshold of 30% non-compliance was chosen because it is generally the accepted cut-off at which a corrective action is needed following an audit from the Office of Health Care Quality (OHCQ) or an accreditation audit from accrediting agencies such as the Community Health Accreditation Program (CHAP). [68] Data was reviewed from audits carried out in Calendar Year (CY) 2016, CY2017, and CY2018 for PDN services provided to individuals on the REM program between CY2014 and CY2017. Of note, any item on the medical On-site/Desk Audit form that had a response of not submitted, were coded as "NO" for the analyses. This is because of the nurse documentation standard which states that anything that is not documented should be considered that it was not done.[73] [74] Any missing documentation in the audit records was considered as though the documentation did not exist. Since the records were redacted, this researcher did not have a direct way of coding for the actual agencies that were involved in the audits. In the absence of the agency name, this researcher relied on the DONS program for the count of the

[73] Maria Grazia De Marinis et al., "'If It Is Not Recorded, It Has Not Been Done!'? Consistency between Nursing Records and Observed Nursing Care in an Italian Hospital," *Journal of Clinical Nursing* 19, no. 11-12 (2010): pp. 1544-1552, https://doi.org/10.1111/j.1365-2702.2009.03012.x.

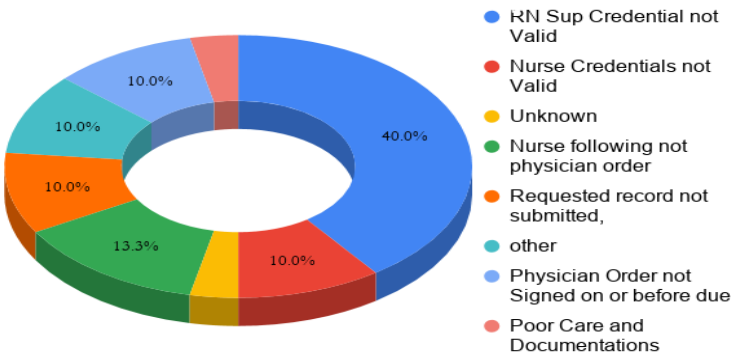
[74] *Maryland Nurse Practice Act: Reprinted from the Annotated Code of Maryland and 1981 Cumulative Supplement* (Charlottesville, VA: Michie, 1981).

actual number of agencies that were involved in these audits. After a review of the un-redacted version of the audit records, the DONS program auditor shared in a separate communication that the data analyzed in this study were from an audit of a total of 29 PDN provider agencies.

RESULTS

A total of 30 client records from 29 PDN provider agencies were examined according to the criteria in the Medical On-site/Desk Audit form. The reasons for the audit were mostly as a result of client complaints, client deaths, reportable incidents, and review for medical necessities. A total of about $480,000 was recovered from the PDN provider agencies due to deficiencies found in the records. The recovery reasons ranged from; invalid RN credentials (40%), invalid Staff Nurse Credentials (10%), nurse not following physician orders (13%), requested records not submitted (10%), physician orders (PO) not signed on or before due date (10%), poor care and documentation (10%), and the remaining 7% was for other and unknown reasons. 100% of the records that were reviewed were subject to a money recovery for multiple reasons. Figure 1.1 illustrates the percentage of money recovery distributed by the primary reasons why the monies were recovered.

Figure 1.1: Primary Reason for Money Recovery



Physician Information:

The audit of the physician information section revealed two main deficiencies. Half or more of the 30 client records that were reviewed did not have completed medication orders (63%) and/or signed physician orders (PO) on or before the effective date of the orders (50%). Thirty-six percent of the records did not have their orders reviewed every 60 days as required by the regulation. Note that most of the records were signed by the primary physicians who were licensed in the state of Maryland (see Table 1.1).

Table 1.1: Percentage of Non-Compliance on the physician Information Audit

Audit Parameter	True Count, n	Non-Compliance records n (%)	Proportion of complaint records 95% CI (%)
Physician order signed by primary physician	25.00	3 (12)	2.5 - 31
Signing physician licensed in Maryland	25.00	5 (20)	6 - 40
Physician order signed and dated on or before effective date	26.00	13 (50)*	30 - 70
Plan of care renewed q60 days	14.00	5 (36)*	12 - 64
Medication order Complete	27.00	17 (63)*	42 - 81

*Non-compliance greater than 30% threshold per DONS requirement

Medication Administration Records:

A review of the Medication Administration Records (MAR) revealed that 80% of the records had a discrepancy between the PO and the MARs (see Table 1.2). Generally, a physician order is received by the supervisory nurse in the PDN provider agency, and the order is transcribed on the MAR that is placed in the home of the REM program participant. The MAR is utilized by the nurse in the home as a guide when he/she is administering any treatment to the clients. So this finding indicates that nurses in the home were not administering what was ordered by the doctors 80% of the time.

Table 1.2: Percentage of non-compliance on Medication Administration Records

MAR Audit Items	True Count, n	Non-Compliance records n (%)	Proportion of complaint records 95% CI (%)
Discrepancy between PO and MAR	25	20 (80)*	59 - 93

*Non-compliance greater than 30% threshold per DONS requirement

Plan of Care:

The audit of the Plans of Care (POC) revealed mixed results, showing some strengths and weaknesses in the documentation (See Table 1.3). Although none of the records had their POCs completed in their entirety, most of the items on the POC had more than 60% completion rate. The following were identified and documented correctly on the plans of care; all of the different diagnoses of the participants (67%), prognoses of the participants conditions (85%), type of treatments needed by the participants (81%), types of nursing services (78%) that are required and the frequency of nursing services (74%) needed, functional limitations (70%) of the client and the list of permitted activities (81%) and prohibited activities (60%) they can/cannot engage in, types of diets (81%) the clients are allowed to have, medications (85%) prescribed for the clients and the medical supplies (67%) and equipment (63%) being used in the homes by the

clients, mental status (67%) of the clients and the type of safety measures (89%) in place needed to keep the clients safe at home.

Some deficiencies stand out and are of great concern with the following items having less than 50% completion rate; treatment goals (11%), Backup NCP (83%), Family Involvement (8%), PDS (100%) and, Rehab Potential (85%). A review of the Emergency Management Plan (EMP) section revealed that in 77% of the records (n=30) reviewed, the EMP was not completed in its entirety. Fifty percent (50%) of the POCs did not have their EMP section completed. Fifty-six percent (56%) of the records did not identify parameters around when to start emergency measures for a client going into crisis, and 52% did not have special instructions on what to do when a client is in crisis. Sixty-two percent (62%) of the records did not have a backup nursing contingency plan in an emergency situation when the nurse could not come in to provide care. Eighty-nine percent (89%) of the staff working with these clients had no identified treatment goal, 85% did not identify the rehabilitation potential of the client and 100% of the records had no plans to decrease nursing services as the clients' conditions improved. In addition, 92% of the records did not identify ways in which the nurses could involve the family in the care of the client so as to empower the family. Of the records that indicated a change in the REM program participant's medical condition requiring a change in skilled nursing, 70% (n=10) of the plan of care did not reflect the change, 100% (n=13) did not notified the physician and 100% (n=15) did not decrease the service as the participant's conditions improved or the family was better able to care for the client.

Table 1.3: Percentage of Non-Compliance on the Plan of Care

Plan of Care Audit Items	True Count, n	Non-Compliance records n	Proportion of complaint records 95% CI (%)

		(%)	
Diagnosis	27	9 (33)	17 - 54
Prognosis	27	4 (15)	4 - 34
Treatment	27	5 (19)	6- 38
Treatment Goals	27	24 (89)*	70 - 97
Services Required	27	6 (22)	8 - 42
Frequency of Nursing	27	7 (26)	11 - 46
Functional Limitation	27	8 (30)*	14 - 50
Permitted activities	27	5 (19)	6 - 38
Prohibited Activities	27	10 (37)*	19 - 58
Diet	27	5 (19)	1 - 28
Medication	27	4 (15)	4 - 34
Mental Status	27	9 (33)*	17 - 54
Medical Supplies	27	9 (33)*	17 - 54
Medical Equipment	27	10 (37)*	19- 58
Safety Measures	27	3 (11)	2 - 29
EMP completed with name and phone number of physician	27	3 (11)	2 - 29
EMP initiation Parameters	27	15 (56)*	35 - 75
EMP special instructions	27	14 (52)*	32 - 71
EMP completed with family or guardian contact information	27	15 (56)*	35 - 75
EMP completed in its entirety	30	23 (77)*	58 - 90
Backup nursing contingency plan	26	16 (62)*	41 - 80
Family Involvement in care	26	24 (92)*	74 - 99
Plan to Decrease Nursing Services	27	27 (100)*	87 -100
Rehab Potential	27	23 (85)*	66 - 96
Plan of care reflects major changes in Medical Condition or Skilled Nursing needs	10	7 (70)*	34 -93
Agency notified physician of changes in Medical Condition or Skilled Nursing needs	13	13 (100)*	75 - 100
Agency decrease services as participants condition improves or as the family caregiver's is better able to meet the participant's needs	15	15 (100)*	78 - 100

*Non-compliance greater than 30% threshold per DONS requirement

Progress Notes:

Table 1.4 shows the results from the audits of progress notes. One hundred percent (100%) of the notes audited had a deficiency. In nursing practice, progress notes should contain documentation on the nursing intervention that was provided to the client in the home. The note should describe what was done for the client and what was the outcome from the intervention. These findings would suggest that the progress notes did not contain these key details in the records. The audit records showed 80% non-compliance with the presence of completed notes for every shift billed and the presence of a beginning of shift assessment. Only 78% of the notes were legible and 59% had the signature of the recipient/caregiver confirming the presence of the nurse. Seventy-eight percent (78%) of the notes were not consistent with the POC and the PO, 93% of the notes did not document the administration of PRN medication correctly and more than 60% did not have documentation for each intervention (67%), hourly documentation (69%) or correct documentation on the seizure protocol (67%).

Table 1.4: Percentage of Non-Compliance on the Progress Notes

Progress Notes Audit Items	True Count, n	Non-Compliance records n (%)	Proportion of complaint records 95% CI (%)
Progress note is Consistent with Plan of care and Physician order	27	21(78)*	58 - 91
Every Shift has a complete note that is dated and signed by the Nurse/Aide working with participant	27	5 (19)	6 - 38
Beginning Shift Assessment Done	25	2 (8)	0.9 - 26
Note adequately describe each intervention rendered	27	18 (67)*	46 - 83
Note has hourly document for each intervention	26	18 (69)*	48 - 86
Note - Seizure documentation include time of occurrence, length of seizure, intervention, and after effect	6	4 (67)*	22 - 96
Note- PRN med documentation includes time of occurrence, reason for administration and effect	14	13 (93)*	66 - 100

Note Legibility	27	6 (22)	9 - 42
Note-Error Corrected with single line drawn through and initialed	27	9 (33)	17 - 54
Recipient/Caregiver Signature on each note to verify service	27	11 (41)	22 - 61
Adequatecy of Notes	28	30 (100)*	88 - 100

*Non-compliance greater than 30% threshold per DONS requirement

Supervision:

The results of the audit on the supervisory visit and documentation is represented in table 1.5 below. The compliance rate was not more than 50% on each requirement. Essentially, this table shows that, among others, the RN supervisors did not do most of their visits on time (50%), did not assess the clients (59%) on time, or review the PO and ensure that they were accurately transcribed to the MAR 64% of the time, and did not assess the family caregivers' need for more training or implement a training plan for them 86% of the time. In other words, none of the supervisory visits were done and documented according to the requirements of the program.

Table 1.5: Percentage of Non-Compliance on the Supervision

Progress Notes Audit Items	True Count, n	Non-Compliance records n (%)	Proportion of complaint records 95% CI (%)
Supervisory visit documented with visit date and Sup RN Signature	4	2 (50)*	7 - 93
Timely Supervisory visit	10	5 (50)*	19 - 81
Recipient Assessment	22	13 (59)*	36 - 79
Review PO and Transcription Accuracy	22	14 (64)*	41 - 83
PN review	22	14 (64)*	41 - 83
Caregiver training needs assessment and implementation	21	18 (86)*	64 - 97

*Non-compliance greater than 30% threshold per DONS requirement

Program Requirement:

From the Program requirement audits, most agencies are in compliance with 4 out of the 6 audited requirements. As you can see in Table 1.6, 70% of the records were in compliance with a progress notes (78%) and timesheets (70%) for each billed date. One hundred percent (100%) of the agencies ensured that they had pre-authorizations for service on file before they provided services and a nurse did not work more than 16 hours per day or 60 hours per week in 84% of the records. On the other hand, 82% of the agencies did not check the status of the client's insurance and did not submit a denial letter to the state from the insurance company before applying for authorization.

Table 1.6: Percentage of Non-Compliance on the Program Requirement

Program Requirement Audit Items	True Count, n	Non-Compliance records n (%)	Proportion of complaint records 95% CI (%)
PN present for Each Billed Date	27	6 (22)	9 - 42
TS present for Each billed Date	27	8 (30)*	14 - 50
Shift Preauthorized	27	0.00	0 - 13
Nurse work >60hrs/wk and >16hrs/day	25	4 (16)	5 - 36
Participant Primary Health Insurance status checked	22	18 (82)*	60 - 95
Agency submitted a denial for PDN from Primary Insurance	3	3 (100)*	29 - 100

*Non-compliance greater than 30% threshold per DONS requirement

DISCUSSION

The findings from this audit suggest that there are several shortcomings in PDN nursing documentation and that PDN provider agencies will have to implement some major reforms in order to avoid losing money in the audit and recovery process. It is important to note that 100%

of the records that were reviewed were subject to a money recovery for multiple reasons. This may means that most PDN provider agencies that are currently providing services in the REM program would potentially lose money today if they were audited by the state. Besides the possibility that the provider agencies could lose money, there are critical clinical implications for the clients receiving services in this program.

First and foremost, is the finding that 80% of the records audited had discrepancies between the MAR and the doctor's orders and 78% of the progress notes were not consistent with the plan of care and the doctor's orders. Given the complex medical conditions of the clients in the REM program and the fact that PDN services are being provided to ensure accurate administration of medication and care to these clients, it is alarming that these deficiencies exist at such a high rate. Mistakes of such magnitude could mean life or death for the clients receiving services.

In addition, 67% of the records did not have adequate documentation of the nursing interventions. Other studies have found that nursing-specific interventions are not emphasized in the documentation. [62] As a result, this discrepancy in documentation creates misunderstandings, discontinuity of care and compromises patient safety.[75]

Furthermore, the plan of care for a client should accurately reflect their needs, and include the client's treatment goals, a complete EMP and nursing interventions and outcomes. A review by Suhonen *et al*., found that a number of studies had reported that plans of care have positive effects on the quality of care of clients when implemented correctly, as they promote

[75] Paivi Voutilainen, Arja Isola, and Seija Muurinen, "Nursing Documentation in Nursing Homes - State-of-the-Art and Implications for Quality Improvement," *Scandinavian Journal of Caring Sciences* 18, no. 1 (2004): pp. 72-81, https://doi.org/10.1111/j.1471-6712.2004.00265.x.

wellness and good health by maintaining client functional abilities and autonomy.[76] None of the audited records in this study had the clients' plans of care completed in their entirety - many of the plans of care had missing sections. It is also extremely worrisome to have found that the emergency back up plans for these clients were not being addressed on their plans of care. As seen in table 1.2, 77% of the records did not have their emergency back up plans completed. Given that, most of the clients who receive PDN services are likely to be technology-dependent on mechanical ventilation, tracheostomy care and oxygen therapy, the lack of emergency backup plans can result in serious negative consequences for the client.[2] These are interventions that require the need for emergency action if something were to go wrong, such as a child pulling the trach tube out of their body or a power outage at the home of a ventilator dependent client. All of these scenarios would need immediate and urgent lifesaving care, usually outlined in an emergency backup plan. Therefore, the lack of an emergency backup plan for the staff and family to follow is potentially very detrimental to the health of the clients.

Several studies have shown that effective progress notes should be revised continually and updated and should evaluate the items in the nursing care plan to capture changes in the patients' conditions to ensure continuity of care.[59] [63] **Error! Bookmark not defined.** Muller-S taub *et al.*, also found that linking progress notes to a structured nursing care plan can contribute to focused and effective communication between health professionals.[60] For the records audited in the current study, 78% of the progress notes were inconsistent with the plan of care and physician order, 67% did not adequately describe each intervention rendered, and 69% did not have an hourly document for each intervention. This is a big problem because nurses in home

[76] Riitta Suhonen, Maritta Välimäki, and Helena Leino-Kilpi, "'Individualised Care' from Patients', Nurses' and Relatives' Perspective—a Review of the Literature," *International Journal of Nursing Studies* 39, no. 6 (2002): pp. 645-654, https://doi.org/10.1016/s0020-7489(02)00004-4.

care settings operate on a continuum which requires good communication for the nurse taking over a shift to continue providing safe care. Furthermore, the idea that "if it is not documented, it is not done" may lead to double administration of medication or treatment which could result in harm to the patient.[73]

The deficiencies found in the supervisory records, are an indication that none of the supervisory visits are being done correctly. This is a critical finding because it may explain why the other deficiencies listed above exist. In addition, considering the nature of the practice setting for PDN services, this is even more detrimental to the care of the individual. Unlike nurses in facility settings, nurses who work in the PDN setting, work independently with very minimal direct supervision on an individual basis. These nurses tend to be transient in their employment patterns, generally working on as-needed (prn) basis and tend to migrate from one employer to another, based on the availability of work. [58] As a result, the need for regular ongoing supervision is vital because it is during this time that the supervisory nurse would make sure that the care is being provided according to the plan of care and the doctors' orders. The supervisory nurse also takes the time to identify any deficiencies and retrains the nurses. For these reasons, it is important that changes are made at the PDN provider agency level to address all the patterns of deficiencies uncovered in the audits reported in this study.

Forty-one percent (41%) of the progress notes audited did not have the patients' signatures needed to confirm that the notes were created and completed in the homes. This could be for one of two reasons; it could be that the notes were not created at the homes or that the staff did not give the family caregiver the chance to review and sign the notes. This would suggest that the patients' families may not always appreciate the importance of signing all progress notes, even though the notes are crucial in ensuring effective continuity of care for their loved

ones. Some family members may judge the quality of care simply by the duration of the staff and patient/nurse interaction or family/nurse interaction. The family may not consistently have access to the progress notes which would provide a more accurate picture about the care being provided to the patient. Without daily access to, review and approval (signing) of the progress notes, the family caregivers miss the opportunity of actually serving in the monitoring role expected for the care of their loved one at home.

It is also important to point out that the PDN provider agencies bear overall responsibility for the deficiencies found on the records specifically relating to documentation of progress notes. It is the responsibility of the PDN provider agency to ensure that services are rendered and documented accurately. The inability to do so, suggest that the audited agencies were not structurally set up for fostering quality services. It also suggests that the agencies did not provide the appropriate training needed by the supervisory nurses to know what was expected of them. The issues with deficient documentation of progress notes are very grave and highly damning for the agencies. The most obvious consequence to the agencies is the money they lost in the recovery process. In addition, it's possible these agencies have also had to deal with losing clients and losing employees due to these deficiencies.

Finally, MDH and Maryland state regulations combined with the low Medicaid reimbursement rates may be contributory factors to these extensive deficiencies as they affect the ability of agencies to hire and train qualified nurses to provide home care services.[5] In addition the DONS program may need to conduct more frequent and random audits in order to hold the agencies more accountable to the establish standards. DONS should also provide additional support for the agencies by providing them with feedback from their audit results so that the agencies can utilize the findings to improve their services.

LIMITATION

The sample size for this study was small and it was limited to just a four-year time frame. Audit results from only 30 client records were received from the DONS, which included audits that were done for services rendered between CY2014 to CY2017. When this researcher takes into account that this program has been in existence for over 20 years, it would have been very valuable to gain access to the audit records that were done from the start of the program until the present. This would have provided a larger sample size and the ability to look at the trends over a more extended timeframe. In addition, because the records were redacted, it was difficult to know the exact agencies whose records were audited. Gaining access to this information would have afforded this researcher the ability to consider the characteristics of the PDN provider agencies as the data was analyzed. Another limiting factor was that these audits were all done by one nurse reviewer. As a result, this researcher could not control for any personal biases that could be in the results of the audit. The small sample size and possible biases that may have been introduced by the nurse reviewer have greatly affected the ability to generalize the results of this study.

CONCLUSIONS

The results of this study indicate that there are significant deficiencies with the quality of care received by Maryland State Medicaid REM program participants. These range from patient safety issues, to poor documentation, and lack of adequate supervision and training. This study provides a starting point for the PDN provider agencies to get information about issues with the services they provide and recommendations on how to start working on improving the services.

On the other hand, the DONS program would need to provide more oversight to the PDN provider agencies. The severe deficiencies found in the audit records point to a need for more

frequent random audits to ensure that the agencies are providing services per the DONS and state guidelines. In addition, the DONS program should provide feedback of their audit results to PDN provider agencies; this could be communicated to all provider agencies in the form of quarterly memos or webinars. This will go a long way to help the agencies improve their service delivery.

Finally, there is a need for more research to explore specific ways that agencies can change their processes to improve the quality of care. It will also be great to evaluate quality of care using clinical outcomes such as (re)hospitalization rates, improvements in client condition, reduction in complications, and patient/family satisfaction based on survey results.

Chapter 3: STUDY 2: Policy Impact: Effects of Policy Regulation on the quality of private duty nursing services provided to individuals in the Maryland Medicaid Rare and Expensive Case Management program

INTRODUCTION

Private Duty Nursing (PDN) provider agencies serving individuals with complex medical needs in the Maryland Medicaid Rare and Expensive Case Management (REM) program face significant staffing shortages that negatively impact their ability to meet the needs of individuals and their families in the program.[6] These individuals are most often children with complex clinical conditions that cause them to be dependent on medical technology to survive at home.[2] Increasingly, REM program participants are having to go without adequate nursing staff, which leave their parents and/or families to provide the care for their children at home alone, while struggling to maintain their own health and remain employed. The main contributing factor to this PDN workforce crisis in Maryland is the inability of the PDN provider agencies to recruit, train and retain adequately compensated nurses to meet the needs of these individuals. Several studies have shown that this problem is largely because of the generalized nursing shortage across the country,[25] [26] low Medicaid reimbursement rate [77] [62] and State policies and regulations.[78] [79] [80]

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[77] The Henry J. Kaiser Family Foundation, "Waiting List Enrollment for Medicaid Section 1915(c) Home and Community-Based Services Waivers," The Henry J. Kaiser Family Foundation, February 27, 2020, https://www.kff.org/health-reform/state-indicator/waiting-lists-for-hcbs-waivers/?currentTimeframe=0&sortModel=%7B%22colId%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D.

[78] Summer Cross and Patricia Kelly, "Access to Care Based on State Nurse Practitioner Practice Regulation: Secondary Data Analysis Results in the Medicare Population," *Journal of the American Association of Nurse Practitioners* 27, no. 1 (2015): pp. 21-30, https://doi.org/10.1002/2327-6924.12191.

[79] Julie A. Fairman et al., "Broadening the Scope of Nursing Practice," *New England Journal of Medicine* 364, no. 3 (2011): pp. 193-196, https://doi.org/10.1056/nejmp1012121.

[80] Patricia B. Reagan and Pamela J. Salsberry, "The Effects of State-Level Scope-of-Practice Regulations on the Number and Growth of Nurse Practitioners," *Nursing Outlook* 61, no. 6 (2013): pp. 392-399, https://doi.org/10.1016/j.outlook.2013.04.007.

One such policy that is of great concern, is the requirement outlined in the Code of Maryland Regulations (COMAR) that nurses who provide services to children in the REM program must have at least one (1) year of specialized pediatric experience within the most recent three (3) years.[81] To meet this requirement, PDN provider agencies would need to hire nurses with experience working in the hospital pediatric unit, Neonatal Intensive Care Unit (NICU) or the general Intensive Care Units (ICU) managing clients with complex medical needs. Unfortunately, the substantially lower wages offered in home care makes such jobs unattractive to nurses with such specialized experience. The ZipRecruiter salary estimator estimates that the national average salary for a Licensed Practical Nurse (LPN) is about $49,000 per year in home care while their counterparts in facilities like nursing homes and assisted living facilities make an average of about $60,000 per year. [82] On the other hand, new nursing school graduates who are available to work home care shifts to broaden their skills, and can be trained to provide the necessary care, do not have the experience needed to meet the requirements of this regulation.

This regulation places an undue burden on the agencies and further compounds the PDN nursing shortage in Maryland. This shortage impedes the capacity of agencies to deliver sufficient care to REM program participants.[83] The aim of this paper was to examine the policy context for this workforce crisis and propose possible solutions to address the current failures in providing adequate staffing in the Maryland Medicaid REM program. The research question for

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[81] Code of Maryland Regulation, "COMAR 10.09.53 - Early and Periodic Screening, Diagnosis, and Treatment: Nursing Services for Individuals Younger than 21 Years Old," Division of State Documents, May 5, 1993, http://www.dsd.state.md.us/comar/comarhtml/10/10.09.53.03.htm.

[82] ZipRecruiter Salary Estimator, "Estimator Annual Salary," ZipRecruiter, 2020, https://www.ziprecruiter.com/Salaries/Estimator-Salary.

[83] HB 1696 (Chapter 798 of the Acts of 2018), "Task Force Report on Access to Home Health Care for Children and Adults with Medicaid Disabilities," Maryland Department of Health, 2018, https://mmcp.health.maryland.gov/Documents/JCRs/2018/Report%20on%20Access%20to%20Home%20Health%20Care%20for%20Children%20and%20Adults%20with%20Medical%20Disabilities.pdf.

this study was are there structural deficiencies in the delivery of PDN Services to individuals on the REM Program, if yes, what are they and what are the implications for the quality of client care?

METHODS

In this study, a retrospective analysis was performed using audit results of employee records carried out by the Division of the Nursing Services (DONS) at the Maryland Department of Health (MDH). A total of 99 employee records from about 13 PDN provider agencies were audited. The audits were done in Calendar Year (CY) 2016, CY2017, and CY2018. The records were for employees who worked with individuals in the REM program between CY2014 to CY2017. The data collection process has been explained in detail in the methods section of study 1. Access to this data was gained by filling a freedom of information request with the state. The reasons for the audit were mostly as a result of client complaints, client deaths, reportable incidents, and review for medical necessities. The DONS program emailed redacted PDF copies of audit results of 99 employee records. Of note, the 99 employees whose records were reviewed in this study, were involved in the care of the 30 clients whose records were audited in study 1 either as direct care nurses or supervisory nurses during the audit period.

CODING PROCESS

Each audit record was reviewed by the state auditor using an audit instrument designed by the DONS staff specifically for auditing REM program client and employee records. As outlined in the Methods section of study 1, this audit instrument is made up of 10 sections. For the purpose of this study, This researcher focused on section 9 (Personnel Records section) and section 10 (Money Recovery Section). Section 9 reviewed employee records for the following credentials; 1) presence of professional license, license type and expiration date, CPR expiration

date, presence of employment application and interview date, verification of employee references, presence of criminal background check results, presence of an initial skills checklist and an ongoing skills checklist for employees with more than one year of employment, and Verification of Clinical/Pediatric experience. Each section has specific questions that the reviewer uses as a guide for the records audit. For Section 10, the reviewer put in the amount of money that was being requested back from the PDN provider agency (see sample in Appendix 3).

In Section 9 the reviewer's responses were a combination of dates and comments. The responses were coded as follows; 1) YES, if the item was present or if the item did not expire within the dates of service being audited, 2) NO, if the time was missing or the item expired during the dates of service being audited, 3) N/A, if the state reviewer marked it as "n/a", 4) Unknown, if the state reviewer left it blank with no comments, 5) Not Submitted, if the state reviewer put in a comment that it was not submitted.

In Section 10 wherein the reviewer put in the amount of money that was being requested back from the PDN provider agency, separate recovery amounts were listed for each deficiency that was cited. For example, if an employee had a license that was 10 days past expiration on the last day the employee provided services to the matched audited client during the audited period and had worked a total of 8 hours during the time the license had expired, the agency was asked to refund the amount billed for the 8 hours of care. In some instances, the employee had more than one deficiency on their record affecting different dates during the audit period, in which case the money was requested back for the hours worked during the affected time period. For example, if an employee has an expired license for one week and an expired CPR card in the next week, and worked a total of 80 hours in the two week period (40 hours each week), the

agency would be asked to pay back the entire amount billed for the 80 hours worked. In a situation wherein the two deficiencies overlapped, the agency is asked to pay back the larger amount of money affected by the deficiencies as the primary debt. However, the smaller portion is recorded against the agency as a secondary or tertiary debt that would be applied if ever the agency could provide a good reason to waive the primary debt. These secondary and tertiary debts were indicated in brackets on the money recovery section. For coding purposes, primary debts were entered as positive numbers while the secondary/tertiary debts (indicated in brackets) were entered as negative numbers on the Google sheets. The deficiency that corresponds to the money that was requested back was considered the primary deficiency reasons.

DATA ANALYSIS

Google sheets and Stata software were used for statistical analysis to calculate frequencies and percentage scores for all the items in section 9 of the audit. For Section 10, the sum of the amount requested back for each primary deficiency was calculated. As detailed in study 1, any records that were not submitted to DONS for the audit were coded as "NO". This is because of the nurse documentation standard which states that anything that is not documented was not done.[73 74] Any missing documentation in the audit records was considered as though the documentation did not exist. In addition, the number of the PDN provider agencies included in this study was derived by analyzing the pattern of the audit dates and comments.

RESULTS

A total of 30 client records from 29 PDN provider agencies were examined according to the criteria in the Medical On-site/Desk Audit form. In addition to the 30 patient records, a total of 99 employee records were audited of which 9% were Aides, 58% where LPN and 33% where RN (Table 2.1). This researcher decided to include the personnel records for the aides in this

analysis because they function in the home under the delegation of the RNs. In essence, they do work that would be considered nursing tasks, but this work must be delegated to them under the supervision of the registered nurse.

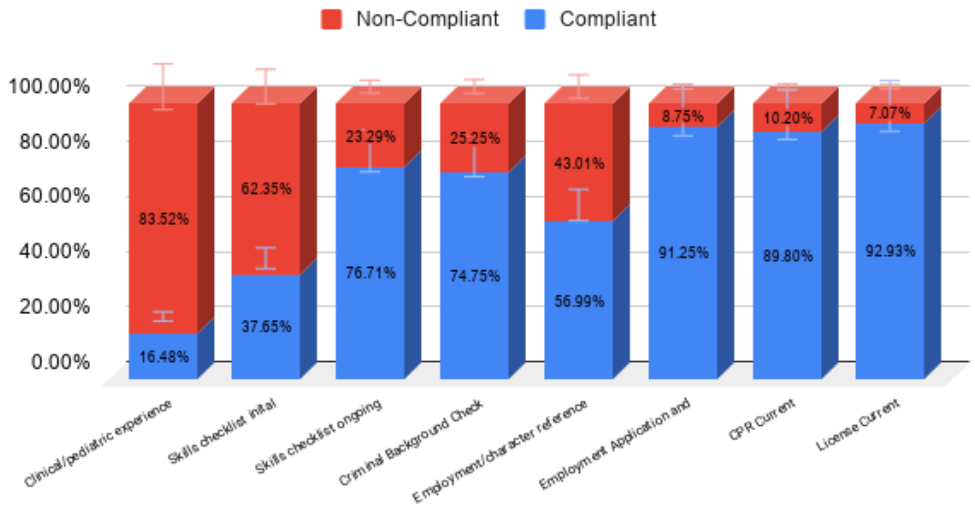
Table 2.1: Staff breakdown by license/certification type

License Type	# Nurse Type	Percent Nurse Type
Aide (CNA/HHA/MT)	6	9%
LPN	60	58%
RN	33	33%
Grand Total	99	100%

The personnel records were reviewed for the license type, license status (current or expired), CPR status (current or expired), employment application/interview conducted, employment/character reference check and criminal background check, initial and ongoing skills checklist and verification of clinical/pediatric experience. A majority of the personnel records that were reviewed were mostly out of compliance regarding documentation of clinical/pediatric experience (84%) compared to any of the other requirements. The second and third source of non-compliance in the employee records were in the area of completion of the initial skills checklist and completion of employment/character reference checks of employees. Forty-three percent (43%) of the employee records audited did not have their employment references and character reference checks completed before they started to work. Of the employees who records were audited, 62.4% did not have their skills checked at the time they started working. However, the employees who had been working for more than one year were more likely to have their skills checked on an ongoing basis. Of note, 76.7% of the audited employee records had a skills checklist that was completed by the supervisory nurse yearly. The highest compliance scores

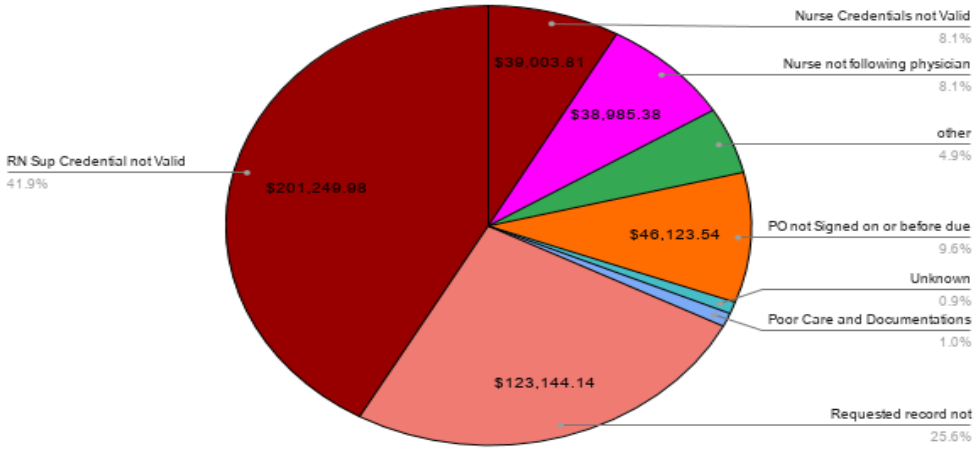
were found in the audit of the documentation of the licenses of staff (93%), CPR training (89.8%), the presence of criminal background check records (74.8%), and the presence of employment applications (91.3%) (see Figure 2.1).

Figure 2.1: Personnel Record of Compliance



In summary, there are ten main reasons why money was recovered from the PDN provider agencies. Of these 10 reasons, the top three are; records not submitted (26%), invalid RN supervisor credentials (42%) and the physician orders not signed on or before the due date (10%). Of particular note, approximately $500,000.00 was recovered following these audits due to deficiencies in the client and personnel records. About 50% of the money recovered was due to deficiencies in the personnel records; 42% of the money was recovered as a result of invalid RN supervisor credentials and 8% as a result of invalid direct care nurse credentials. It is important to point out that only 1% of money recovered seemed to be directly attributed to poor care and/or documentation (see Table 2.3 and Figure 2.2).

Figure 2.2: Illustration of Money Recovered by Primary Reasons



DISCUSSION

The results of this audit indicate that PDN provider agencies in Maryland have difficulties recruiting nurses who have the required clinical and pediatric experience. As seen above, about 86% of the records that were reviewed revealed that the PDN nurses did not have the required clinical/pediatric experience, and as a result the agencies had to pay back money to the state. Fifty percent (50%) of the money that was recovered was due to a combination of invalid direct care nurse credentials (8%) and invalid RN supervisor credentials (42%). It is evident that the inability to meet this regulatory requirement is costing the agencies a lot of money.

The 83% non-compliance in clinical/pediatric experience is not a surprising finding given that the nation is currently experiencing a serious nursing shortage and the low Maryland Medicaid reimbursement rate and low pay rates for nurses further exacerbates the problem of the

home care nursing shortage.[84] [85] [86] This shortage can also partially be explained by the fact that many older nurses with pediatric experience that meet the DONS requirements are retiring.[87] It could also be attributed to the low pay that is offered to nurses in the home health field. [82] [74]

In the 20 years since the Maryland Medicaid REM program has been in existence, there have been remarkable changes in the nursing workforce. Prior to the implementation of this program, medically fragile children resided mainly in long and short-term care medical facilities. The existence of these facilities allowed for many nurses to be able to gain the on the job training and experience that is required in the regulation. However, over time, many of these facilities have closed. In addition, in these 20 years the program has gradually shifted from using RNs to provide the home care services to using mostly LPNs in an effort to reduce the cost of the programs, given the fact that LPNs have fewer years of nursing school training and are paid less. Furthermore, due to a recent change in regulation in most states, LPNs can no longer work in hospitals where they can gain the necessary pediatric and clinical experience. For these reasons, it is very difficult to find LPNs who have the clinical and pediatric experience needed to provide care to REM program participants.

Although less than 20% of nurses had the necessary pediatric experience, the audit showed that only 1% of the money was recovered due to deficits in clinical care. There are three possible reasons for this. The first reason could be that the agencies are hiring nurses who do not

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[84] Linda H. Aiken, Robyn B. Cheung, and Danielle M. Olds, "Education Policy Initiatives To Address The Nurse Shortage In The United States," *Health Affairs* 28, no. Supplement 3 (2009), https://doi.org/10.1377/hlthaff.28.4.w646.

[85] Peter I. Buerhaus, "Current and Future State of the US Nursing Workforce," *Jama* 300, no. 20 (2008): p. 2422, https://doi.org/10.1001/jama.2008.729.

[86] U.S. Department of Labor, "Registered Nurses : Occupational Outlook Handbook," U.S. Bureau of Labor Statistics (U.S. Bureau of Labor Statistics, February 21, 2020), https://www.bls.gov/ooh/healthcare/registered-nurses.htm.

[87] Jeremye D. Cohen, "The Aging Nursing Workforce: How to Retain Experienced Nurses," *Journal of Healthcare Management* 51, no. 4 (2006): pp. 233-245, https://doi.org/10.1097/00115514-200607000-00006.

have the required clinical/pediatric experience but have general clinical experience that still meet the needs of the client. The second reason may be that the agencies are providing the necessary training needed to foster the provision of good care to these clients. A third possible reason could be related to one of the limitations of this study, which is the reality that the initial survey was not designed to evaluate the clinical outcomes. This might explain why only 1% of the money was recouped due to deficiencies related to clinical outcome.

Finally, of the 10 reasons that led to the agencies paying money back to the state, the top three were; 1) records not submitted, 2) invalid RN supervisor credentials and 3) the physician orders not signed on or before the due date. Eliminating these three reasons would potentially save these agencies a lot of money which could be put towards other uses such as enhanced on the job training of nurses. Of the 3 top primary reasons for money recovery, the invalid supervisor credentials stands out as an issue that is sometimes beyond the control of the provider agencies. Given that 86% of the reasons for the invalid credentials was the lack of clinical/pediatric experience per DONS requirement, one can postulate that if this regulation were replaced with a requirement for training, this may lead to even better clinical outcomes for these clients. Although many studies have shown that one important factor that contributes to a nurse's clinical performance is the nurse's years of experience,[88] [89] there is also strong evidence

[88] Joan Burritt and Cynthia Steckel, "Supporting the Learning Curve for Contemporary Nursing Practice," *JONA: The Journal of Nursing Administration* 39, no. 11 (2009): pp. 479-484, https://doi.org/10.1097/nna.0b013e3181bd5fd5.

[89] Barbara J. Daley, "Novice to Expert: An Exploration of How Professionals Learn," *Adult Education Quarterly* 49, no. 4 (1999): pp. 133-147, https://doi.org/10.1177/074171369904900401.

suggesting that provision of the right training to nursing staff would lead to an increase in the quality of care for the client.[90] [91]

LIMITATION

The sample size for this study was small and it was limited to a four-year time frame. Only 30 audit record results were received from the DONS for audits that were carried out for services rendered between CY2014 to CY2017. Taking into account that this program has been in existence for over 20 years, it would have been very valuable to gain access to all the results from the audits that were done from the inception of the program. Another limiting factor was that these audits were all done by one nurse reviewer. As a result, this researcher could not control for any personal biases that could be in the results of the audit. The small sample size and possible biases in the survey have greatly affected the generalizability of the results of this study.

CONCLUSION

In light of these findings, Maryland should consider changing the requirement for prior pediatric experience for nurses seeking employment with PDN agencies to a requirement for specific training on targeted skills such as tracheostomy care. This would help in alleviating the difficulty of attracting nurses from an already limited pool to home care and would help reduce the issue of understaffing of these agencies. In addition, if the state does change the regulation, there will be a need to design and implement training standards and certification programs that can be utilized by nurses new to home care to gain the necessary knowledge to be able provide services adequately to REM program participants.

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[90] Linda R Delunas and Linda A Rooda, "A New Model for the Clinical Instruction of Undergraduate Nursing Students," *Nursing Education Perspectives* 30, no. 6 (2009): pp. 377-380.

[91] Nancy Dunton et al., *The Relationship of Nursing Workforce Characteristics to Patient Outcomes* 12, no. 3 (September 30, 2007), https://doi.org/10.3912/OJIN.Vol12No03Man03.

The state should also consider doing a cost-based rate study to determine the actual reimbursement rate needed to be able to attract qualified nurses to the home care practice practices. The cost-based rate study entails collecting cost data online items like overhead and salaries for direct care nurses from all PDN provider agencies and analyzing the data to determine the best reimbursement rate.

Chapter 4: STUDY 3: Improving the quality of care provided to individuals receiving private duty nursing services through the Maryland Medicaid Rare and Expensive Case Management program

INTRODUCTION

The increase in popularity of home care as an alternative to institutionalized care [92] [4] [17] and the expansion of the Medicaid community first choice program[93] in the state of Maryland has presented a great opportunity for entrepreneurs to meet these demands through the opening of Private Duty Nursing (PDN) provider agencies. This also presents an excellent opportunity for current PDN provider agencies in the state to expand and grow their business as they care for more people with chronic medical conditions at home. However, home care for individuals with chronic and complex medical needs must meet some minimum quality standards to be a cost effective alternative to providing care in short term or long term care facilities.[94] However, individuals with chronic and complex condition and their families must trust that PDN provider agencies can provide the best quality of care that meets their needs.

PDN provider agencies in the state of Maryland are Residential Service Agencies (RSA) licensed by the Office of Health Care Quality (OHCQ) at the Maryland Department of Health (MDH). These agencies are governed by a Code of Maryland Regulation (COMAR), that requires them to maintain some minimum standards of care for the patients they serve. There are also additional regulations and guidelines on RSAs depending on the insurance, or Medicaid

[92] Steven Landers et al., "The Future of Home Health Care," *Home Health Care Management & Practice* 28, no. 4 (May 2016): pp. 262-278, https://doi.org/10.1177/1084822316666368.

[93] Julia Burgdorf et al., "Expanding Medicaid Coverage for Community-Based Long-Term Services and Supports: Lessons From Maryland's Community First Choice Program," *Journal of Applied Gerontology*, May 2018, p. 073346481877994, https://doi.org/10.1177/0733464818779942.

[94] Ronda Hughes et al., "Patient Safety and Quality in Home Health Care ," in *Patient Safety and Quality: an Evidence-Based Handbook for Nurses* (Rockville, MD, MD: Agency for Healthcare Research and Quality, 2008), pp. 301-336..

program in which they are contracted as providers. One such Medicaid program in the state of Maryland is the REM program.

The REM program is a Maryland Medicaid program that covers health care services to children with complex medical needs. REM program participants receive care for prolonged periods of time from multiple health care providers.[31] Most REM program participants are technologically dependent, requiring services such as tracheostomy care, mechanical ventilator care and gastrostomy tube care at home. [95] Home care for REM program participants is provided by PDN provider agencies. These home care services are vital to keeping these individuals out of institutional facilities and in the community.[92 17] To ensure good quality of care for these individuals, PDN provider agencies that are contracted to provide home care services to REM program participants are required to comply with COMAR 10.09.36, 10.09.53 and 10.09.69. COMARs are an official compilation of all administrative regulations issued by agencies of the state of Maryland.[23] When the Legislature of the State of Maryland passes a law, the administrative agencies are responsible for drafting, adopting, amending, or repealing regulations that govern the practical implementation of the law. In the Case of PDN services the MDH is the responsible administrative agency that drafts, adopts, amends, and enforces the regulation that governs practice. The Division of Nursing Services (DONS) is responsible for providing the oversight needed to ensure compliance with these regulations. Periodically the DONS program staff conduct audits of the clinical records of clients receiving PDN services through the REM program and the personnel records of staff who provide direct care to clients in the REM program. These records are expected to meet the minimum documentation requirements outlined in specific COMARs.

A World Health Organization (WHO) report directly linked the quality of nursing documentation to improved patient care and safety.[95] High-quality nursing documentation has been shown to result in better communication between caregivers and facilitates continuity of care and patient safety.[54 59 63] A number of studies have also shown that poor communication can lead to fragmented care which can cause errors and adverse events in care, hospital readmissions, lengthy hospital stays, increased health care costs, delays in treatment and diagnoses, lower patient satisfaction, inappropriate treatment and omission of care. [66 66 96 97] Although there have been several studies and systematic reviews on the quality of nursing documentation, there is limited research focused on PDN services and a knowledge gap on the quality of services received by individuals on the Maryland Medicaid REM program. In order to fill this knowledge gap, this study sought to identify process and structural measures that can be utilized by PDN provider agencies to improve their quality of services. As such, the aim of this study was to do a content analysis of the comments provided on the DONS audit records and use the findings to provide PDN provider agencies that serve REM clients with best practice recommendations for improving the quality of nursing documentation and service delivery. The research question was: Are there specific process and structure measures that can be implemented to improve the quality of care for individuals on the REM program?

[95] World Health Organization, *Patient Safety Curriculum Guide: Multi-Professional Edition* (Geneva: World Health Organization, 2011).

[96] Carlton Moore et al., "Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting," *Journal of General Internal Medicine* 18, no. 8 (2003): pp. 646-651, https://doi.org/10.1046/j.1525-1497.2003.20722.x.

[97] Laura A. Petersen, "Does Housestaff Discontinuity of Care Increase the Risk for Preventable Adverse Events?," *Annals of Internal Medicine* 121, no. 11 (January 1994): p. 866, https://doi.org/10.7326/0003-4819-121-11-199412010-00008.

METHODS

This researcher used an inductive content analysis approach to evaluate the narrative comments on audit.[98] [99] A total of 30 client and 99 personnel records from 29 PDN provider agencies were reviewed and analyzed. The actual audit was done by the staff at the DONS in the MDH. The audits were done in Calendar Year (CY) 2016, CY2017, and CY2018 on records for services provided to individuals on the REM program between CY2014 to CY2017. The reasons for the audit were mostly as a result of client complaints, client deaths, reportable incidents, and review for medical necessities. Details about how the records were obtained are outlined in the Methods section of the first study in this dissertation. The coding for this study was done on comments that were listed on the audit documentation by the DONS reviewer.

DATA ANALYSIS

The instrument used for these audits was designed by the DONS staff specifically for auditing of the patient and employee records in the REM program. As mentioned above, the audit instrument was divided into ten different sections; general section, physician information, Medication Administration Record (MAR), Plan of Care (POC), Progress Note, Supervision, Program Requirement, Clinical management Policy, Personnel Records, Money Recovery (see sample in Appendix 3). In each section the reviewer had specific questions and standard responses that guided the review of records that were submitted. However, in addition to the standard responses the reviewer also provided detailed comments on the audit instrument for deficiencies that were found. These comments were a mixture of the reviewer's thought process and quotations that were taken directly from the records. For this study, this researcher extracted these comments from the audit instrument and categorized them under the appropriate sections

[98] Robert P. Weber, *Basic Content Analysis* (Newbury Park, CA: Sage, 1990).
[99] Uwe Flick, *An Introduction to Qualitative Research* (Los Angeles, Ca: SAGE, 2019).

corresponding to each record number. Some comments were placed into more than one category, because some comments addressed aspects of more than one section.

A content analysis was done for each section independently. Each section had about half a page worth of comments from each record. This translated to a 55 pages document which was made up of comments from the following sections: Physician Information (2 pages), Medication Administration Record (7 pages), Plan of Care (3 pages), Progress Note (15 pages), Supervision (4 pages) , Program Requirement (2 pages), Clinical management Policy (1 page), Personnel Records (6 pages), Money Recovery (9 pages) and Summary (6 pages). The general section did not have any comments and there was a special section at the end of some audit results which summarized in words the major deficiencies that were found in the record. The summary section was analyzed independently because it provided an opportunity to see keywords and phrases that were prevalent in all of the records combined. The comments were reviewed for key words or phrases that repeated several times throughout each section. Those keywords or phrases were coded and grouped together to form major themes (See Code book in appendix 5).

Content analysis was used to analyze every comment that was written by the DONS auditor on the audit instrument, and these comments were interpreted to find conformity with major themes.[98] Each comment was, however, individually interpreted and appraised to find its meaning with respect to quality of care. It was also important to consider how the need for improvement in quality of care was described, and if deficiencies in care interventions and evaluations were described. The analyses aimed to identify and confirm a pattern within the documented comments. The Inductive approach was used to guide the formation of a theory as the data was analyzed. In addition, this researcher counted the keywords found in the comments in each section and calculated the frequency and percentage of occurrence of each keyword to

determine the major themes and weight of evidence. The key deficiencies that occurred in a section more than or equal to 30% of the time were reported in the results. A threshold of 30% non-compliance was chosen because it is generally the accepted point at which a corrective action is needed during a state audit done by the Office of Health Care Quality (OHCQ) or an accreditation audit from the Community Health Accreditation Program (CHAP).[68] The key deficiencies found in each section are listed below with illustrative quotes in italics, "AR" (Audit Record) followed by the record identification numbers.

RESULTS

Generally, there was one comment that reverberated throughout every section. This was the fact that some of the records were not even submitted for review. This comment meant that some agencies did not submit the documents that were requested. In many instances the agency submitted the wrong document in place of what was requested. There was one situation where the agency failed to send all the documents that were requested.

PHYSICIAN INFORMATION SECTION

For the Physician information section, 24 of the 30 client records that were audited had comments attached to the audit responses. The issues that were found in this section had to do with completing the doctor's orders correctly and having the order signed in time before the start of care or the new certification period began.

> ***AR09****: "Physician signature is not legible…, Orders 7/4116-9/ l/16 were signed 7/7/16…, and RN documented a verbal order on 7/1/16. She did not document the name of the physician providing the verbal order…"*

As seen in table 3.9, these two issues had a 42% weight of evidence. This means that these two problems were seen in the physician information section of almost half of the records that were

audited. Some other findings included the fact that some of the physician orders were not legible and some were not transcribed accurately onto the client's medication administration record. See table 3.1 for examples of more comments.

Table 3.1: Sample of Comments in Physician information section

MAJOR THEMES	AR #	COMMENTS RECORDED
Not signed before the due date	**AR09**	*"Physician signature is not legible…, Orders 7/4116-9/ l/16 were signed 7/7/16…, and RN documented a verbal order on 7/1/16. She did not document the name of the physician providing the verbal order…"*
	AR03	*physician orders dated 8/7/15 -10/5/15 were signed 8/12/15*
	AR05	*Physician orders dated 12/4/15-2/1/16 were signed 12/7/15 Recover $952.36 as orders were signed after the due date*
	AR26	*order dated 12/16/16-2/13/17 were signed 12/27/16*
Incomplete documentation of order	**AR27**	*"The following orders were not transcribed correctly…"*
	AR26	*The following was written in box 23 of the 485 Verbal order received by RN, did not document the name of the physician providing the verbal order*
	AR30	*the nurse did not document a valid verbal order with the name of the physician and time/date of the receipt of the order*

Clinical Management Policy:

The DONS program requested Incident Report (IR) policies from 5 PDN provider agencies. For four of the five policies reviewed, the agencies did not follow their own policies (See table 3.2). Two out of the five policies reviewed were not completed correctly. In both instances, the nurse forgot to sign or date the IR form. One of the policies had some misleading information about the submission of a Reportable Event (RE) form. In this particular case the agency had instructions for the completed RE form to be sent to the REM case manager who should not be receiving the form.

AR10: *"Policy provides instructions for completion of the reportable event form; this form is used for model waiver participants; although it could be used for other lines of business, there is not requirement to send it to the REM case manager as in the model waiver program."*

Table 3.2: Sample of Comments in Clinical Management Policy

MAJOR THEMES	AR#	COMMENTS RECORDED
Agency did not follow the policy	**AR02**	*"Agency did not follow their policy for this event as the nurse assigned to the child did not complete an incident report"*
	AR08	*"The agency did not submit documentation that the patient's hospitalization was reviewed."*
	AR27	*"Nurse did not follow the physician's orders and failed to notify the appropriate parties when she (Client) became ill on 2/26/14"*
	AR31	*"Agency did not follow the policy which states, "The employee involved in discovering or responding to the incident will complete the HQCN incident report form."*

Employee Records:

The employee records section had one major theme that was identified. Outside of the general theme of records not being submitted, the employee skills checklist was not done or not done correctly. This theme had the fourth highest weight of evidence. This meant that in 15 out of the 23 records that had comments in this section, the skills of the nurse were not checked correctly. In some instances, it was not done at all before the employee started work. In other cases, it was done for some skills but not for others. See Table 3.3 for more comments that stood out during the coding process.

Table 3.3: Sample of Comments in Employee Records

MAJOR THEMES	AR #	COMMENTS RECORDED
Agency did	**AR02**	*Agency did not submit the CPR card that was in effect for the dates of the audit November to December 2015*

not Submit	**AR04**	*Agency did not submit personnel files for the following nurses*
	AR08	*Skills Assessment was not submitted*
	AR17	*Agency did not submit a skills assessment per COMAR 10.09.53.030(2); agency submitted a skills self-assessment form dated 11/4/16*
	AR23	*For the dates under review for this audit, the agency did not submit documentation that Ms. had clinical skills required by COMAR to perform the duties of a RN Supervisor*
	AR25	*Licensure: Agency did not submit verification of certification per COMAR 10.09.69.11C(2); 10.09.53.01B(13)*
Skills Assessment not done/not done correctly	**AR06**	*G tube feedings are not included on the skills assessment that supervisory nurse signed on 5/17/16*
	AR08	*Skills Assessment was dated 2/ 1 /16; nursing was provided before this date*
	AR12	*10/6/15 Skills Assessment: Irrigating a wound was not checked off under the "competent" heading; under the heading "Supervisor Initial"' and "date" the RN placed arrows through every skill on the checklist including irrigating a wound*
	AR13	*RN signed off on the trilogy ventilator, RN signed off on the rest of the assessment; training for IPV (Intrapulmonary percussive ventilation) was not included in the assessment; employee initiated but the RN did not sign off on transdermal medication*
	AR23	*12/4/14 RN signed the pediatric and adult checklists which was after the dates of this audit* *11/22/10: Interview with RN who stated the applicant was an "adult nurse" (LPN)* *11/18/11: Interview with RN who assessed her skills as a pediatric nurse; at the top of the form "updated" was written*
	AR25	*Skills Assessment: This document in invalid as the RN Supervisor noted that all skills were evaluated via "oral question and answer session" with the exception of two that were assessed via "Direct Observation/Demonstrate of skill on patient"*
	AR28	*8/19/16: The following applicable skills were not demonstrated: respiratory assessment, pulse oximetry, chest PT, and clean trach stoma, change trach ties, 01 assessment, Pussy-Muir Valve, Administration of enteral feeding, oxygen*

	AR30	*Skills Assessment: None of the nurses have current skills assessments*

Money Recovery:

In this section, the two major themes that stood out were agency under-billing for services or over billing for services. Out of the 12 records that had comments in this section, 5 records showed that the provider agencies did not bill for one or more days of services that were provided to clients, and 7 records showed that the agencies over billed for services that were provided to clients. In at least one instance the agency billed for a different date from the date when the service was provided. See table 3.4 for some examples of comments that were found in this section.

Table 3.4: Sample of Comments in Money Recovery

MAJOR THEMES	AR #	COMMENTS RECORDED
Agency Did not Bill / Agency Over Billed	**AR03**	*Agency did not bill, Nurse A worked 8 hours and Nurse B worked 8 hour*
	AR08	*Time sheet and nursing notes totaled 19 hours; agency was paid for 22 hours*
	AR12	*agency did not receive payment for this date*
	AR13	*11/2 Agency was paid for a RN Supervisor visit; note was dated 11/5*
	AR18	*Agency paid for 20 hours but time sheets and nursing notes document 13.5 hours worked*

Plan of Care:

As in the physician information section, the plan of care section also had incomplete information. In this section, 21 out of the 30 client records had comments elaborating deficiencies that were found on the audit results. The audit uncovered incomplete diagnoses and

no start dates for most of the diagnoses that were listed on the POC. In addition, the treatment goals on the POC were not measurable and no objectives were listed.

***AR02**: "did not include dates of diagnoses, No measurable or objective treatment goals..."*

Table 3.5 shows some more examples of comments that illustrate this point. The lack of diagnoses on the POC was found in 11 out of the 21 Records that had a deficiency comment in this section. In 8 out of 21 records even when diagnoses were listed, they did not have the start date of the diagnoses on the POC. These two problems had a 52% and a 38% weight of evidence as seen in table below.

Table 3.5: Sample of Comments in Plan of Care Section

MAJOR THEMES	AR #	COMMENTS RECORDED
Treatment goals not Measurable	**AR02**	*"did not include dates of diagnoses, No measurable or objective treatment goals..."*
	AR03	*Treatment goals are not measurable and objective, frequency of nursing orders stated" see wean-down authorization" but did not include the nursing orders*
	AR13	*Five other problems were listed in the care plan. None of the goals were objective and measurable.*
	AR01	*Treatment goals are not measurable and objective. No prohibited activities. No special parameters for initializing emergencies. No Nurse's role in including family care. No plan to decrease services. No rehabilitation potential. No special instructions for emergencies*

Medication Administrative Section:

In the medication administrative section, out of the 30 client records that were audited 21 of them had written comments identifying the specific deficiencies that were found on the MARs. The three common deficiencies were; Orders not transcribed on the MAR, for the orders that were transcribed, discrepancies were found between the MAR and the doctor's orders and others lacked parameters for medication administration.

***AR13**: "The following orders were not transcribed correctly onto the MAR: Miralax was ordered daily but was transcribed onto the MAR as a prn medication..."*

These three major themes had weights of evidence percentages that were between 33% and 38%. See table 3.9 for the weight of evidence and table 3.6 for examples of more comments.

Table 3.6: Sample of Comments in Medication administrative section

MAJOR THEMES	AR #	COMMENTS RECORDED
Discrepancies were noted between the MAR and physician order form	**AR30**	*The following treatment was included on the MAR but not ordered by the physician: Chest PT every 4 hours and prn*
	AR05	*Feeding order and MAR do not match*
	AR04	*The following discrepancies were noted between the MAR and physician order form: Lasix, Captopril, Glycolax, Eryped* *The following changes to physician orders were not submitted: trach changes, wound care* *Orders were not updated (information regarding physician visits from September were included in the 10/14/15-12/12/15 orders)*
	AR13	*"The following orders were not transcribed correctly onto the MAR: Miralax was ordered daily but was transcribed onto the MAR as a prn medication..."*

Progress Notes Section:

The review of the progress notes section revealed significant deficiencies in the documentation of care provided in the home. An overwhelming number of the records (21 out of 23) showed that the nurses did not document the nursing intervention that they were placed in the home to provide to the client. This finding had the highest (90%) weight of evidence of all the themes that were identify (See table 3.9). Most nurses did not document or incorrectly documented the required nursing intervention. On more than one occasion, the nurse was found to have documented issues that were irrelevant to the required nursing intervention such as;

doing the clients laundry or cleaning the client's home (See Table 3.7). Another theme that was identified was that some nurses did not follow physician orders.

> ***AR13***: *"The nurse administered an enema: due to the foul odor from the bowel movement. The mother awoke to see the child: the physician ordered an enema when there was no bowel movement for 3 days: the nurse recorded two bowel movements on [12/4 on the 7:45am - 5:45PM shift....]"*

Table 3.7: Sample of Comments in Progress note section

MAJOR THEMES	AR #	COMMENTS RECORDED
Nurses did not document or the nurses documented incorrectly	**AR13**	*"The nurse administered an enema: due to the foul odor from the bowel movement. The mother awoke to see the child: the physician ordered an enema when there was no bowel movement for 3 days: the nurse recorded two bowel movements on 12/4 on the 7:45am - 5:45PM shift...."*
	AR04	*At the beginning of the shift (7PM) the pulse ox was 90%. The physician order states, "Maintain oxygen saturation greater than 95%." The nurse did not document oxygen administration and pulse ox was monitoring at the beginning of the shift when the reading was 90%*
	AR09	*The order for the G tube feeding rate beginning 6/15/16 was 9cc/hour with an increase of lee per hour every 5 days as tolerated; the order was transcribed onto the August MAR with a rate of 21cc/hour; the nurses did not document the feedings and the rate on the MAR the entire month; per the nursing notes the rate on August 1 was either l7cc/ hour or 19cc/hour (the hand writing was difficult to decipher) and 2lcc/hour on August 25; the nurses did not document an assessment per physician order prior to increasing the feeding rate; the RN Supervisor did not document an assessment of the feeding schedule in her note for the August 25 supervisory visit.*
	AR15	*Seizures: "Stay with the patient during the seizure. Turn the patient on his side": • Nurse documented holding and wrapping her hand around the participant's upper body during seizures*

	AR26	*Nurses did not document that physician orders were followed:* *• catheterization was not documented every 3 hours as ordered* *• nurses documented that they took direction from the parent and provided care for which orders were not submitted*
	AR26	*Linens washed (this is not a skilled nursing intervention)* *"Laundry folded and put away (this is not a skilled nursing intervention)*

RN supervision section:

On the RN supervision section most of the records were not submitted. This meant that the supervisory visit was not done in 11 out of the 23 records that had deficiency comments in this section. See table 3.8 for examples of more comments. This had a weighted evidence of 48% confirming that the visits to assess of the client and the staff in the home were not done. However, for those that were submitted, on two occasions the supervisory nurse failed to do the assessment of the client. They also did not do the assessment of the need for training the staff in the home. On more than one occasion, the assessment was done later than the required time frame after discharge from the hospital, which is a violation of the COMAR regulations.

> ***AR03****: "10/08/15 "Hospital discharge Assessment" (Hospitalized 9/29/15 - 10/06/15) was completed two days after discharge by RN; the information on the form was brief, there was no documentation of a head to toe assessment, a review of the physician orders, and an assessment of patient educational needs. The reason for the hospital admission was "respiratory distress". Although there was documentation of rhonchi in all lobes, the nurse did not complete further assessment. The participant was hospitalized the next day (10/9) with bronchitis...."*

Table 3.8: Sample of Comments in RN supervision section

MAJOR THEMES	AR#	COMMENTS RECORDED
Supervisory	**AR02**	*RN supervisory visit was not submitted No head-to-toe assessment of*

Visit not Submit/Done		*recipient. No review of physician's orders and accuracy of transcription. No review of progress notes. No documentation does not show*
	AR22	*RN Supervisor note was not submitted*
Late Assessment	**AR03**	*10/08/15 "Hospital discharge Assessment" (Hospitalized 9/29/15 - 10/06/15) was completed two days after discharge by RN; the information on the form was brief, there was no documentation of a head to toe assessment, a review of the physician orders, and an assessment of patient educational needs. The reason for the hospital admission was "respiratory distress". Although there was documentation of rhonchi in all lobes, the nurse did not complete further assessment. The participant was hospitalized the next day (10/9) with bronchitis...."*

Table 3.9: Weight of Evidence for Major Themes

Audit Section Name	*N*	*Key Deficiency*	*Number/ Percent of Record with Deficiency*	
Clinical Management Policies	5	Agency did not follow the policy	4	80%
		Inaccurate completion of IR Form	2	40%
Employee Records	23	Agency did not Submit	16	70%
		Skills Assessment not done/not done correctly	15	65%
MAR	21	Discrepancies were noted between the MAR and physician order form	7	33%
		Medication did not include Parameters	7	33%
		Order was not transcribed to the MAR	8	38%
Money Recovery	12	Agency did not bill or receive payment	5	42%
		Over Billing	7	58%
Physician Information	24	Incomplete complement of order	10	42%
		Not signed before the due date	10	42%
Plan of Care	21	diagnoses is not complete	11	52%

		diagnoses not dated	8	38%
Program Requirement	10	not submitted	4	40%
	23	Not the following physician order	8	35%
Progress Note		nurses did not document or the nurses documented wrongly	21	91%
RN Supervision	23	Supervisory visit not Submit/Done	11	48%
Summary	12	not submit	7	58%

DISCUSSION

Smith's (2007) article on the nuts and bolts of starting a PDN provider agency business emphasizes the need to set up the infrastructures of the business correctly from the very beginning in order to ensure clients' safety and business success.[100] The results of this study, as a whole, point to an urgent need for structural improvements in the administrative processes of PDN provider agencies. Most of the deficiencies indicate that many of these agencies lack the infrastructure to support the clients in the REM program. For example, the inability of these agencies to submit some documents to the DONS program upon request, would suggest that the documents were either not available or were mishandled by administrative staff. In addition, the inability to obtain the signed doctor's order within the appropriate time frame, the inability to bill for services rendered and the high instances of errors in over billing, also suggest that a lot of these agencies do not have clear and efficient processes on how to request, follow up and receive physician orders from doctor's offices after they have been signed and to bill for services timely and accurately. Therefore, it would be particularly important for PDN provider agencies to restructure their organizational processes to ensure that these deficiencies are corrected.

[100] Cheryl Smith, "Turning Caring Into Business," *Home Healthcare Nurse: The Journal for the Home Care and Hospice Professional* 25, no. 9 (2007): pp. 560-565, https://doi.org/10.1097/01.nhh.0000296112.48943.48.

Some suggested changes that can be made to the administrative process is implementing an electronic system to manage the client care and the Human Resource (HR) process.[58] There are several existing Electronic Management Portals (EMP) that can be purchased for a monthly fee. These systems allow the agency to manage both scheduling and documentation within the same portal. They allow for easy access of the notes by both the provider and the nurse and help to promote continuity of care between shifts. Another benefit is the ability for the Quality assurance (QA) division to easily QA notes and provide immediate feedback to the nurse so that corrections can be made in real time. There are two potential drawbacks to this solution. The providers would have to provide the electronic devices (laptops, tablets, cell phones etc.) for the nurses to use in the clients' homes and would need to provide wireless internet connection to ensure that the data is synced in real time as the documentation is done. Although this may be costly to do, providers may find some cost savings in terms of the efficiencies in the system and eliminate the potential to lose money due to poor documentation. More importantly, it enhances the quality of services provided to the clients.

In the same vain, agencies could leverage the electronic resources to manage the recruitment and onboarding process. HR software can provide agencies with the ability to advertise jobs on employment search engines on the web, accept employment applications online, track and manage the interview process, hire and collect all necessary paperwork from the employee and finally customize and deploy training programs to employees all with a click of a button. This process is very efficient and would reduce the risk of losing money due to deficiencies in employee records.

In addition to the administrative restructuring, there is also a great need for robust quality assurance (QA) processes in these agencies. Depending on the size of the agency, the QA

process could range from designating a single person to establishing an entire QA department that would be responsible for reviewing the progress notes, medication records and doctors' orders for clients. In a 2011 publication, Wang *et al*., reported that instituting a robust QA process is the best way to eliminate deficiencies such as discrepancies between the MARs and the POC/doctor order.[64] It will also go a long way to catch and correct some of the documentation errors that are found on the progress notes and POCs. Issues such as: no signature on a doctor's order or no date on the POCs, or incomplete POCs would quickly be caught and rectified before they are picked up in a state audit or worse, result in harm to a client.

Many of these deficiencies indicate the need for PDN provider agencies to develop good and consistent training programs for direct care and supervisory nursing staff. A number of studies have demonstrated that training programs are the best ways to improve knowledge and mitigate deficiencies such as, correctly documenting the nursing intervention, completing accurate and appropriate nursing assessments and following the doctor's order.[89] [90] Although, it is expected that a nurse who has gone through 2 to 4 years of a nursing program would be proficient in the above listed tasks, it is important to realize that on the job training is always needed to help nurses assimilate in any nursing specialty such as home care. Therefore, on the job training programs for PDNs could help eliminate some of these deficiencies.

Another way of enhancing the nurse's knowledge is by providing certification programs for specific skill sets that are needed in the PDN arena. A few of such programs have recently started operations in the state of Maryland; however, they are not many, and they don't provide training to the direct care nurse in the home. These programs are set up in a train-the-trainer format which essentially trains the RN supervisor who is then responsible for training the nurses in the field. However, the results of the supervisory section of this study, indicate that the train-

the-trainer format may not solve the problem. If the visits are not being done, then it means the field nurses are not getting the training. So, in place of the train-the-trainer format this researcher would suggest the use of a certification model. This approach would mean PDN agencies, working with the state and other stakeholders would create certification programs for vent care, trach care and/or G-tube care, which teach nurses through theory and practices, how to care for a client with those skilled needs. At the end of each training the nurse would be awarded a certificate that could be used as verification that the skill has been learned. It is obvious that this would not be a quick fix, but it may be quicker than the Maryland state legislature voting to increase the Medicaid reimbursement rate to the level needed to provide competitive pay to attract experienced skilled nurses to the area of PDN services.

If these changes are made, there is a potential for indirect cost savings through protection from non-compliance related recoupment of funds following state audits. Agencies would not lose money as a result of their failure to submit the correct documentation. They will also be able to retain the current clients and attract new clients who are looking for better quality of service. Finally, they will retain more of their workforce who will feel supported through the training programs that are provided. This will increase the nurse retention rate and reduce the overhead cost of constantly hiring and training new nursing staff.

LIMITATIONS

The sample size for this study was small and it was limited to just a four-year time frame. Only 30 client audit results were received from the DONS which included audits that were done for services rendered between CY2014 to CY2017. Taking into account that this program has been in existence for over 20 years, it would have been very valuable to gain access to the audit records that were done from the start of the program until the present. This would have provided

a larger sample size and the ability to look at the trends over a more extended timeframe. In addition, because the records were redacted, it was difficult to know the agencies whose records were audited. Gaining access to this information would have afforded this researcher the ability to consider the characteristics of the agencies as the data was analyzed. Another limiting factor was that these audits were all done by one nurse reviewer. As a result, this researcher could not control for any personal biases that could be in the results of the audit. The small sample size and possible biases that may have been introduced by the nurse reviewer have greatly affected the ability to generalize the results of this study.

CONCLUSIONS

In conclusion, results from this study show that there are opportunities for PDN provider agencies to improve the quality of services delivered to REM program participants. It will be beneficial for these agencies to implement;

- A robust on-the-job training program for their nurses. For example, provide training to the supervisory nurse on the duties and how they connect to the care of the client and supervision of the field staff.
- Put in place quality assurance processes to ensure good documentation. For example, assigning someone who is not involved in the care process to audit the records for compliance with the care standard and using the findings to immediately retrain the nurses involved with the care.
- Work with other stakeholders to create a certification program for the skills needed by direct care nurses to provide optimal care to the client.
- Restructure their administrative staff to ensure better coordination of care with physicians and the DONS program.

These are all quick and easy measures that will improve the quality of services to REM program participants with limited financial cost and the potential for indirect cost savings through protection from non-compliance related recoupment of funds following state audits. These changes will go a long way to benefit the REM program participants in terms of the quality of care they receive as well as the PDN provider agencies' bottom line. Finally, additional research is needed to identify best practices that are working for the current PDN provider agencies. For example, survey current agencies to understand how they are dealing with the aspect of staff training, electronic documentation, and obtaining physician signatures, would provide valuable lessons that can be utilized by all PDN provider agencies.

CHAPTER 5: CONCLUSIONS

SUMMARY FINDINGS

MAJOR FINDINGS OF STUDY ONE

The first study found some significant deficiencies in the processes that are used to provide services to the Maryland Medicaid Rare and Expensive Case Management (REM) program participants. The most notable deficiencies were; 80% of the records reviewed had a discrepancy between the Physician orders (PO) and the Medication Administration Records (MARs), 100% of the Plans of Care (POC) were not completed accurately, 78% of Progress notes were inconsistent with POCs and/or POs and last but not least, 100% of the supervisory visits were not done or documented correctly. This is important because discrepancies like this can potentially lead to harmful consequences for the clients. So, this can server as a starting point for the providers to work on improving their services.

MAJOR FINDINGS OF STUDY TWO

The second study found that the most prevalent instances of non-compliance with personnel records were centered on documentation of clinical/pediatric experience of nursing staff; about 84% compared to any of the other requirements. Consequently, about 50% of the money recovered from the PDN provider agencies was as a result of invalid credentials for the field (direct care) and supervisory nurse. This finding indicated that this regulation may be adding to the workforce shortage that currently exists in this program. It also provides the state with some recommendation as to how they can mitigate this problem.

MAJOR FINDINGS OF STUDY THREE

The last study found that many PDN provider agencies had difficulty getting their clients' physicians to sign POs and POCs in a timely manner per Division of Nursing Services (DONS) guidelines. Of note, a significant number of audit records had POCs that were not completed in their entirety; that is, they had large sections missing vital information. In addition, most POs were not transcribed accurately on to the MAR and consequently, the direct care nurses were not administering the medication correctly. Last but not the least, the nurses were not documenting the nursing intervention for which they went to the home. These are process measures that can be changed to improve the quality of care for these individuals.

RESEARCH LIMITATIONS AND STRENGTHS

The sample size for this study was small and it was limited to just a four-year time frame. Only 30 client records were obtained from the DONS office for audits that were carried out reviewing services rendered between CY2014 to CY2017. Considering that this program has been in existence for over 20 years, it would have been valuable to obtain audit records covering a longer period of time.

In addition, the reasons for the audit were mostly as a result of client complaints, client deaths, reportable incidents, and review for medical necessities. This cluster data approach may be biased toward records that already have deficiency and limit the generalizability of the results of the study. As a result, we will recommend that the DONS program consider doing a true randomized audit in order to get results that can be generalized to the entire client population.

Furthermore, because the records were redacted, it was difficult to know the agencies whose records were audited. Gaining access to this information would have been valuable to help this researcher take in to account the characteristics of the agencies as the data was

analyzed. Another limiting factor was that these audits were all done by one nurse reviewer. As a result, this researcher could not control for any personal biases that could be in the results of the audit. The small sample size and possible biases that may have been introduced by the nurse reviewer have greatly affected the ability to generalize the results of this study. Of note, the audit instrument that was used was created by the DONS program and has not been tested for reliability and validity.

Another limitation of this study is the lack of clinical outcome data. Unfortunately, the survey was not designed to collect such data. However, the available audit data was used to evaluate process and structural measures of care. This researcher strongly recommends that future studies should look at evaluating the quality of care for the REM program participants by utilizing clinical outcome measures.

Despite these limitations, this study has key strengths that make it valuable. First and foremost, it is the first study of its kind that evaluated the quality of PDN services provided to individuals in the Maryland Medicaid REM program. More importantly, data collected directly from the 29 PDN provider agencies by the DONS were used in this study, thus making the results truly relevant to the agencies given the findings. Finally, this study's findings provide PDN provider agencies and the state with tangible evidence and recommendations that can be implemented to improve the quality of care for REM program participants.

POLICY IMPLICATIONS AND FUTURE RESEARCH

There are three public health implications from this study. Firstly, this study's results will inform changes that may lead to improvements in the quality of PDN services provided to REM program participants. The results of this study will be shared with PDN provider agencies and the recommendations therein should help in improving their practices. It is my hope that

implementation of these recommendations will translate to better quality of care for REM program participants. This will also lead to a better quality of life for the clients and their families.

The second implication of the results of this study is dependent on the first one, as it has been well-documented that PDN services are very cost effective, and result in cost-savings for the healthcare system as a whole. This means that better quality of care for REM program participants at home will lead to a reduction in emergency room visits and (re)hospitalizations. This improvement will save money for the state. In addition, the ability to provide reliable and more consistent services may allow the primary caregivers for these individuals to be able to work out of the home and contribute to the economy as productive members of the society.

The third implication is the possibility for the findings of this study to influence regulation and policy changes in the state of Maryland. Study findings suggest that some regulations, such as the requirement that nurses have prior pediatric experience before working in home care, may create a bottleneck in the recruitment process and exacerbate the already acute problem of nursing shortage in home care. As such, there is a need to eliminate this requirement and replace it with one that calls for specific targeted training for nurses upon hire by PDN provider agencies before they start working. This also provides an opportunity for the Maryland legislature to consider passing the education bill with a slight modification for the state to provide a grant for the implementation of the training program. This researcher hopes to convince the legislature to utilize some of the money from PDN provider agency non-compliance penalties to fund the training program.

SUMMARY

The findings from this study indicate that there are significant problems with the quality of PDN services delivered to REM program participants. However, with some targeted interventions, PDN provider agencies can increase the quality of care provided to individuals with complex medical needs in the REM program. These interventions can be implemented at the provider level, at the executive level, and at the legislative level. This researcher hopes that the results of this project will help to inform solutions to the quality-related problems identified by this study of PDN services provided to REM program participants.

First, at the agency level, the PDN provider agencies can use the findings of the first and the third paper to revise some current practices and improve the quality of care for the REM program participants. More specifically, findings from the first paper can inform corrective action training for their field (direct care) nurses and nurse supervisors. They can also use the information to set up or strengthen their QA processes to ensure the deficiencies seen on these audit records are reviewed and corrected in time to avoid any potential harm to clients. Finally, PDN provider agencies should consider restructuring their organizations or putting processes in place that would help them to better communicate with other providers and the state as needed.

At the executive level, the findings of this study could be used to advocate for changes in regulations that negatively impact patient care. The DONS is the department at the MDH responsible for ensuring that PDN services to REM program participants are delivered in accordance with the regulations and program requirements. This places the staff at the DONS office in a unique position to be able to advocate for the REM program participants whenever a change is needed. Findings from the second paper can be used by DONS staff to advocate for changes in the current regulations, to substitute the requirement for prior pediatric experience

with a requirement for specific training for the direct care nurses or nurse supervisors working with REM program participants.

Finally, at the legislative level, the results of this study could inform the drafting of policies aimed at improving the quality of PDN services provided to REM program participants. Of note, it has been very difficult to convince the Maryland legislature to pass the two bills that have been proposed to fix the issue of quality of care for REM program participants. This resistance has mostly been due to the cost associated with the proposed bills. In light of the findings from these three studies, this researcher hopes that the legislative branch would be more inclined to draft and pass a training bill that can be funded partially with the funds that are recovered from PDN provider agencies following DONS compliance audits.

Appendices

Appendix 1: Freedom of information request

August 31, 2019

Carlita Lindsey,
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REQUEST LETTER

Dear Ms. Lindsey:

This is a request under the Maryland Public Information Act, Title 4 of the General Provisions of the Maryland Code. I am making this request on behalf of my Dissertation Research project team at the University of Maryland College Park. Please note that this request is to the Maryland Department of Health pertaining to records related to the Division of Nursing Services ("DONS") and Maryland Medicaid Billable Data. I wish to inspect all public records in your custody and control pertaining to, among other things:

- Any and all public records from January 1, 2014, to the present reporting any findings and/or conclusions resulting from audits by the Division of Nursing Services of a provider of private duty nursing services under COMAR 10.09.69 and/or COMAR 10.09.53, with personal identifying information redacted.

I wish to inspect all public records in your custody and control pertaining to the following:

- Any and all public records, with personal identifying information redacted, reporting any findings and/or conclusions resulting from the ten (10) audits conducted by DONS of a provider of private duty nursing services under COMAR 10.09.69 and/or COMAR 10.09.53, from January 3, 2017, to present;
- Any and all public records received or generated by DONS after June 11, 2014, related to the preauthorization of private duty nursing services under the procedure billing code of T1003, T1004, W100, T1002, T1031, Or T1021.
- Any and all records received or generated by DONS after June 11, 2014 to present, related to the Medicaid Billing of private duty nursing services under the procedure billing code of T1003, T1004, W100, T1002, T1031, Or T1021.

"Public record" has the meaning given that term in Md. Code Ann., G.P. § 4-101.

If all or any part of this request is denied, I request that I be provided with a written statement of the grounds for the denial. If you determine that some portions of the requested records are exempt from disclosure, please provide me with the portions that can be disclosed. Please advise me as to the cost, if any, for inspecting the records described above. I anticipate that I will want copies of some or all of the records sought. If you have adopted a fee schedule for obtaining copies of records and other rules or regulations implementing the Act, please send me a copy.

I look forward to receiving disclosable records promptly and, in any event, to a decision about all of the requested records within 30 days. Thank you for your cooperation. If you have any questions regarding this request, please telephone me at the below number.

Sincerely,
Dyllis Minang., RN, BSN. MS.
PhD Candidate
University of Maryland
School of Public Health,
Department of Health Policy and Management
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cc:
Dr. Luisa Franzini
Dr. Lori Simon-Rusinowitz
Ms. Dawnn Williams

Appendix 2: REM diagnosis list

Rare and Expensive Disease List as of October 16, 2000			
ICD-9 Code	**Disease**	**Age Group**	**Guidelines**
042. x all	Symptomatic HIV disease/AIDS (pediatric)	0-20	(A) A child <18 mos. who is known to be HIV seropositive or born to an HIV-infected mother and: * Has positive results on two separate specimens (excluding cord blood) from any of the following HIV detection tests: --HIV culture (2 separate cultures) --HIV polymerase chain reaction (PCR) --HIV antigen (p24) N.B. Repeated testing in first 6 mos. of life; optimal timing is age 1 month and age 4-6 mos. or * Meets criteria for Acquired Immunodeficiency Syndrome (AIDS) diagnosis based on the 1987 AIDS surveillance case definition
V08	Asymptomatic HIV status (pediatric)	0-20	(B) A child >18 mos. born to an HIV-infected mother or any child infected by blood, blood products, or other known modes of transmission (e.g., sexual contact) who: * Is HIV-antibody positive by confirmatory Western blot or immunofluorescense assay (IFA) or * Meets any of the criteria in (A) above
795.71	Infant with inconclusive HIV result	0-12 months	(E) A child who does not meet the criteria above who: * Is HIV seropositive by ELISA and confirmatory Western blot or IFA and is 18 mos. or less in age at the time of the test or * Has unknown antibody status, but was born to a mother known to be infected with HIV
270.0	Disturbances of amino-acid transport Cystinosis Cystinuria Hartnup disease	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
270.1	Phenylketonuria - PKU	0-20	Clinical history and physical exam; laboratory

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
			studies supporting diagnosis. Subspecialist consultation note may be required. Lab test: high plasma phenylalanine and normal/low tyrosine
270.2	Other disturbances of aromatic-acid metabolism	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
270.3	Disturbances of branched-chain amino-acid metabolism	0-20	
270.4	Disturbances of sulphur-bearing amino-acid metabolism	0-20	
270.5	Disturbances of histidine metabolism Carnosinemia Histidinemia Hyperhistidinemia Imidazole aminoaciduria	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
270.6	Disorders of urea cycle metabolism	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
270.7	Other disturbances of straight-chain amino-acid Glucoglycinuria Glycinemia (with methylmalonic acidemia) Hyperglycinemia Hyperlysinemia Pipecolic acidemia Saccharopinuria Other disturbances of metabolism of glycine, threonine, serine, glutamine, and lysine	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
270.8	Other specified disorders of amino-acid metabolism Alaninemia Ethanolaminuria Glycoprolinuria Hydroxyprolinemia Hyperprolinemia Iminoacidopathy Prolinemia Prolinuria	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
	Sarcosinemia		
271.0	Glycogenosis	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
271.1	Galactosemia	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
271.2	Hereditary fructose intolerance	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
272.7	Lipidoses	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
277.0	Cystic fibrosis	0-64	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
277.00	Cystic fibrosis w/o ileus	0-64	
277.01	Cystic fibrosis with ileus	0-64	
277.2	Other disorders of purine and pyrimidine metabolism	0-64	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required. Demonstration of deficient enzyme such as: alpha-L-Idurondase, Iduronosulfate sulfatase, Heparan sulfate sulfatase, N-Acetyl-alpha-D-glucosaminidase, Arylsulfatase B, Beta-Glucuronidase, Beta-Galactosidase, N-Aacetylhexosaminidase-6-SO4 sulfatase.
277.5	Mucopolysaccharidosis	0-64	
277.8	Other specified disorders of metabolism	0-64	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
284.0	Constitutional aplastic anemia	0-20	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
286.0	Congenital factor VIII disorder	0-64	Clinical history and physical exam; laboratory studies supporting diagnosis. Subspecialist consultation note may be required.
286.1	Congenital factor IX disorder	0-64	
286.2	Congenital factor XI deficiency	0-64	
286.3	Congenital deficiency of other clotting factors	0-64	

Rare and Expensive Disease List as of October 16, 2000			
ICD-9 Code	**Disease**	**Age Group**	**Guidelines**
286.4	von Willebrand's disease	0-64	
330	Cerebral degenerations in childhood	0-20	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
330.0	Leukodystrophy	0-20	
330.1	Cerebral lipidoses	0-20	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
330.2	Cerebral degenerations in generalized lipidoses	0-20	
330.3	Cerebral degeneration of childhood in other diseases classified	0-20	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
330.8	Other specified cerebral degeneration in childhood	0-20	
330.9	Unspecified cerebral degeneration in childhood	0-20	
331.3	Communicating hydrocephalus	0-20	Clinical history and physical exam; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
331.4	Obstructive hydrocephalus	0-20	
333.2	Myoclonus	0-5	Clinical history and physical exam. Subspecialist consultation note may be required.
333.6	Idiopathic torsion dystonia	0-64	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
333.7	Symptomatic torsion dystonia	0-64	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
333.90	Unspecified extrapyramidal disease and abnormal movement disorder	0-20	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
334	Spinocerebellar disease	0-20	Clinical history and physical exam.

Rare and Expensive Disease List as of October 16, 2000			
ICD-9 Code	**Disease**	**Age Group**	**Guidelines**
334.0	Friedreich's ataxia	0-20	Neurology consultation note.
334.1	Hereditary spastic paraplegia	0-20	
334.2	Primary cerebellar degeneration	0-20	
334.3	Cerebellar ataxia NOS	0-20	
334.4	Cerebellar ataxia in other diseases	0-20	
334.8	Other spinocerebellar diseases NEC	0-20	
334.9	Spinocerebellar disease NOS	0-20	
335	Anterior horn cell disease	0-20	Clinical history and physical exam. Neurology consultation note.
335.0	Werdnig-Hoffmann disease	0-20	
335.1	Spinal muscular atrophy	0-20	
335.10	Spinal muscular atrophy NOS	0-20	
335.11	Kugelberg-Welander disease	0-20	
335.19	Spinal muscular atrophy NEC	0-20	
335.2	Motor neuron disease	0-20	
335.20	Amyotrophic lateral sclerosis	0-20	
335.21	Progressive muscular atrophy	0-20	
335.22	Progressive bulbar palsy	0-20	
335.23	Pseudobulbar palsy	0-20	
335.24	Primary lateral sclerosis	0-20	
335.29	Motor neuron disease NEC	0-20	
335.8	Anterior horn disease NEC	0-20	
335.9	Anterior horn disease NOS	0-20	

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
341.1	Schilder's disease	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
343.0	Diplegic infantile cerebral palsy	0-20	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
343.2	Quadriplegic infantile cerebral palsy	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
344.0	Quadriplegia	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
359.0	Congenital hereditary muscular dystrophy	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
359.1	Hereditary progressive muscular dystrophy	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
359.2	Congenital myotonic dystrophy (Steinert's only)	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
437.5	Moyamoya disease	0-64	Clinical history and physical examination; supporting imaging studies and neurologic consultation note may be required.
579.3	Short gut syndrome	0-20	Clinical history and imaging studies supporting diagnosis. Gastrointestinal subspecialist consultation note may be required.
582	Chronic glomerulonephritis	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.0	Chronic glomerulonephritis with lesion of proliferative glomerulonephritis	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.1	Chronic glomerulonephritis with lesion of membranous glomerulonephritis	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.2	Chronic glomerulonephritis	0-20	Clinical history, laboratory evidence of renal

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
	with lesion of membranoproliferative glomerulonephritis		disease. Nephrology subspecialist consultation note may be required.
582.4	Chronic glomerulonephritis with lesion of rapidly progressive glomerulonephritis	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.8	Chronic glomerulonephritis with other specified pathological lesion in kidney	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.81	Chronic glomerulonephritis in diseases classified elsewhere	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.89	Other Chronic glomerulonephritis with lesion of exudative nephritis interstitial (diffuse) (focal) nephritis	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
582.9	With unspecified pathological lesion in kidney Glomerulonephritis: NOS specified as chronic hemorrhagic specified as chronic Nephritis specified as chronic Nephropathy specified as chronic	0-20	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
585	Chronic renal failure A) diagnosed by a pediatric nephrologist	0-20	Clinical history, laboratory evidence of renal disease. Pediatric nephrology subspecialist consultation note required.
585, V45.1	B) with dialysis	21-64	Clinical history, laboratory evidence of renal disease. Nephrology subspecialist consultation note may be required.
741	Spina bifida	0-64	Clinical history and physical exam. Imaging studies supporting diagnosis. Subspecialist consultation note may be required.
741.0	Spina bifida with hydrocephalus	0-64	
741.00	Spina bifida with hydrocephalus NOS	0-64	

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
741.01	Spina bifida with hydrocephalus cervical region	0-64	
741.02	Spina bifida with hydrocephalus dorsal region	0-64	
741.03	Spina bifida with hydrocephalus lumbar region	0-64	
741.9	Spina bifida without hydrocephalus	0-64	
741.90	Spina bifida unspecified region	0-64	
741.91	Spina bifida cervical region	0-64	
741.92	Spina bifida dorsal region	0-64	
741.93	Spina bifida lumbar region	0-64	
742.0	Encephalocele Encephalocystocele Encephalomyelocele Hydroencephalocele Hydromeningocele, cranial Meningocele, cerebral Menigoencephalocele	0-20	Clinical history and physical examination, radiographic or other neuroimaging studies. Neurology or neurosurgery consultation note may be required.
742.1	Microcephalus Hydromicrocephaly Micrencephaly	0-20	Clinical history and physical examination, radiographic or other neuroimaging studies. Neurology or neurosurgery consultation note may be required.
742.3	Congenital hydrocephalus	0-20	Clinical history and physical examination, radiographic or other neuroimaging studies. Neurology or neurosurgery consultation note may be required.
742.4	Other specified anomalies of brain	0-20	Clinical history and physical examination, radiographic or other neuroimaging studies. Neurology or neurosurgery consultation note may be required.
742.5	Other specified anomalies of spinal cord	0-64	Clinical history and physical examination, radiographic or other neuroimaging studies. Neurology or neurosurgery consultation note may be required.
742.59	Other specified anomalies of	0-64	Clinical history and physical examination,

Rare and Expensive Disease List as of October 16, 2000			
ICD-9 Code	**Disease**	**Age Group**	**Guidelines**
	spinal cord Amyelia Congenital anomaly of spinal meninges Myelodysplasia Hypoplasia of spinal cord		radiographic or other neuroimaging studies. Neurology or neurosurgery consultation note may be required.
748.1	Nose anomaly - cleft or absent nose ONLY	0-5	Clinical history and physical examination. Radiographic or imaging studies and specialist consultation note (ENT, plastic surgery) may be required.
748.2	Web of larynx	0-20	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
748.3	Laryngotracheal anomaly NEC- Atresia or agenesis of larynx, bronchus, trachea, only	0-20	
748.4	Congenital cystic lung	0-20	Clinical history and physical exam; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
748.5	Agenesis, hypoplasia and dysplasia of lung	0-20	
749 except 749.1x	Cleft palate and cleft lip	0-20	Clinical history and physical examination. Supporting consultation note from ENT/plastic surgery may be required.
749.0	Cleft palate	0-20	Clinical history and physical examination. Supporting consultation note from ENT/plastic surgery may be required.
749.00	Cleft palate NOS	0-20	
749.01	Unilateral cleft palate complete	0-20	
749.02	Unilateral cleft palate incomplete	0-20	
749.03	Bilateral cleft palate complete	0-20	
749.04	Bilateral cleft palate incomplete	0-20	
749.2	Cleft palate with cleft lip	0-20	
749.20	Cleft palate and cleft lip NOS	0-20	
749.21	Unilateral cleft palate with cleft lip complete	0-20	

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
749.22	Unilateral cleft palate with cleft lip incomplete	0-20	
749.23	Bilateral cleft palate with cleft lip complete	0-20	
749.24	Bilateral cleft palate with cleft lip incomplete	0-20	
749.25	Cleft palate with cleft lip NEC	0-20	
750.3	Congenital tracheoesophageal fistula, esophageal atresia and stenosis	0-3	Clinical history, physical examination; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
751.2	Atresia large intestine	0-5	Clinical history and physical exam; laboratory or imaging studies suporting diagnosis. Subspecialist consultation note may be required.
751.3	Hirschsprung's disease	0-15	
751.61	Biliary atresia	0-20	
751.62	Congenital cystic liver disease	0-20	
751.7	Pancreas anomalies	0-5	
751.8	Other specified anomalies of digestive system NOS	0-10	
753.0	Renal agenesis and dysgenesis, bilateral only Atrophy of kidney: congenital infantile Congenital absence of kidney(s) Hypoplasia of kidney(s)	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.1	Cystic kidney disease, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.12	Polycystic kidney, unspecified type, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.13	Polycystic kidney, autosomal dominant, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies.

Rare and Expensive Disease List as of October 16, 2000

ICD-9 Code	Disease	Age Group	Guidelines
			Subspecialist consultation note may be required.
753.14	Polycystic kidney, autosomal recessive, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.15	Renal dysplasia, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.16	Medullary cystic kidney, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.17	Medullary sponge kidney, bilateral only	0-20	Clinical history, physical examination, radiographic or other imaging studies. Subspecialist consultation note may be required.
753.5	Exstrophy of urinary bladder	0-20	Clinical history, physical examination, radiographic and/or other imaging studies. Subspecialist consultation note may be required.
756.0	Musculoskeletal--skull and face bones Absence of skull bones Acrocephaly Congenital deformity of forehead Craniosynostosis Crouzon's disease Hypertelorism Imperfect fusion of skull Oxycephaly Platybasia Premature closure of cranial sutures Tower skull Trigonocephaly	0-20	Clinical history, physical examination; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
756.4	Chondrodystrophy	0-1	Clinical history and physical exam; imaging studies supporting diagnosis. Subspecialist consultation note may be required.

Rare and Expensive Disease List as of October 16, 2000			
ICD-9 Code	**Disease**	**Age Group**	**Guidelines**
756.50	Osteodystrophy NOS	0-1	Clinical history and physical exam; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
756.51	Osteogenesis imperfecta	0-20	Clinical history, physical examination, radiologic studies. Specialist consultation report (genetics, orthopedics) may be required.
756.52	Osteopetrosis	0-1	Clinical history and physical exam; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
756.53	Osteopoikilosis	0-1	
756.54	Polyostotic fibrous dysplasia of bone	0-1	
756.55	Chondroectodermal dysplasia	0-1	
756.56	Multiple epiphyseal dysplasia	0-1	
756.59	Osteodystrophy NEC	0-1	
756.6	Anomalies of diaphragm	0-1	Clinical history and physical exam; imaging studies supporting diagnosis. Subspecialist consultation note may be required.
756.7	Abdominal wall anomalies	0-1	Clinical history and physical exam.
759.7	Multiple congenital anomalies NOS	0-10	Clinical history and physical exam; laboratory or imaging studies supporting diagnosis. Subspecialist consultation note may be required.
V46.1	Dependence on respirator	1-64	Clinical history and physical exam. Specialist consultation note required.
V46.9	Machine dependence NOS	1-64	

Appendix 3: Sample Medical On-site/DESK Audit form

MARYLAND
Department of Health
Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Dennis Schrader, Secretary

October 4, 2017

Provider Number: #

RE:
MA#:

Dear Ms.

The Division of Nursing Services (DONS) completed a review of the documentation you submitted on behalf of your agency related to the nursing services rendered to Medical Assistance recipient . This review was completed to determine whether the nursing services provided by were rendered in accordance with Medicaid Program regulations governing the Early and Periodic Screening, Diagnosis and Treatment – Nursing Services Program (COMAR 10.09.53). Based on the findings of this review which are attached, it has been determined that billed and received inappropriate payments totaling $16,970.74 for the period July 4, 2016 through September 1, 2016.

201 W. Preston Street • Baltimore, MD 21201 • health.maryland.gov • Toll Free: 1-877-463-3464 • TTY: 1-800-735-2258

You may reimburse the State of Maryland for these payments by making your check payable to the Department of Health and Hygiene and mailing it to:

Ms. Margaret Thompson
TPL Coordination
Division of Recoveries & Financial Services
Medical Care Operations Administration
P.O. Box 13045
Baltimore, Maryland 21203

. has the right to appeal the DONS' decision to initiate a recovery of these payments to the Maryland Office of Administrative Hearings (OAH) pursuant to COMAR 10.09.36 by writing within thirty (30) days of the date of this letter to the address listed below:

Executive Director's Office
Department of Health and Mental Hygiene
Office of Health Services
Attention: Appeals
201 West Preston Street, 1st Floor
Baltimore, Maryland 21201
Fax: #410-333-5154

Additionally, . must address the noted issue(s) on the Medical On-Site/ Desk Audit form that require a Plan of Correction. Please submit this documentation as directed to the DONS by close of business (5:00pm) on Thursday, October 26, 2017 to the following address:

Division of Nursing Services
Maryland Department of Health – Office of Health Services
201 West Preston Street, Unit 79, Room 130
Baltimore, Maryland 21201
Attention: Toby Cornish, RN

If you have any questions regarding this letter or the attached findings, please call me at (410) 767-1448.

Sincerely,

Toby Cornish, RN
Compliance Coordinator
Division of Nursing Services

Attachments

cc: Files
Dawnn Williams

LONG TERM CARE AND COMMUNITY SUPPORT SERVICES
ADMINSTRATION

DIVISION OF NURSING SERVICES (DONS)

Medical On-Site/DESK Audit

Purpose: The purpose of this audit is to verify that services are/were delivered in accordance with program regulations, the physician's orders and were reimbursed appropriately.

Participant Name:
MA#:
Diagnosis: Gastroschisis; Short Bowel Syndrome
Type of Service: REM PDN
Provider Name:
Provider #:
Date of Audit: 10/3/17
Time period reviewed: 7/4/16-9/1/16
Nurse: Toby Cornish, RN

Total Recovery Amount: $16,970.74

PHYSICIAN INFORMATION: ☒ COMAR 10.09.53.03, 10.09.53.04 and 10.09.53.05 ☐ COMAR 10.09.69.11 and 10.09.69.12

Primary Physician: Clarivet Torres, MD
Name of Physician signing the Plan of Care: Signature is not legible

	Yes/No	Comment/Recommendation	Action Required Plan of Correction/Recovery Amount
Physician's Orders:			
· Signed by Primary Physician?	No	"P. Lin, MD for Dr. Torres" was written by the signature	
· Physician licensed in Maryland?	NA	Physician signature is not legible	
· Signed and dated by the physician on or before effective date?	No	Orders 7/4/16-9/1/16 were signed 7/7/16	
· Renewed every 60 days?	NA		
· Medication orders complete?	No	See comments	

2-29-12

Comments:

, RN documented a verbal order on 7/1/16. She did not document the name of the physician providing the verbal order.

MAR ☒ COMAR 10.09.53.03 ☐ COMAR 10.09.69.11

	Yes/No N/A	Comment/Recommendation	Action Required Plan of Correction/Recovery Amount
Any discrepancy between Physician's Order and MAR?	Yes		

Comments:
The physician orders and MAR do not match, specifically the orders for Prevacid, Ferrous Sulfate, and Flagyl were transcribed onto the MAR but there were no corresponding orders submitted

The following orders were not transcribed onto the MAR:

- Oral feedings
- G tube feedings
- Strict intake and output
- Weekly weight
- Physician orders did not include the care of the gastrostomy tube site and frequency of changing the tube

PLAN OF CARE: ☒ COMAR 10.09.53.04, 10.09.53.05 ☐ COMAR 10.09.69.11

Date of most recent Plan of Care: 7/4/16-9/1/16			
How frequently is the Plan of Care updated? (Noting the time span between updates) NA			
	Yes/No N/A	Comment/Recommendation	Action Required Plan of Correction/Recovery Amount
Diagnosis (All applicable diagnoses included)	Yes		
Prognosis	Yes		
Treatment	Yes		
Treatment goals (Measurable and objective)	No	Goals are not measurable and objective	
Services required	Yes		
Frequency of nursing	Yes		
Functional Limitations	No	The limitations listed are developmentally appropriate for an infant and are not considered	

Permitted Activities	Yes	limitations for this age group	
Prohibited Activities	Yes		
Diet	Yes		
Medication	Yes		
Mental Status	Yes		
Medical supplies	Yes		
Medical Equipment	Yes		
Safety Measures	Yes		
Emergency plan:			
• Physician's name and phone number	Yes		
• Parameters for initializing emergency contact	No		
• Special instructions for emergencies	Yes		
• Family or guardian contact information	No		
Back up nursing contingency plan	No		
Nurse's role in including family in care	No		
Plan to decrease services	No		
Rehabilitation potential	No		
Are major changes in recipient's medical condition or skilled nursing needs reflected in the Plan of Care?	NA		
Has the provider noted changes in the medical condition and discussed decreasing private duty nursing with the physician?	NA		
Has the provider decreased services as the condition of the participant improves or as the caregiver(s) is better able to meet the participant's needs?	NA		

PROGRESS NOTES: ☐ COMAR 10.09.53.01, 10.09.53.03, 10.09.53.04 & 10.09.53.05 ☐ COMAR 10.09.69.08, 10.09.69.11 & 10.09.69.12

Nursing interventions provided: G tube feedings, oral feedings, medications			
	Yes/No N/A	**Comment/Recommendation**	**Action Required** Plan of Correction/Recovery Amount
Consistent with plan of care and physician's orders?	No	See comments	The agency must submit a plan of correction to comply with the physician orders. The nurses did not comply with the physician orders as noted in this audit. The Plan of Correction must be received within 3 weeks of the date on the audit letter.
Each shift has a completed Progress Note that is dated and signed by the nurse/HHA/CNA?	Yes		
Beginning of shift assessment done?	Yes		
Notes adequately describe the services rendered?			
• Each intervention documented.	Yes		
• Hour noted for each intervention.	No		
• Seizure documentation includes time of occurrence, length of seizure, intervention and after effects.	NA		
• PRN medication documentation Includes: time of occurrence, reason for and effect.	NA		
• Legible.	No	Some notes are difficult to read	
• Errors corrected with single line drawn through and initialed.	Yes		
Recipient/caregiver signature to verify services?	Yes		

Comments:

- The order for the G tube feeding rate beginning 6/15/16 was 9cc/hour with an increase of 1cc per hour every 5 days as tolerated; the order was transcribed onto the August MAR with a rate of 21cc/hour; the nurses did not document the feedings and the rate on the MAR the entire month; per the nursing notes the rate on August 1 was either 17cc/ hour or 19cc/hour (the hand writing was difficult to decipher) and 21cc/hour on August 25; the nurses did not document an assessment per physician order prior to increasing the feeding rate; the RN Supervisor did not document an assessment of the feeding schedule in her note for the August 25 supervisory visit.
- The order for oral feedings was 6cc four times per day; the nurses document administration of 10cc per feeding; the agency did not submit an order for the increase in oral feedings
- The physician ordered the following regarding the Broviac line which includes TPN and Lipids administration:
  - Care of the Broviac line is limited to caregivers trained by CNMC staff with sterile technique procedure in order to limit incidence of central line infections"

- Physician order for line care: "Care of the Broviac should be limited to guardians who were trained by the nursing staff at CNMC"
  - The nurses documented lack of compliance with the above orders as demonstrated by disconnecting the Lipids on the following dates: 8/2, 8/4, 8/5, 8/7, 8/8, 8/10, 8/11, 8/12, 8/13, 8/14

- Nurses did not document the following physician orders:
  - Strict intake and output
  - The order "Notify IR Coordinators for any weight loss" was not followed as weekly weights were not recorded

- Nurses documented in the notes administering ORS (Oral Rehydration Solution) after G tube feedings and after medications. The agency did not submit a physician order and the nurses did not document administration on the MAR.

SUPERVISION: ☒ COMAR 10.09.53.03, 10.09.53.05 and 10.27.11.04 ☐ COMAR 10.09.69.11, 10.09.69.12, and 10.09.04.05

	Yes/No	Comment/Recommendation	Action Required Plan of Correction/Recovery Amount
All supervisory visits must be documented and include the date of the visit and signature of the RN supervisor.			
Supervisory visits must be done on the following basis: • Bi-Weekly for CNA/HHA • Monthly for RN/LPN		Visit 8/25/16	
Head to toe assessment of recipient?	No		
Review physician's orders and accuracy of transcription?	Yes		
Review of progress notes?	No		
Does documentation show assessment of a need for caregiver training and was it implemented?	No		

Comments:
The supervisory note included the following:

- Under the heading "Psychosocial assessment" the nurse wrote, "his parent manages with nursing services;" this is a generic response and does not reflect an assessment of the family and caregiver
- The supervisor documented, "Feeding by TPN is done by parents only" and "TPN 600cc over 20 hours, daily pump only by guardians"
- As noted in the section of this audit under the heading "Progress Notes", the nurses documented disconnecting the Lipids on 10 out of 18 day shift notes which not in compliance with the physician orders; the RN Supervisor did not document whether the nurses were counseled to adhere to the physician orders as noted above
- Weekly weights were not noted in the supervisory note
- The RN Supervisor signed the "Reviewed by Case Manager" box on each part of the MAR on 8/25/16; there is no indication that errors cited in the MAR section of this audit were addressed

PROGRAM REQUIREMENTS: ☒ COMAR 10.09.53.04, 10.09.36.03, 10.09.36.07 ☐ COMAR 10.09.69.07, 10.09.69.11, 10.09.36.03, 10.09.36.07

	Yes/No N/A	Comment/Recommendation	Action Required Plan of Correction/Recovery Amount
Is there a Progress Note present for each date billed?	Yes	See comments	
Is there a time sheet present for each date billed?	Yes	See comments	
Is the Nursing Agency providing the shift preauthorized?	Yes		
Is each nurse working no more than 60 hours per week or no more than 16 consecutive hours per day?	Yes		
Does the participant have primary health insurance?	No		
If the participant has primary health insurance, has the agency submitted a denial for private duty nursing?	NA		

Comments:

- Agency did not submit a time sheet and nursing notes for for 8/24 and 8/25

Audit Summary:

- This audit was conducted when the Division of Nursing Services received notification that the family of the participant filed a complaint regarding the conduct of one of the nurses assigned to the participant. The agency submitted records including a communication log, "Client Grievance Form", and the "Accident/Incident Reporting Policy."
- , RN completed the Communication Log which covered the time period 8/15/16-9/6/16 for the complaints that occurred on 8/12/16 and 8/15/16. , RN completed the "Client Grievance/Complaint Form" on 8/15/16. The documentation on this form met the criteria for the agencies' "Accident/Incident Policy" which states the report form is to "be completed as soon as possible after the event or occurrence becomes known to the agency staff."
- Nurses documented disconnecting the Lipids on 10 of 18 of the day shift notes submitted. As noted in the Progress Notes section of this audit, the agency must submit a plan of correction as the physician order specifies that the parents are responsible for the Broviac line and administration of TPN and Lipids.
- The agency did not submit the nursing notes, time sheet, and personnel records for who initialed the MAR on 8/24, 8/25, and 8/26
- As noted on the Personnel Credentials Audit form, the clinical credentials on the RN job description are not compliant with COMAR.

Signature/date: 12/3/17

Personnel Credentials Audit

Provider Name:]

Client/Participant Name:

Nurses Assigned to Participant	License Type	License Exp. Date	CPR Exp. Date	Interview Conducted/ Employment Application	Employment/ Character Reference Check	Criminal Background Check	Skills Checklist (Ongoing)	COMAR 10.09.53.03.D.(3) (clinical/ pediatric exp.)
	RN	11/16	1/18	Application not signed and dated; interview dated 11/26/11	11/11	11/28/11	5/20/16	Verification was not submitted
	RN	6/18	4/18	Application not signed and dated; interview dated 8/29/10	8/10	8/26/10	5/8/16	Verification was not submitted
	RN	9/17	9/16	Application not signed and dated	7/14	12/2/02	5/5/16	Verification was not submitted
	RN	Virginia 2/17	1/18	Application not signed and dated	1/13	11/3/08	5/26/16	Verification was not submitted
	RN	Information was not submitted	Information was not submitted	Information was not submitted	Information was not submitted	Information was not submitted	Information was not submitted	Information was not submitted
	RN	Virginia 7/18	1/17	Application not signed and dated; interview dated 10/08	10/08	10/15/08	2/12/16	Verification was not submitted

COMMENTS:

- Personnel file was not submitted as requested

RN Job Eescription

- Urless the RN Job Description has been updated since the nurses listed above were hired, the clinical experience requirements do not comply wih COMAR.

Toby Corrish, RN
Date: 10/3/17

Audit Summary for

Date	Physician Orders were not Followed	Physician Order Signed After Due Date	Total Recovery Amount for the Audit Period
7/4/2016	$0.00	$658.41	$0.00
7/5/2016	$0.00	$826.24	$0.00
7/6/2016	$0.00	$826.24	$0.00
7/7/2016	$0.00	$0.00	$0.00
7/8/2016	$0.00	$0.00	$0.00
7/9/2016	$0.00	$0.00	$0.00
7/10/2016	$0.00	$0.00	$0.00
7/11/2016	$0.00	$0.00	$0.00
7/12/2016	$0.00	$0.00	$0.00
7/13/2016	$0.00	$0.00	$0.00
7/14/2016	$0.00	$0.00	$0.00
7/15/2016	$0.00	$0.00	$0.00
7/16/2016	$0.00	$0.00	$0.00
7/17/2016	$0.00	$0.00	$0.00
7/18/2016	$0.00	$0.00	$0.00
7/19/2016	$0.00	$0.00	$0.00
7/20/2016	$0.00	$0.00	$0.00
7/21/2016	$0.00	$0.00	$0.00
7/22/2016	$0.00	$0.00	$0.00
7/23/2016	$0.00	$0.00	$0.00
7/24/2016	$0.00	$0.00	$0.00
7/25/2016	$0.00	$0.00	$0.00
7/26/2016	$0.00	$0.00	$0.00
7/27/2016	$0.00	$0.00	$0.00
7/28/2016	$0.00	$0.00	$0.00
7/29/2016	$0.00	$0.00	$0.00
7/30/2016	$0.00	$0.00	$0.00
7/31/2016	$0.00	$0.00	$0.00
8/1/2016	$800.42	$0.00	$0.00
8/2/2016	$826.24	$0.00	$0.00
8/3/2016	$800.42	$0.00	$0.00
8/4/2016	$535.68	$0.00	$0.00
8/5/2016	$535.68	$0.00	$0.00
8/6/2016	$468.72	$0.00	$0.00
8/7/2016	$468.72	$0.00	$0.00
8/8/2016	$413.12	$0.00	$0.00
8/9/2016	$826.24	$0.00	$0.00
8/10/2016	$826.24	$0.00	$0.00
8/11/2016	$535.68	$0.00	$0.00
8/12/2016	$535.68	$0.00	$0.00
8/13/2016	$722.96	$0.00	$0.00
8/14/2016	$477.09	$0.00	$0.00
8/15/2016	$826.24	$0.00	$0.00
8/16/2016	$413.12	$0.00	$0.00

Audit Summary for

Date	Physician Orders were not Followed	Physician Order Signed After Due Date	Total Recovery Amount for the Audit Period
8/17/2016	$413.12	$0.00	$0.00
8/18/2016	$413.12	$0.00	$0.00
8/19/2016	$413.12	$0.00	$0.00
8/20/2016	$697.14	$0.00	$0.00
8/21/2016	$722.96	$0.00	$0.00
8/22/2016	$335.66	$0.00	$0.00
8/23/2016	$826.24	$0.00	$0.00
8/24/2016	$413.12	$0.00	$0.00
8/25/2016	$413.12	$0.00	$0.00
1/0/1900	**$14,659.85**	**$2,310.89**	**$16,970.74**

Toby Cinan
12/3/17

Appendix 4: IRB approval

UNIVERSITY OF MARYLAND
INSTITUTIONAL REVIEW BOARD

1204 Marie Mount Hall
College Park, MD 20742-5125
TEL 301.405.4212
FAX 301.314.1475
irb@umd.edu
www.umresearch.umd.edu/IRB

DATE:	November 11, 2019
TO:	DYLLIS MINANG, PhD, Candidate
FROM:	University of Maryland College Park (UMCP) IRB
PROJECT TITLE:	[1466544-1] Evaluating the Quality of Home Health Care for Individuals with Complex Medical Needs Receiving Private Duty Nursing Services in the State of Maryland
REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	November 11, 2019
EXPIRATION DATE:	November 10, 2020
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # 7; Subpart D (45CFR46.404)

Thank you for your submission of New Project materials for this project. The University of Maryland College Park (UMCP) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Prior to submission to the IRB Office, this project received scientific review from the departmental IRB Liaison.

This submission has received Expedited Review based on the applicable federal regulations.

This project has been determined to be a MINIMAL RISK project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of November 10, 2020.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Unless a consent waiver or alteration has been approved, Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Please note that all research records must be retained for a minimum of seven years after the completion of the project.

If you have any questions, please contact the IRB Office at 301-405-4212 or irb@umd.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Maryland College Park (UMCP) IRB's records.

Appendix 5: Content Analysis Code Book

Section Name	Key Phases/Sentences	# of Record with Deficiency
Employee Records	CPR Care expired	1
Employee Records	Agency did not Submit	16
Employee Records	Criminal Background check not valid	2
Employee Records	Not Eligible to provide nursing	1
Employee Records	No documentation of / Inadequate Clinical Experience	6
Employee Records	Skills Assessment not done/not done correctly	15
Employee Records	Lack of Training	2
Employee Records	Did not Verify Past Employment	4
MAR	Medication did not include Parameters	7
MAR	Type Date or Signature	2
MAR	Discrepancies were noted between the MAR and physician order form	7
MAR	Order was not transcribed to the MAR	8
MAR	Order not complete on the MAR	3
MAR	Lack of clarification	3
MAR	Not Submitted	3
MAR	not transcribed correctly on MAR	3
MAR	Administration of Wrong Medication	1
MAR	MAR was difficult to read	2
MAR	No order or multiple orders	3
Money Recovery	Agency did not bill or receive payment	5
Money Recovery	Over Billing	7
Money Recovery	Not submitted	2
Money Recovery	Nurse over worked	1
Money Recovery	time sheet was not signed	1
Money Recovery	nursing shifts that overlap	1
Money Recovery	Documentation issue	1
Physician Information	Not signed before the due date	10
Physician Information	Not legible	2
Physician Information	Incomplete complement of order	10

Physician Information	not submitted	2
Physician Information	not transcribed correctly	1
Program Requirement	Over Billed	1
Program Requirement	not submitted	4
Plan of Care	Treatment goals are not measurable and objective	6
Plan of Care	diagnoses not dated	8
Plan of Care	diagnoses is not complete	11
Plan of Care	not submitted	2
Progress Note	nurses did not document or the nurses documented wrongly	21
Progress Note	No Recipient/caregiver signature	5
Progress Note	Not the following physician order	8
Progress Note	not submitted	5
RN Supervision	did not submit	11
RN Supervision	Assessment of Care giver/ family training needs	5
RN Supervision	Late Assessment	2
Summary	not submit	7
Summary	incident report	3
Summary	death	2
Clinical Management Policies	Agency did not follow the policy	4
Clinical Management Policies	Inaccurate completion of IR Form	2
Clinical Management Policies	Misleading Policy instructions	1

Glossary

	TERMS	DEFINITION
1	Clinical record	A written account of all services provided to a client by the agency as well as all pertinent medical information necessary to provide care
2	Doctors Order	A directive given by the physician or other providers with prescriptive authority to a licensed person who is authorized by organization policy to receive and record verbal orders in accordance with law and regulation
3	Home health agency	An agency licensed by Maryland Department of Health office of Health Care Quality in accordance with COMAR 10.07.10.
4	Individuals with Complex Medical Needs	An individual who, due to abuse or neglect, illness, congenital disorder or brain injury, requires medications, treatments and/or specialized care or equipment. They are also called Medically Fragile Individuals.
5	Licensed practical nurse	An individual who is licensed by the Maryland Board of Nursing to practice licensed practical nursing; or has a multistate licensure privilege to practice licensed practical nursing.
6	Medication Administration Records	The report that serves as a legal record of the drugs administered to a patient at a facility by a healthcare professional. Commonly referred to as a MAR, The MAR is a part of a patient's permanent record on their medical chart.
7	Medication technician	An individual who completes a 20-hour course in medication administration approved by the Maryland Board of Nursing and is certified by the Maryland Board of Nursing
8	Plan of Care	A plan developed by a registered nurse that identifies the patient's diagnoses and needs, the goals to be achieved, and the interventions required to meet the patient's medical condition. and is signed by a doctor
9	Private Duty Nursing Services	Skilled nursing services for recipients who require more individual and continuous care than is available under the home health program, and which are provided by a registered nurse or a licensed practical nurse, in a recipient's own home or another setting when normal life activities take the recipient outside his or her home.
10	Progress note	A signed and dated written notation by the home care nurse which: 1) Summarizes facts about the care given and the participant's responses during a given period of time; 2) Specifically addresses the established goals of treatment; 3) Is

		consistent with the participant's plan of care; and 4) Is written during the course of care.
11	Quality of care	The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
12	Registered nurse	An individual who is licensed by the Board to practice registered nursing; or has a multistate licensure privilege to practice registered nursing.
13	Residential service agency	An individual, partnership, firm, association, corporation, or other entity of any kind that is engaged in a nongovernmental business of employing or contracting with individuals to provide at least one home health care service for compensation to an unrelated sick or disabled individual in the residence of that individual; or An agency that employs or contracts with individuals directly for hire as home health care providers. The agency must be licensed by the Department in accordance with COMAR 10.07.05
14	Staff Nurse	A person who is licensed to practice as a registered nurse (RN) or licensed practical nurse (LPN) in the jurisdiction in which services are provided
15	Supervisory Nurse	A licensed registered nurse who provides authoritative, procedural guidance for the accomplishment of a function or activity, as well as the process of critical watching, directing, and evaluating another's performance

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