



Attachment U

Pharmacy Clinical Management Services

Mandatory Scored Response Worksheet

Suppliers must provide responses to all questions in the **Supplier Response section** in this document and submit them as a **single** PDF attachment **bookmarked** in sequential order with the title(s) provided in the question.

Each narrative response must adhere to any assigned page limits and be in Arial, size twelve (12) font. The narrative page count will begin after the page containing the question, i.e., the page with the question and response on the remainder of that page will count as page #0.

The narrative response, along with any required supporting material, will be evaluated and awarded points in accordance with Attachment A – Lead State eRFP, Section 6 Proposal Evaluation and Award. Documents not requested will not be evaluated.

Failure to provide responses and any required supporting documentation for all questions may result in disqualification of the proposal.



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1. **Bookmark Title: MSQ1 – Executive Summary**

The Executive Summary is limited to five (5) pages.

Provide an Executive Summary that illustrates the Supplier's understanding of and capability to provide the requested services as described in Attachment G - Pharmacy Clinical Management Services Scope of Work and Attachment C - Common Scope Requirements and Security Standards.

The Executive Summary must include a brief corporate background of the Supplier, including the date the Supplier was formed, established, or created, total number of employees, Equal Employment Opportunity policy and current percentages in key positions, and location of the Supplier's primary and any satellite offices.

NorthStar HealthCare Consulting (NHC) is pleased to provide our proposal for services in response to the State of Georgia in Conjunction with NASPO ValuePoint's *Request for Proposals (RFP) 41900-DCH0000136 – Pharmacy Benefit Services: Pharmacy Clinical Management Services (PCMS)* via the National Association of State Purchasing Officer's Organization (NASPO) in achieving its goals for improving pharmacy program claim integrity and fiscal stewardship through the provision of clinical pharmacy services. We have partnered with Medicaid Fee-For-Service (FFS) programs throughout the country – programs with similar objectives committed to complying with federal requirements for Drug Utilization Review (DUR) and management, and to combat fraud, waste, and abuse and ensuring responsible fiscal oversight of the Medicaid drug benefit.

Our Understanding of the SOW and Capability to Provide Services

Through this procurement, the Georgia Department of Community Health (DCH) is seeking a vendor to provide clinical management services in support of the Medicaid pharmacy program. As the PCMS incumbent, NHC has enjoyed a collaborative relationship with the Department for 18 years and is intimately familiar with the scope of work. Included in this engagement is the ongoing support of the State Advisory Board (SAB) through the provision of clinical information including drug monographs to further the maintenance of the State's Preferred Drug List (PDL) and the Provider Administered Drug List (PADL). NHC also provides drug information regarding new medications as well as clinical and other updates regarding existing products and participates in regular clinical meetings. In its role of supporting the State with the maintenance of the PDL, NHC assists the State to meet its goals of utilizing cost-effective products, including the use of generic products. Finally, we also perform retrospective review activities to monitor trends impacting patient safety and program cost and advises the State regarding appropriate Utilization Management (UM) criteria and edits to ensure the clinical and fiscal integrity of the pharmacy program.



NHC recognizes that through this eRFP, other participating states have an opportunity to utilize submitted proposals in support of similar programs within their state Medicaid organizations. While we have crafted our proposal with an in-depth understanding of DCH's needs, NHC has the experience that ensures scalability to other Medicaid programs.

Overview

At NHC, we recognize that increased complexity of drug regimens combined with increasing healthcare regulations and complex government requirements leave many states struggling to oversee and manage their pharmacy benefits. Stewardship of public funds grows ever more important in this era of mandated oversight and necessitates that states ensure scarce public funds are used appropriately and in a manner that reduces waste and misuse attributed to clinical factors and redirects those limited resources back to patient care. **It is estimated that the cost of waste, which includes overtreatment or low-value care, accounts for 25% of healthcare costs.**¹

Pharmacy expenditures continue to grow and consume a significant portion of the healthcare dollar. The Congressional Budget Office estimated that from 2009 to 2018 the average net price of brand-name prescription drugs increased substantially from \$147 to \$218 in Medicaid.² The Kaiser Family Foundation reports overall healthcare expenditures are expected to grow at an annual rate of 4.8% between 2022 and 2031.³ These numbers are not inclusive of the recent influx of gene therapy products whose impact is not yet accounted for. Change is inevitable and managing that change properly is crucial. NHC brings best in class integrated clinical pharmacy management and cost containment strategies to our healthcare partners to support flexible and sustainable programs and initiatives. NHC programs not only help states oversee and monitor their prescription drug spend, but they also assist them in meeting CMS requirements and federal regulations for drug utilization review and monitoring.

The Gold Standard of Drug Utilization Review

Retrospective DUR (RetroDUR) programs involve a comprehensive review of prescription claims data after dispensing to ensure clinically and fiscally appropriate prescription decision-making, and safe and positive patient outcomes. State Medicaid agencies are responsible for managing drug utilization trends among their provider and patient membership. RetroDUR programs are integral to help states understand, interpret, and improve medication prescribing, dispensing, and use.

As the incumbent vendor, NorthStar Healthcare Consulting has been DCH's clinical partner in pharmacy for 18 years.



NHC's RetroDUR solution promotes optimal drug therapy that not only meets current standards of care and moves toward achieving the five patient rights of drug therapy (*right drug* to the *right patient* in the *right dose* by the *right route* at the *right time*), but also aligns with the Plan's evolving PDL, coverage guidelines, and unique policies and mandates.

Topics addressed in recent RetroDUR interventions include non-adherence to HIV pre-exposure prophylaxis (PrEP) regimens, duplicate therapy in diabetic patients with DPP-4 and GLP-1 agonists, sub-clinical statin therapy in patients over 40 years of age with diabetes, and naloxone prescribing in patients receiving high opioid doses associated with elevated risk of overdose.

CompassDUR SM: Directions for Change

Through NHC's *CompassDUR* program, providers receive feedback on their prescribing behaviors as compared to plan-specific criteria, accepted standards of practice or treatment guidelines established by professional medical societies and associations (e.g., the American College of Cardiology), as well as national and global health institutes (e.g., the Centers for Disease Control and Prevention or the World Health Organization). State plans to implement policy or coverage changes can be supported and reinforced through RetroDUR.

The NHC Approach: Leveraging the Power of Systems and Experience

Traditional RetroDUR services have commonly relied upon claims extracts and painstaking manual review processes, which limits the scope and depth of reviews. NHC uses a technology-driven data analytics approach which allows for faster claims processing, more variables, and an enhanced ability to ask tough questions of the data when designing review criteria. NHC's systems employ a parameter-driven technical engine on a robust data platform. Our advanced technology combined with a team of talented professionals enables us to develop and deploy unique and innovative RetroDUR queries and interventions.

In addition to our extensive RetroDUR offerings, NHC offers the following services:

- *CompassClinical*SM is a fully integrated suite of programs designed to augment and supplement State activities, including therapeutic class review, new drug evaluations, prior authorization development or protocol review, and assessment of clinical pharmacy guidelines.
- *CompassRx*SM is a complete suite of audit programs that can be tailored to meet the State's needs and fiscal requirements while offering a comprehensive and compliant pharmacy audit program.

Utilization Management

Utilization Management (UM) is a critical component of any Medicaid program. It requires both clinical knowledge and extensive experience to craft a bespoke solution to inappropriate prescribing and excessive medication use within a State's unique provider and patient population. NHC's current suite of UM offerings includes Prior Authorization (PA) criteria, Step Edits, Quantity Level Limits (QLL), and Preferred Drug List (PDL) maintenance - all of which are designed to promote appropriate clinical usage, contain costs, and avoid waste and diversion. This is our Stepwise Approach to UM, as depicted in Figure MSQ1.

Our approach is anchored by our clinical experience including post-doctoral training as well as decades long efforts in the Medicaid space assisting multiple programs with the creation of customized approaches to address state specific populations, program goals, and challenges. One such example of this customized approach is a recent

policy change requiring claims for antihemophilic factor products to be separated into two separate prescriptions, one for breakthrough bleeding and one for ongoing prophylaxis to prevent bleeding episodes. Requiring this change provided clearer visibility into the amount of antihemophilic factor product needed to control bleeding episodes and enhanced utilization management controls for prophylaxis dosing.

Where applicable, NHC may create customized forms to ensure all required information is compiled prior to review and facilitate expedited clinical reviews. Select examples of UM programs leveraging such forms include atypical antipsychotics in pediatric patients, hepatitis C virus NS5A inhibitor retreatment, and Synagis.

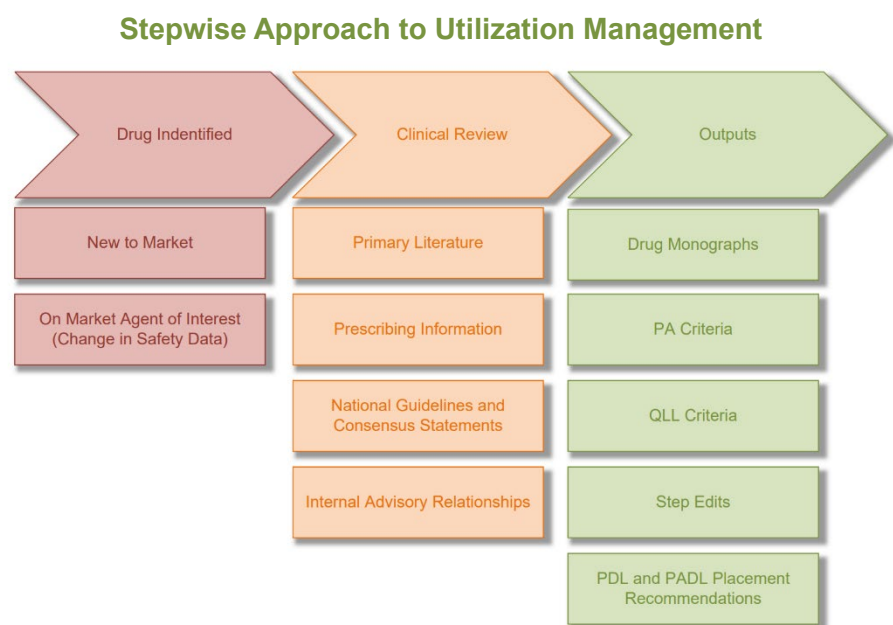


Figure MSQ1: NHC offers a suite of service offerings that support appropriate usage, cost containment, and waste avoidance/diversion.



State Advisory Board Experience

NHC has been the incumbent clinical vendor for the State of Georgia having served its Advisory Board since 2006. NHC provides crucial clinical leaders to support the State's program who have assisted over 15 State Medicaid programs in various capacities. Our clinical leaders – Dr. Emily Baker and Dr. Chad Nicholson – have almost 30 years of Georgia Medicaid specific combined experience.

Emily Baker, PharmD, BCPS is the President and CEO of NHC and is no stranger to Medicaid programs. Dr. Baker has accumulated over 25 years' experience as a clinical pharmacist of which 18 of those years are specific to the state of Georgia.

Chad Nicholson, PharmD is a Clinical Pharmacist as well as NHC's Director of Clinical Programs assigned to the Georgia Medicaid program and has been interfacing with the State's team for nine years.

Drs. Baker and Nicholson both attended the University of Georgia College of Pharmacy and are supported by additional clinical pharmacists who also have extensive Medicaid and State Advisory Board experience including Mary-Beth Plum, PharmD who brings over five years of RetroDUR experience to the State and Catherine "Amy" Baker, PharmD who has been with NHC for 12 years – supporting the Clinical Pharmacy Services department.

Common Scope Requirements

NHC utilizes a comprehensive approach to project organization and management, understanding that such an approach is imperative to the success of a project of this magnitude. Beginning in the Design, Development, and Implementation (DDI) stage, NHC will leverage its Communications Plan to facilitate a kick-off meeting in which project schedule, risks, quality, and change management will be discussed. Additionally, project costs will be actively managed in this stage and all others. While continuing to focus on these areas into the Operations and Maintenance stage of the project, we will incorporate our Requirements Management Plan to ensure all applicable deliverables are reliably met. NHC will also offer relevant training to State employees and other stakeholders as needed. Throughout the life of the project, NHC will work with the State's Independent Verification and Validation (IV&V) vendor, responding to their requests for project information and providing necessary deliverables.

About NorthStar HealthCare Consulting

NHC has the experience, insight, and innovation to customize pharmacy spend management solutions to meet the unique needs of government sponsored pharmacy programs. Since 2003, NHC has been providing its clients with clinically appropriate, customized cost initiatives that have produced improved quality, transparency, and cost



outcomes. Since its inception and today, NHC is proud to be a Georgia-domiciled, woman-owned small business.

NHC is independently owned and has no commercial holdings or contractual relationships with any chain or independent pharmacies, which can cause an actual or perceived conflict of interest. To mitigate any appearance of conflict, NHC operates in a fee-for-service environment whenever possible. With our corporate headquarters located in Alpharetta, Georgia, more than 75% of NHC's revenue is retained within the state of Georgia through its locally based employees. Indeed, eight of NHC's nine employees are located within 60 miles of the State's offices.

Collectively, our staff of clinicians possess more than 100 years of Medicaid, managed care, retail pharmacy, and fraud and abuse experience, and almost 40 years of collective experience working with Georgia Medicaid. All staff clinicians possess two primary credentials — Doctor of Pharmacy degrees and experience in Medicaid and formulary management. As true experts in the markets served, our understanding of the clinical environment enables us to think creatively to develop the most practical, cost-effective solutions to the challenges of rising pharmacy costs. Currently, 67% of our clinical staff are in key positions under this scope of work, although **100% of the clinical management team is performing work for DCH often in collaborative cross functional capacities.**

NHC's Equal Employment Opportunity Commission (EEOC) Policy

It is the established policy of NorthStar Healthcare Consulting (the "Company"), to provide equal employment opportunities to all qualified persons and to administer all aspects and conditions of employment without regard to race, religion, color, sex, gender, gender-based wage discrimination, sexual orientation, pregnancy, age, national origin, ancestry, physical or mental disability, severe/morbid obesity, medical condition, military or veteran status, genetic information, marital status, ethnicity, alienage or any other protected classification, in accordance with applicable federal, state, and local laws. The Company takes allegations of discrimination, intimidation, harassment, and retaliation very seriously and will promptly investigate when warranted. Equal employment opportunity includes, but is not limited to, employment, training, promotion, demotion, transfer, leaves of absence and termination.



2.	Bookmark Title: MSQ2 – State Advisory Board Bookmark Title for Supporting Material: <u>MSQ2.1 – Sample HIV Clinical Drug Monographs</u> Narrative description is limited to five (5) pages, not including the required supporting material. Describe your experience, ability, and method (both administrative and clinical) for providing support to the State Advisory Board as described in Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.2 State Advisory Board.
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Experience

NorthStar HealthCare Consulting (NHC) has been the incumbent vendor for the State of Georgia's Advisory Board since 2006 and our clinical team has almost 40 years of combined clinical experience serving the State of Georgia alone. NHC provides key clinical leaders to support the State's program. Emily Baker, PharmD, BCPS is the President and CEO of NHC and is no stranger to Medicaid, having worked with more than 15 state Medicaid programs over the last 25 years. Dr. Baker received her Doctor of Pharmacy from the University of Georgia and completed a Drug Information Specialty Residency at Samford University. She has been active in providing clinical services in support of the State's programs for the past 18 years.

Chad Nicholson, PharmD is a Clinical Pharmacist as well as NHC's Director of Clinical Programs for the Georgia Medicaid program and has been interfacing with the State's team for nine years. Drs. Baker and Nicholson are supported by additional clinical pharmacists who also have extensive Medicaid and State Advisory Board experience. Catherine "Amy" Baker, PharmD, has been with NHC for 12 years and supports its Clinical Pharmacy Services department, ensuring that prior authorization decisions are consistent with covered benefits, quality of care, and medical necessity. Mary-Beth Plum, PharmD, is the newest member of NHC's Clinical Pharmacy Services department, joining the team in 2024. Dr. Plum has several years of experience working with pharmacy benefit administrators and providing clinical pharmacy services, including to state Medicaid programs.

Capabilities

The function of the State Advisory Board (SAB) is to promote patient safety by reviewing outpatient drug prescribing and dispensing behaviors in service to the Medicaid patient population. Functions of the SAB can include Drug Utilization Review (DUR) – prospective, retrospective, and concurrent – as well as educational



interventions in both the Managed Medicaid and Fee-for-Service (FFS) arenas. Additional responsibilities may include oversight in an advisory or binding capacity of the Preferred Drug List and Supplemental Rebate Programs, and by extension, Utilization Management (UM) Programs including Prior Authorization (PA), Quantity Level Limits (QLLs), and Step Edits (SE). SABs are typically comprised of pharmacists, medical providers, and medical specialists who practice within the state and serve the Medicaid population. Other members may include academicians, consumer advocates, and representatives of the Medicaid program. Indeed, the SAB is critical in providing decision-making transparency and eliciting buy-in from key members of the community, including patients, prescribers, advocacy groups, legislators, and other stakeholders.

NHC is tasked with supporting the State and its Advisory Board in their mission to promote patient safety and to ensure fiscally prudent clinical decision making. Support can vary in both form and function, ultimately depending on the specific issue before the Board. Nevertheless, NHC's support of the SAB remains constant. We leverage experienced clinicians with advanced training, including residencies whenever possible. This experience is critical to our approach to drug literature review and evaluation, which leads to clinically defensible recommendations that incorporate fiscal prudence. We review medications in totality, meaning not only do we review them as individual agents within their therapeutic classes, but also their place in therapy across the clinical armamentarium of their respective disease states, paying close attention to clinical and safety data. Once this review is completed, our efforts are focused on developing customized recommendations to the State, being ever cognizant of the fact that every state and its Medicaid program is unique. Once final decisions are made, the NHC team demonstrates its wealth of experience and consistency by providing detailed clinical literature reviews and program analytics that support the efforts of the SAB.

Methods

Clinical Literature Review and Evaluation

NHC's approach to clinical literature evaluation and analysis is comprehensive, consistent with, and guided by our team's advanced education and training in drug utilization review. Prior to market approval, we track medications of particular interest to Medicaid programs via Horizon Watch, our pipeline report. While line extensions and new products within a mature drug class might be tangentially tracked, our primary focus is on first-to-market drugs, or new additions to drug classes that desperately need a competitor. In either case, NHC recognizes that utilization management of all managed therapeutic classes should be subject to annual reevaluation as part of a quality assurance initiative.

New chemical entities that are approved by the Food and Drug Administration (FDA) and are subject to coverage under the Medicaid program are tracked by approval date and date of market entry. Once a product has been identified, we begin our medication review process to develop a drug monograph or in some cases a Therapeutic Class



Review (TCR). Our approach is based on post-doctoral training and is consistent with the guidance set forth by the American Society of Health-System Pharmacists (ASHP) and the Academy of Managed Care Pharmacy (AMCP). The overarching goal of this evaluation is to provide a comprehensive picture of the new product's place in therapy, within the current treatment paradigm, paying close attention to efficacy and safety data. As such, drug monographs are structured, evidence-based documents that are free from marketing influence or bias. They provide a thorough, accurate, and unbiased review developed from a critical analysis of the available primary literature — starting with randomized controlled clinical trials (RCTs) and progressing to nationally recognized clinical guidelines and expert consensus compendia. Any available meta-analyses and manufacturer dossiers may also be reviewed.

Monograph Development

NHC's drug monographs follow a formulaic approach. We start by listing a summary of drug-specific indicators including brand and generic name, manufacturer name, FDA-approved indications as well as off-label indications supported by the compendia or primary literature, pharmacokinetic data, available formulations, routes of administration, and dosing. A disease state review is then presented, followed by a summary of the relevant data from the drug's pivotal clinical trial, including the number of enrollees, inclusion and exclusion criteria, a description of the intervention and its comparators, and the results of the primary and secondary endpoints along with their associated statistical and clinical significance. Finally, any notable product differentiators, safety data, and the drug's place in therapy is reviewed, culminating in a summary paragraph that presents our recommendations for PDL placement and UM criteria where applicable, based on the reviewed clinical and safety data. For products that undergo an abbreviated review, such as new-to-market agents that are similar to other available agents or line extensions, an Executive Summary may be provided. Alternatively, a therapeutic class review may be provided if the entire drug class or disease state would benefit from a broader review. Please refer to **MSQ2.1** for samples of our HIV Clinical Drug Monographs.

Recommendations for Utilization Management Programs

NHC makes recommendations for UM criteria (PAs, QLLs, and SEs) after the development of the drug monograph is complete. At the discretion of the State, this information can be provided to the SAB for consideration when a medication is reviewed for PDL placement. PA criteria are developed based on numerous factors and in consideration of study inclusion criteria, disease states, alternative agents, and the product's place in therapy based on available guidelines. Additionally, the net cost to the State after available rebates is considered, particularly with respect to any SEs or automated "fail first" edits. Lastly, QLLs are often considered when there are strict upper limits to product dosing, when the product has abuse or diversion potential, or when tiered pricing is at play.



Manufacturer's Forum

Prior to each SAB meeting, NHC's clinical team coordinates, schedules, and attends a Manufacturer's Forum for companies with drug products being reviewed at the upcoming meeting. The forum provides a venue for drug manufacturers to present their drug's clinical data and ensures that the most up-to-date clinical literature is incorporated and made available for Board review. During the forum, manufacturers are given the opportunity to submit a one-page product summary to be included in the presentation materials provided to the Board.

Drug Utilization Review

Drug Utilization Review (DUR) is an effective and targeted approach to ensure medication safety in patient populations. DUR focuses on ensuring that medication use is consistent with predetermined, product-specific criteria. Deviations from the specified criteria are flagged for educational intervention. This review provides a comprehensive assessment of a patient's prescription and medical data prior (e.g., prospectively or ProDUR), during (e.g., concurrently or CDUR) or after (retrospectively or RetroDUR) dispensation to ensure patient-specific medication goals are achieved, and preventable or controllable adverse outcomes are avoided. As the focus is educational, DUR programs provide actionable information to prescribers for further review and response to the Medicaid program.

In sum, a comprehensive DUR program includes interventions at three points in time:

- **Prospectively** – the evaluation of a patient's drug therapy occurs before the medication is dispensed
- **Concurrently** – the evaluation of a patient's drug therapy occurs at initiation or during treatment
- **Retrospectively** – the evaluation of a patient's drug therapy occurs after the patient has initiated therapy

Prospective DUR

Prospective DUR or ProDUR occurs prior to dispensation and gives the pharmacist an opportunity to prevent any adverse outcomes before therapy is initiated. ProDUR information is communicated to pharmacists in the form of edits, either soft or hard, when part of a real time point-of-sale claims adjudication system. These edits prompt a review of patient information for conflicts in dosing, drug interactions, and drug plus disease state contraindications. Common ProDUR edits include the following:

- Drug – Disease state contraindications
- Drug – Drug interactions often associated with increasing levels of severity



- Drug – Patient alerts that may post based on age, gender, pregnancy status, allergies, etc.
- PDL edits that require therapeutic interchange, brand over generic, or generic substitutions
- Drug abuse or misuse including exceeding Morphine Milligram Equivalents (MME) or duplicative therapy

Concurrent DUR

Concurrent DUR or CDUR occurs at initiation or during medication therapy and seeks to optimize patient outcomes and prevent adverse effects. Pharmacists can provide prescribers with valuable information to enhance dose optimization and avoid drug–drug interactions or duplicative therapy. Ideally, CDUR should occur when a prescriber transmits an electronic prescription. However, pharmacists may also serve in this role as an additional check in the system, particularly if they have access to all medication records and up-to-date allergy information. Common CDUR interventions include:

- Dose optimization
- Therapeutic interchange
- Over/under utilization

Retrospective DUR

Retrospective DUR or RetroDUR occurs after medication dispensation or completion of therapy. The primary goal is to detect and intervene upon prescribing or dispensing patterns that may run counter to patient safety. Based on predetermined criteria of acceptable medication use, educational interventions are developed to provide actionable information to prescribers to improve patient care whether at the individual level or across patient populations. Common intervention types include:

- Abuse or misuse
- Inappropriate duration of treatment
- Overutilization or underutilization (including lack of therapy when indicated)

State Advisory Board Presentation Materials

To facilitate review with the State Advisory Board, NHC clinical staff compiles a binder of presentation materials that is provided to Board members two weeks prior to each meeting via an encrypted electronic format. The contents of the binder will vary from meeting to meeting and may include:

- The meeting agenda;



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- Minutes from the previous meeting for Board approval;
 - New product monographs (or TCRs) for review;
 - One-page summary of each product solicited from the drug manufacturer;
 - Any additional documents submitted by the State, prescribers, patient advocates, and/or other stakeholders pursuant to the drugs under review and allowed for by policy;
 - UM criteria recommendations consisting of new or updated clinical utilization criteria, QLLs, SEs, and formulary status changes (preferred vs. non-preferred);
 - DUR intervention proposals;
 - Pipeline reports in the form of Horizon Watch; and
 - Clinical Newsletters for providers based on current topics.

To foster an engaging discussion among Board members during drug reviews, NHC clinical staff develops and delivers a visual presentation summarizing the new drug monographs for review, including background information, clinical efficacy, place in therapy, and recommendations for UM criteria.

Administrative Services to State Advisory Board

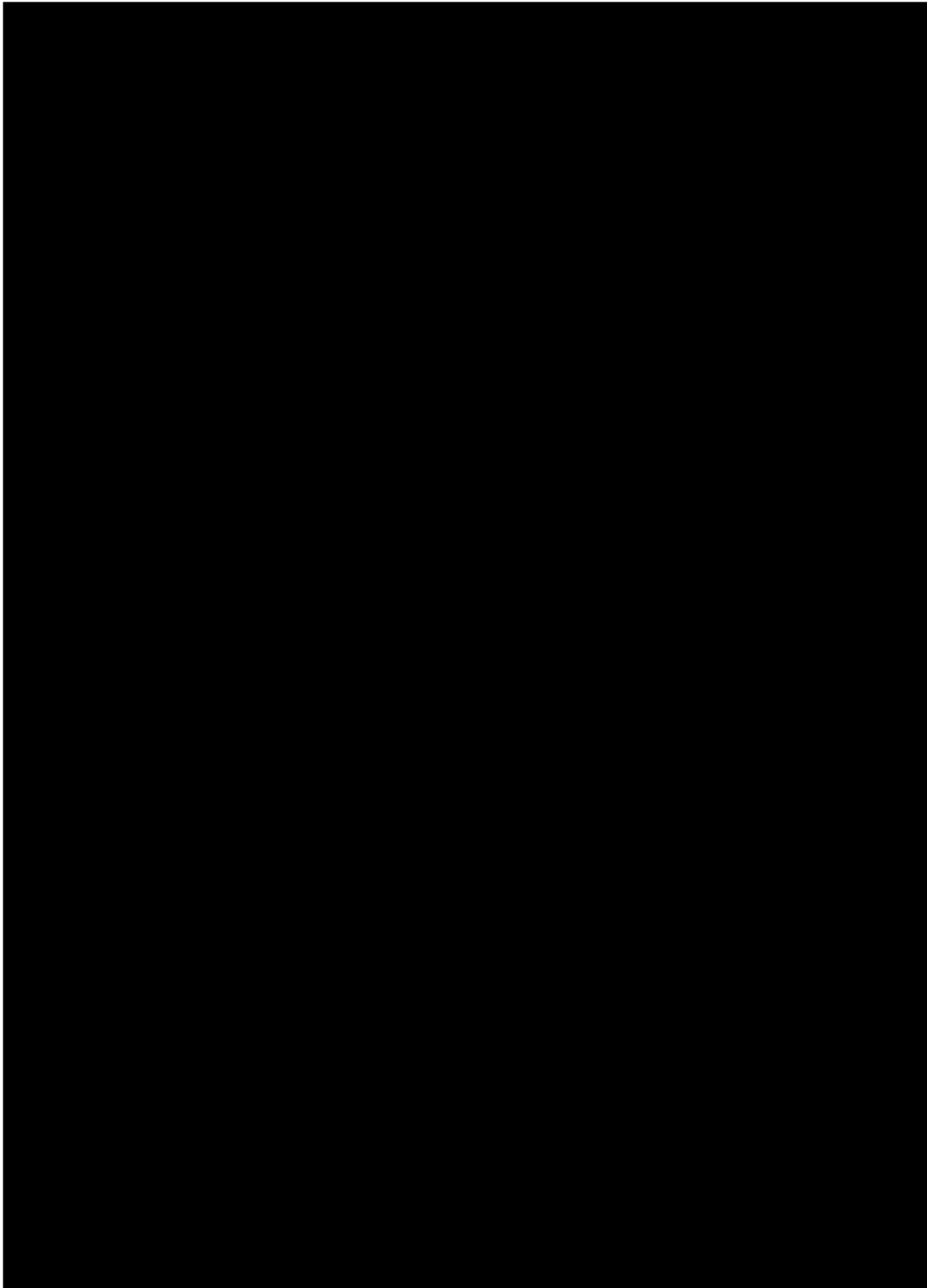
In addition to providing clinical review materials, NHC supports the administration of the SAB in several other ways. The proposed meeting agenda is sent to the State for approval and posted on the State's website prior to the corresponding Board meeting. NHC drafts and submits a document listing the new drugs under review for posting on the State Advisory Board website. After the drugs under review and agenda documents have been posted, NHC serves as an intermediary between key stakeholders, the State, and the SAB via a dedicated email address monitored for all inquiries related to the Board meeting agenda. Our staff correspond directly with Board members regarding meeting dates, materials, and member attendance, and collect any relevant conflicts of interest disclosures from Board members to be forwarded to the State.

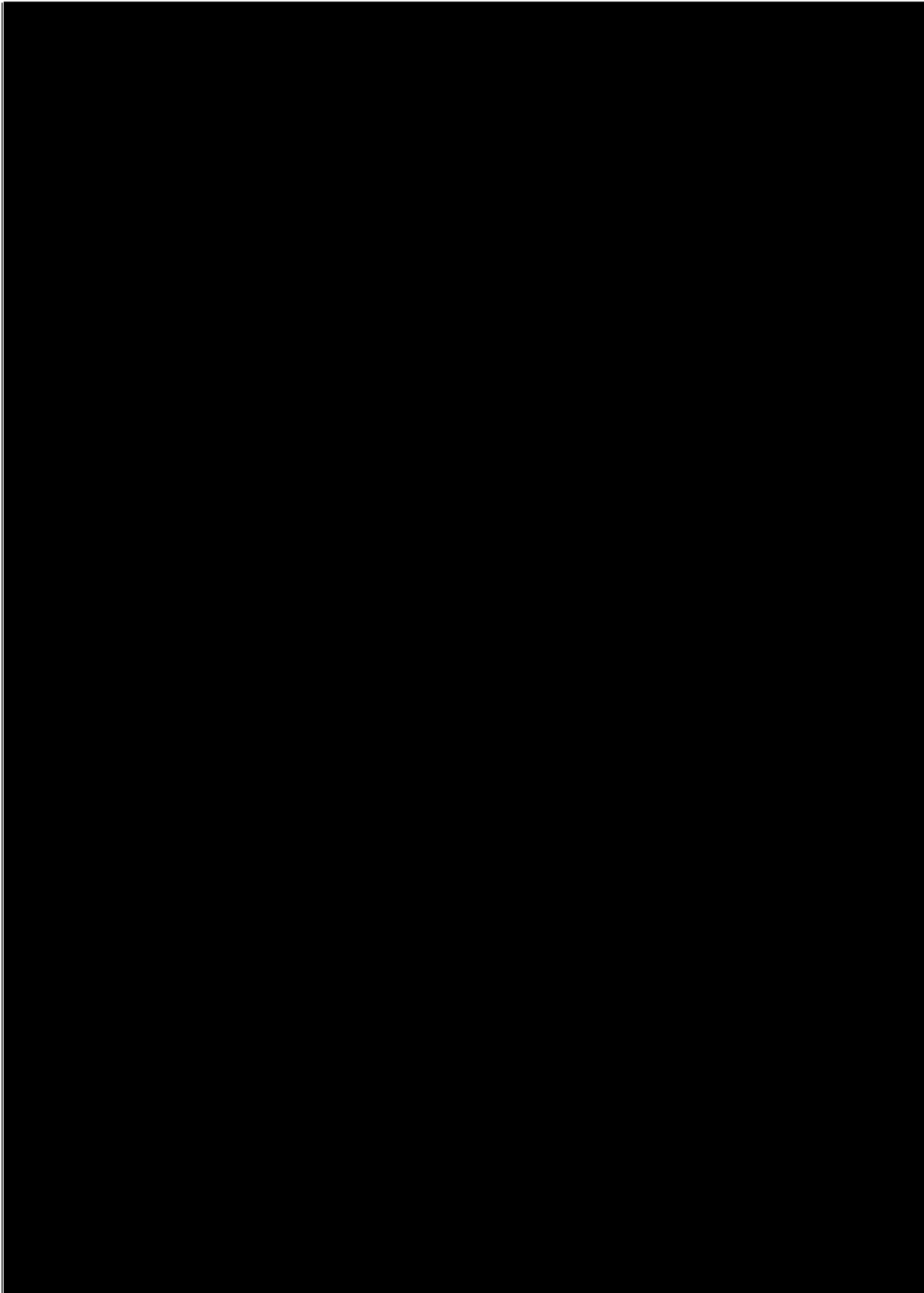
During the Board meeting, NHC prepares and distributes meeting handouts to Board members and public attendees and collects conflict of interest disclosure forms from any attendees wishing to speak during the designated time for consumer comment. The meeting minutes are submitted to the State for approval and posted to the State website in accordance with the State's preferred timelines.

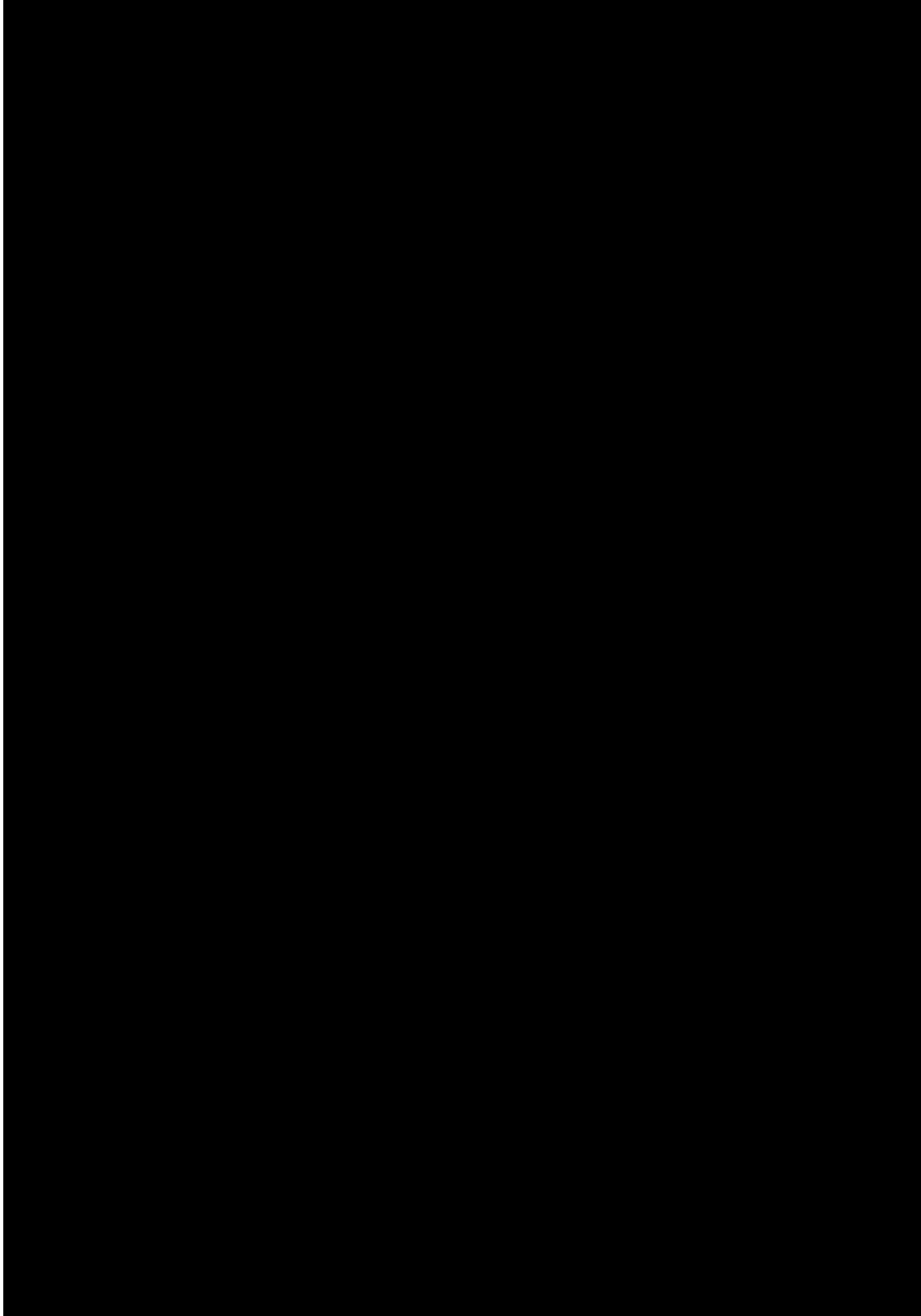
Lastly, NHC can act on behalf of the State to recruit nominees for appointment to the Board pending approval from the State. A nominee may be considered when the State receives written or verbal communication containing the curriculum vitae or resume of a qualified candidate from individuals, representatives of various professional organizations, or academic institutions.

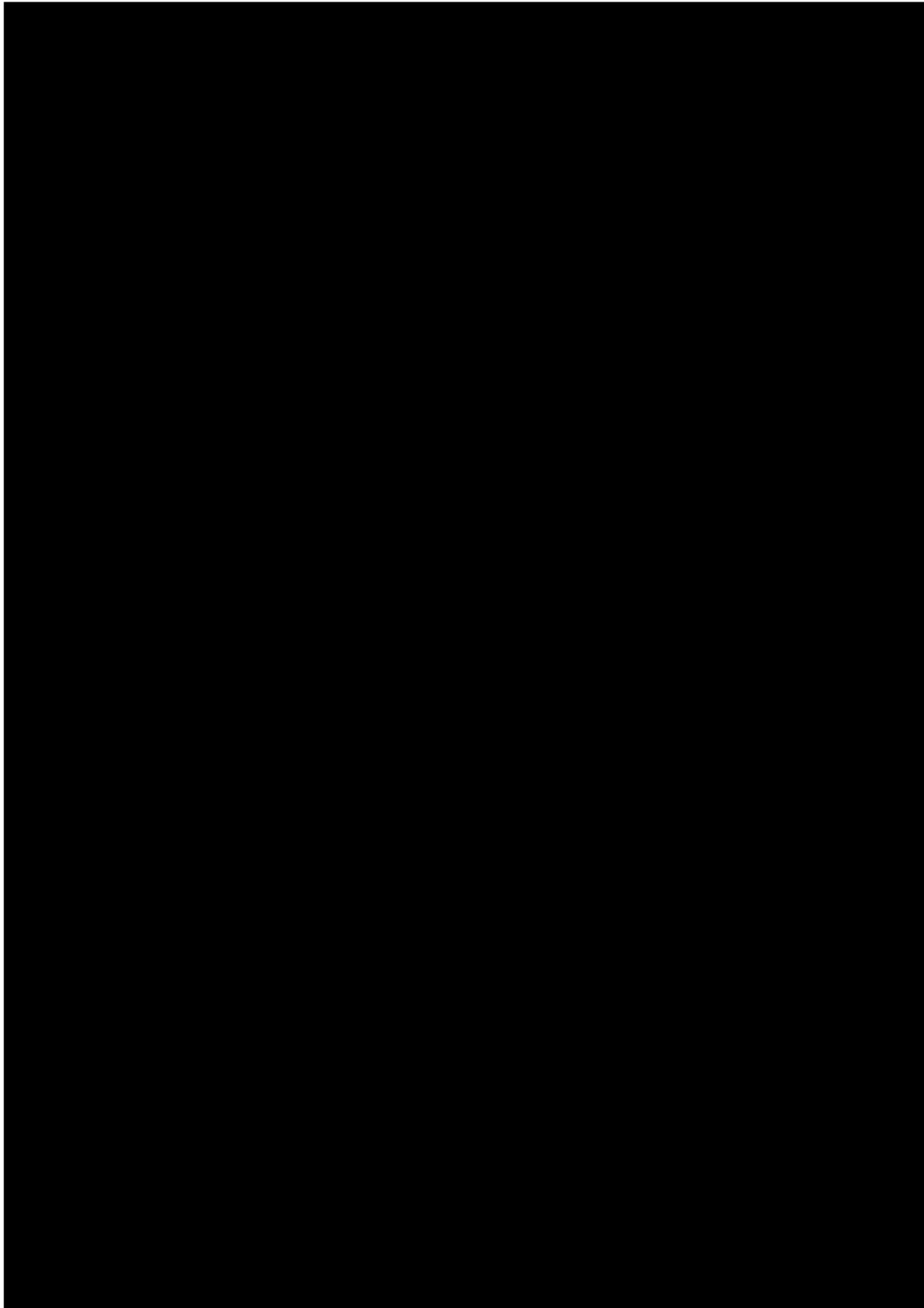


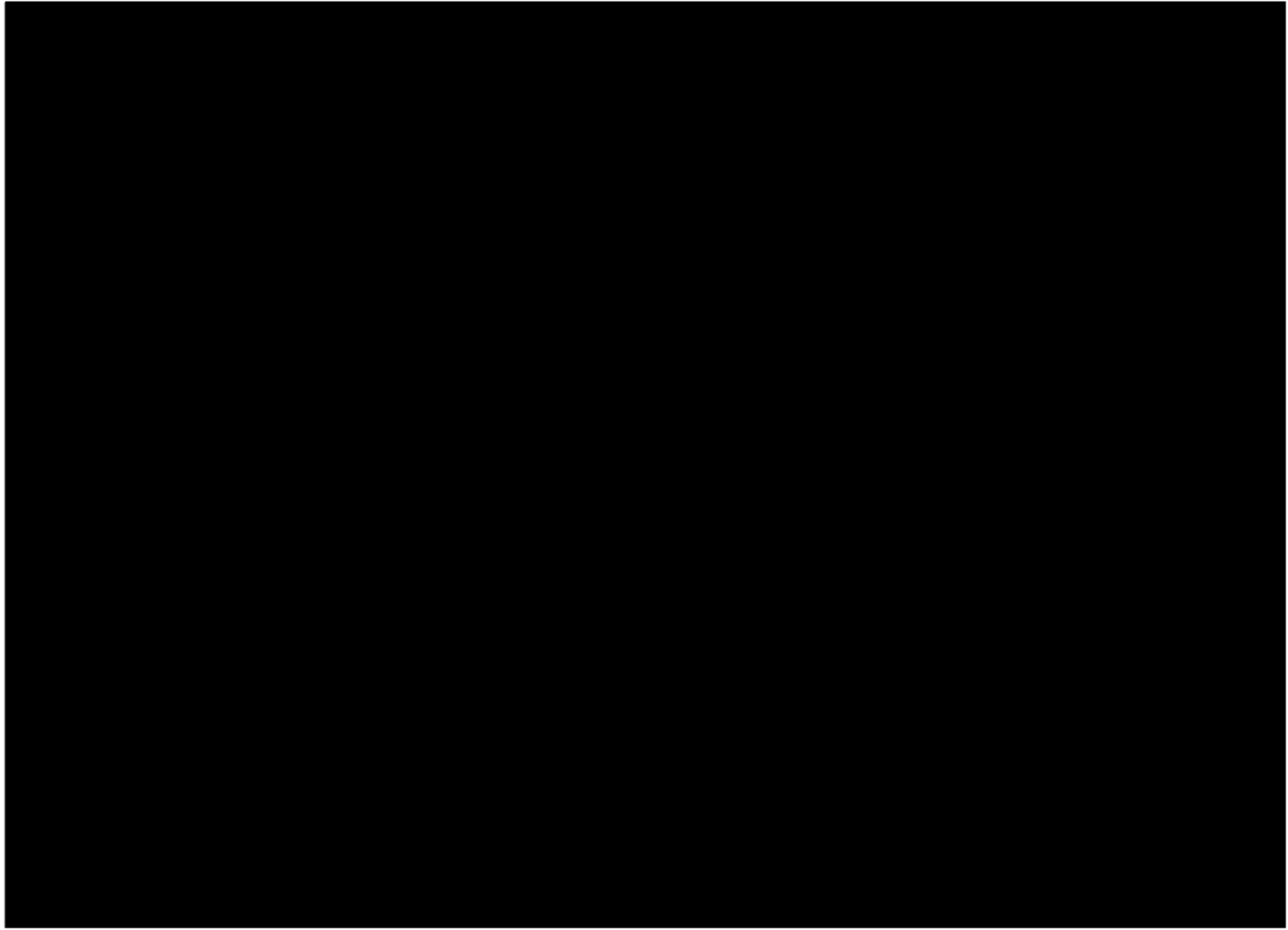
MSQ2.1 – Sample HIV Clinical Drug Monographs

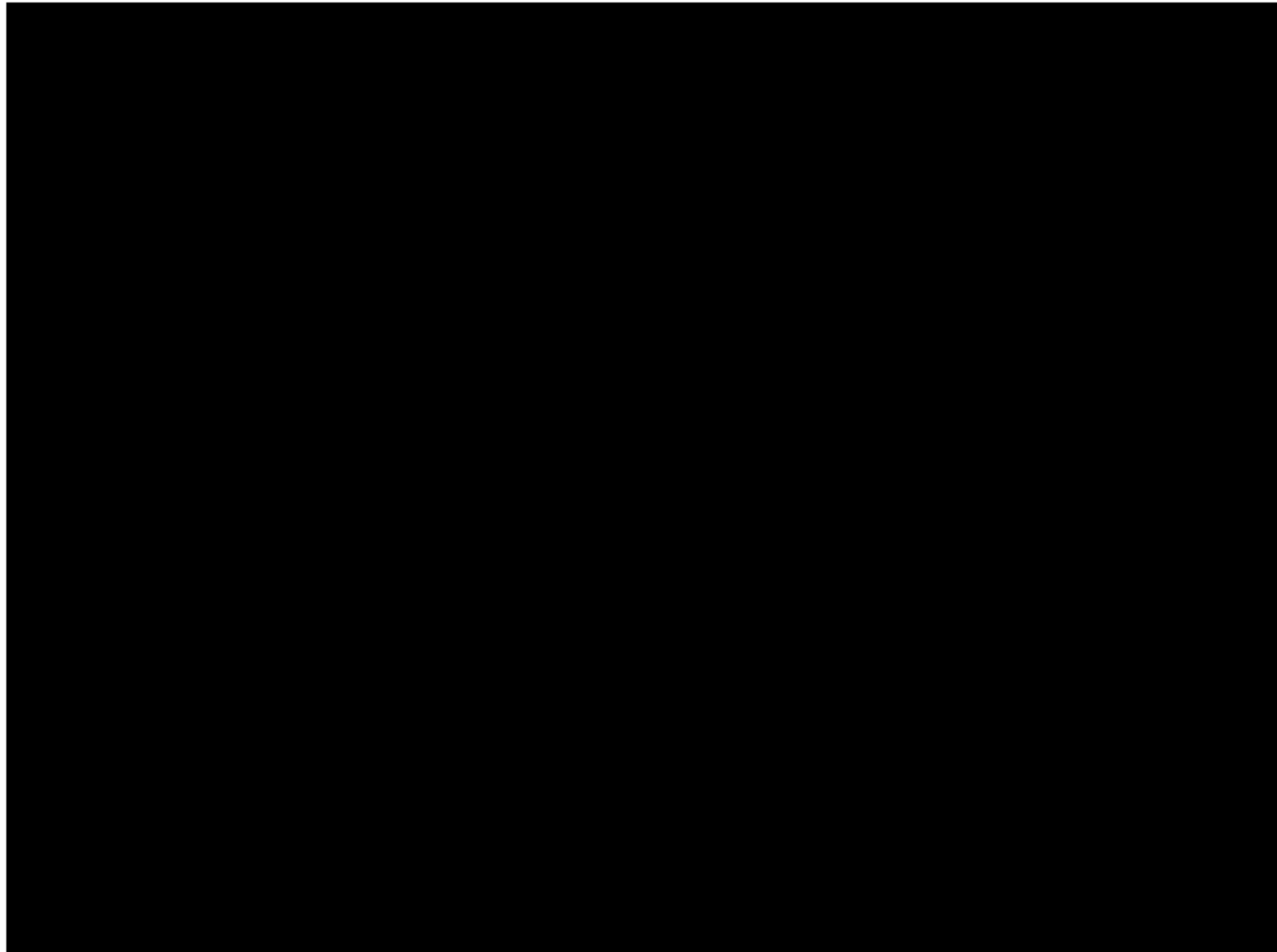


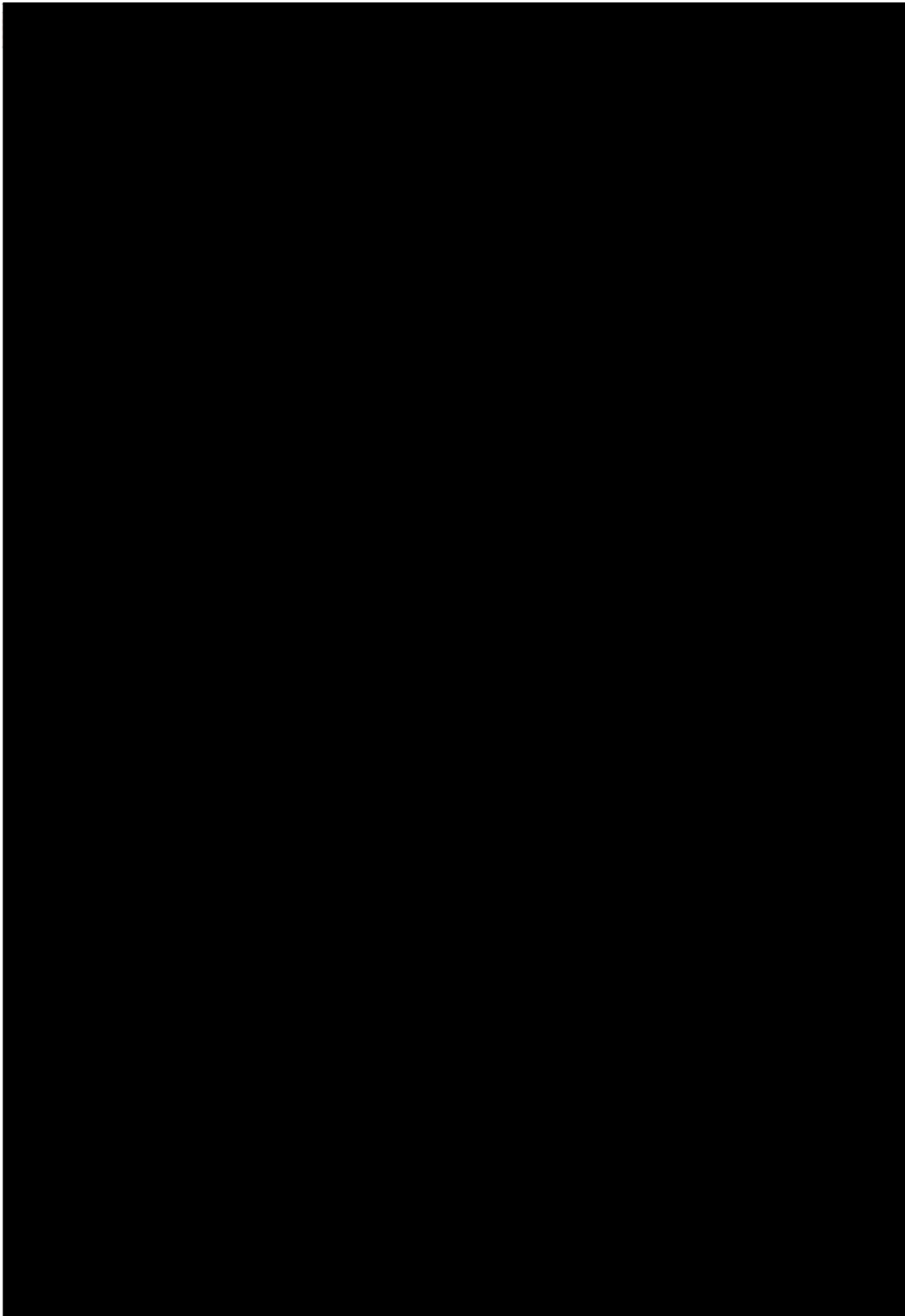


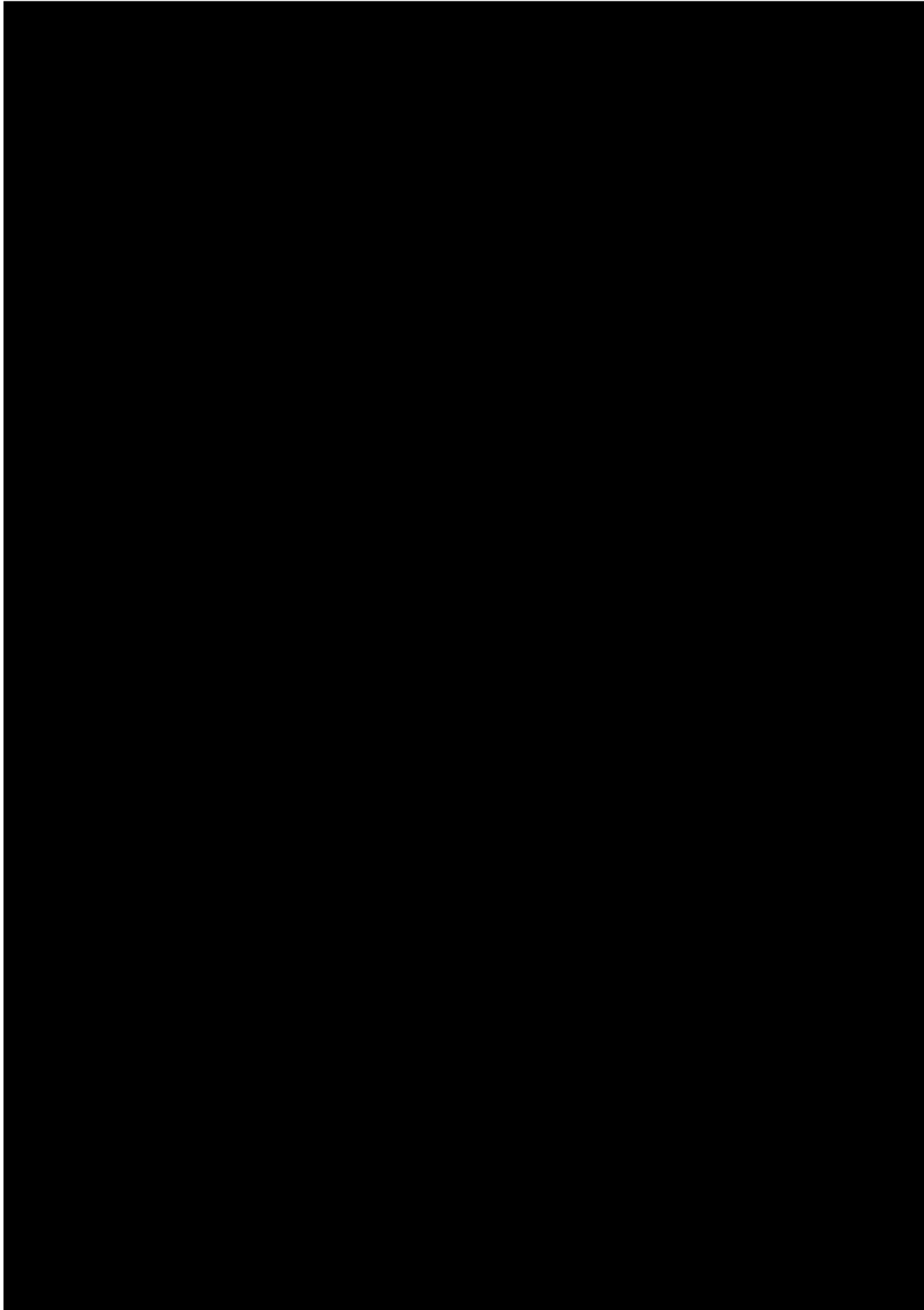


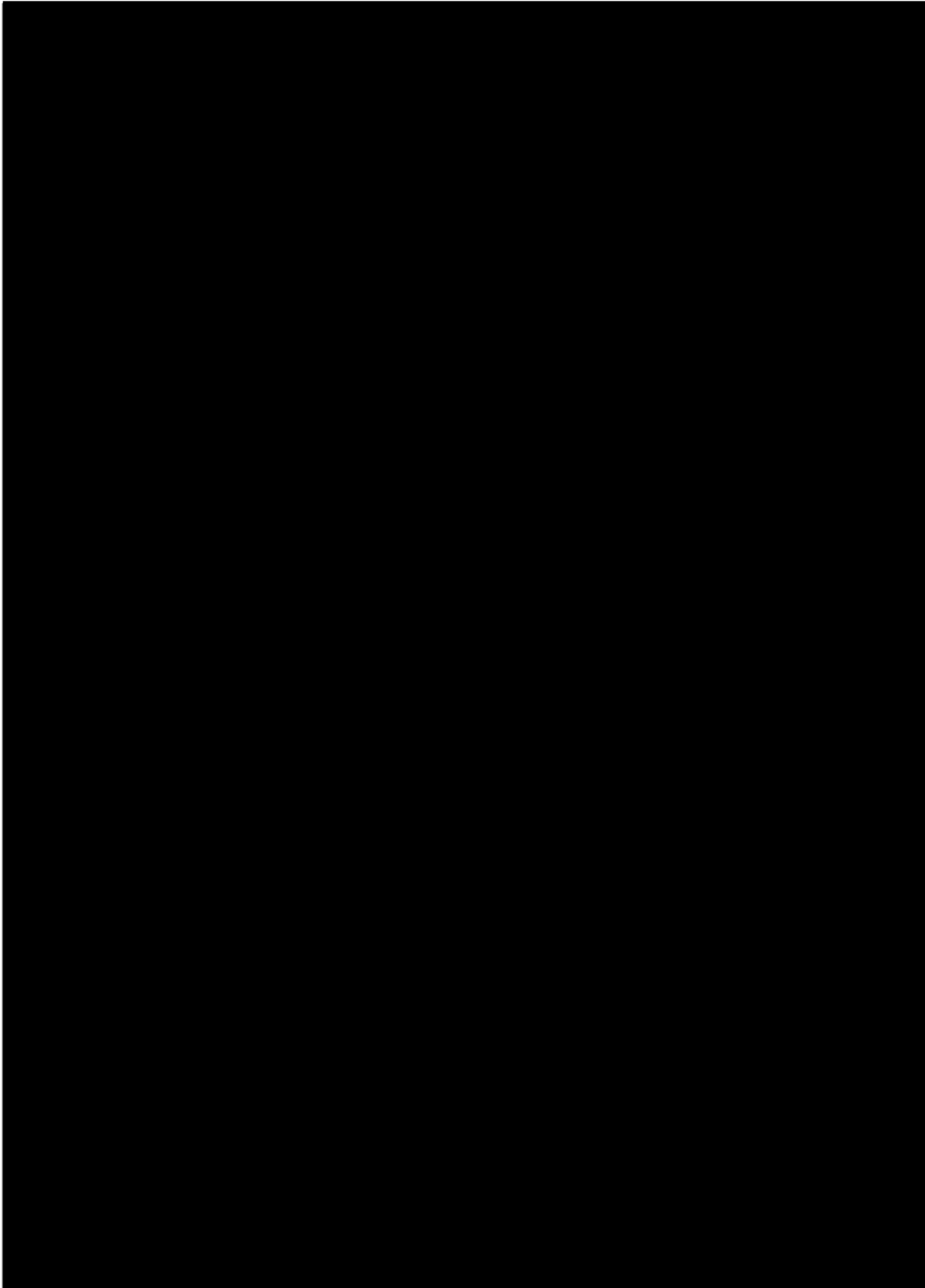


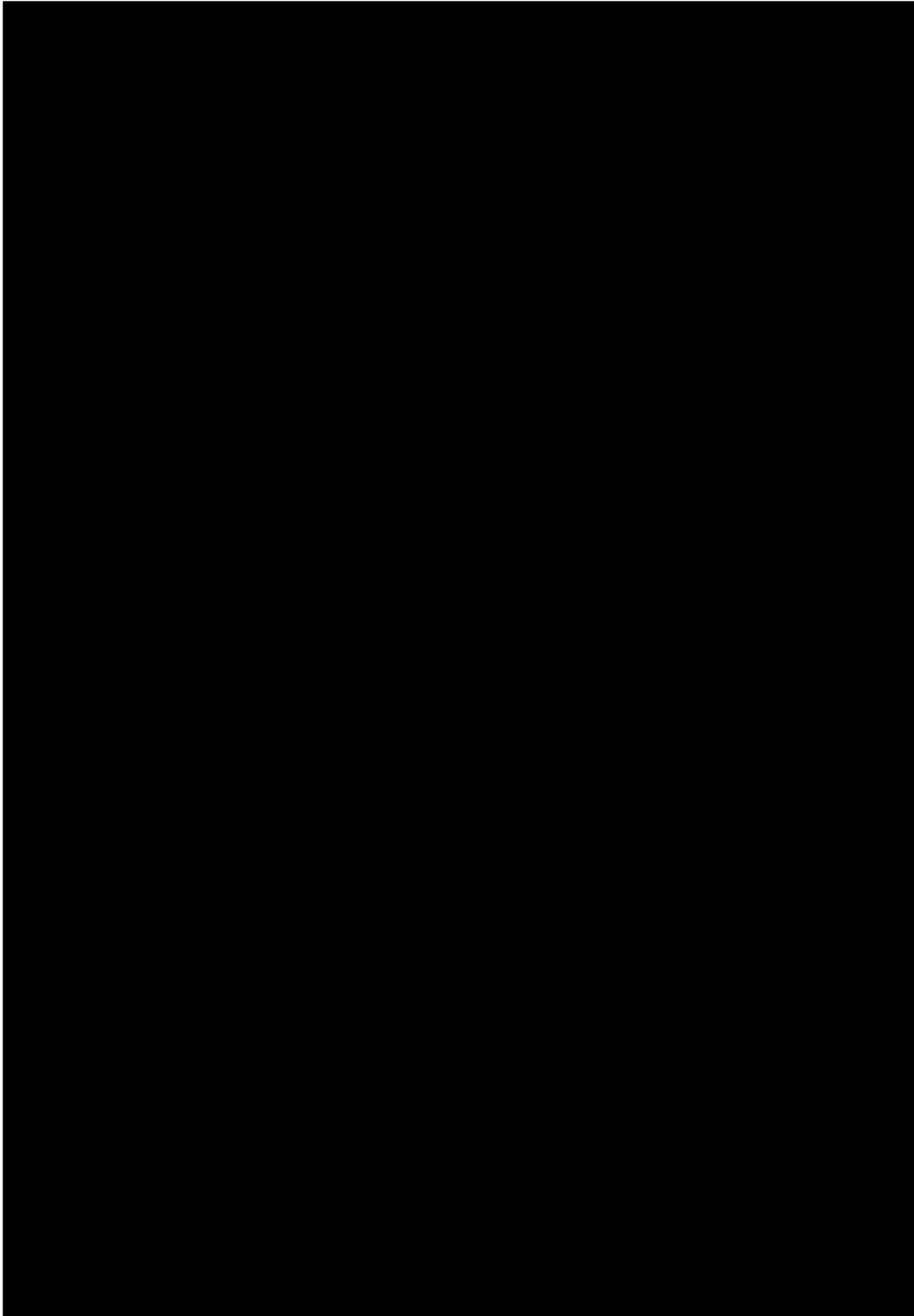


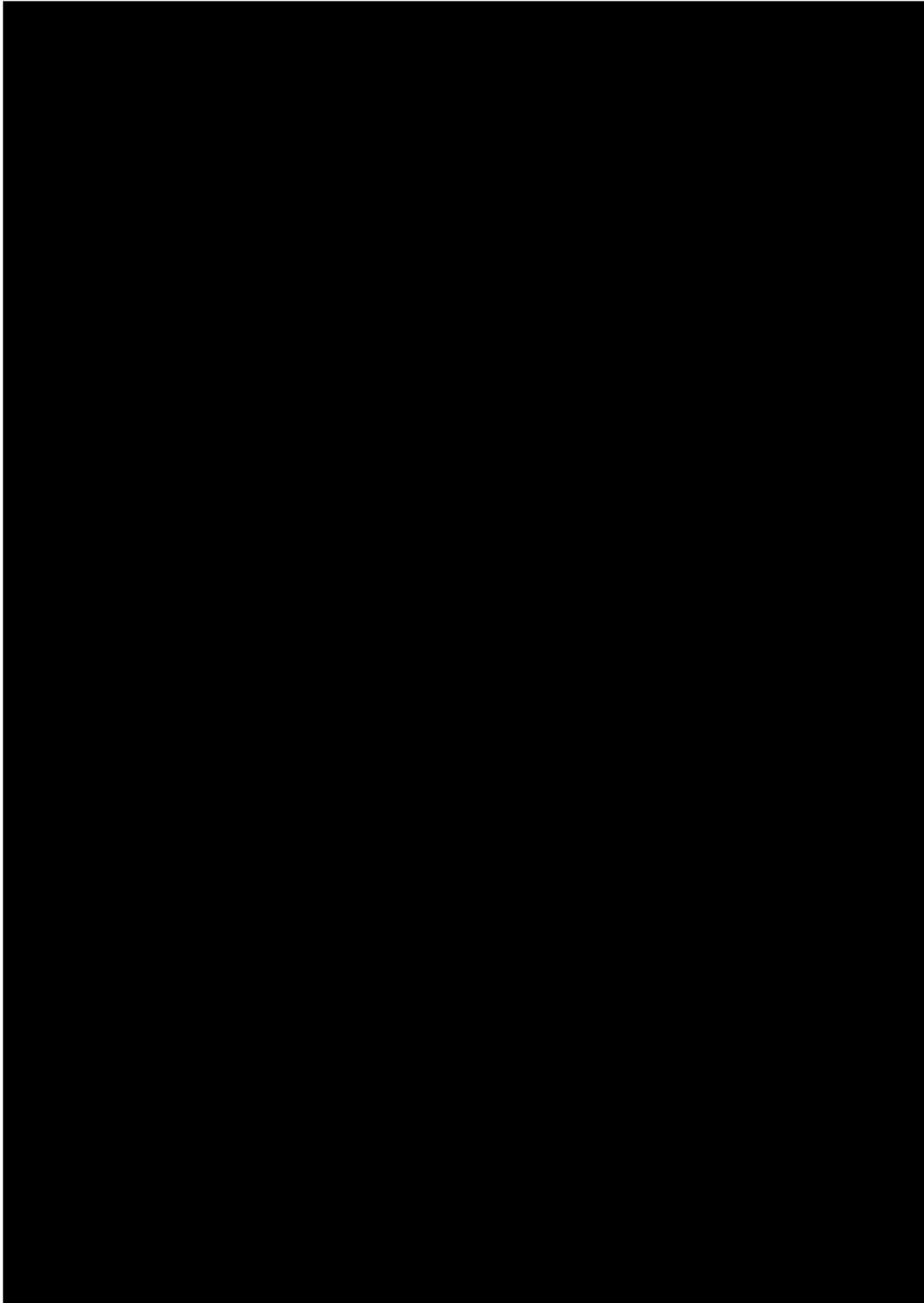


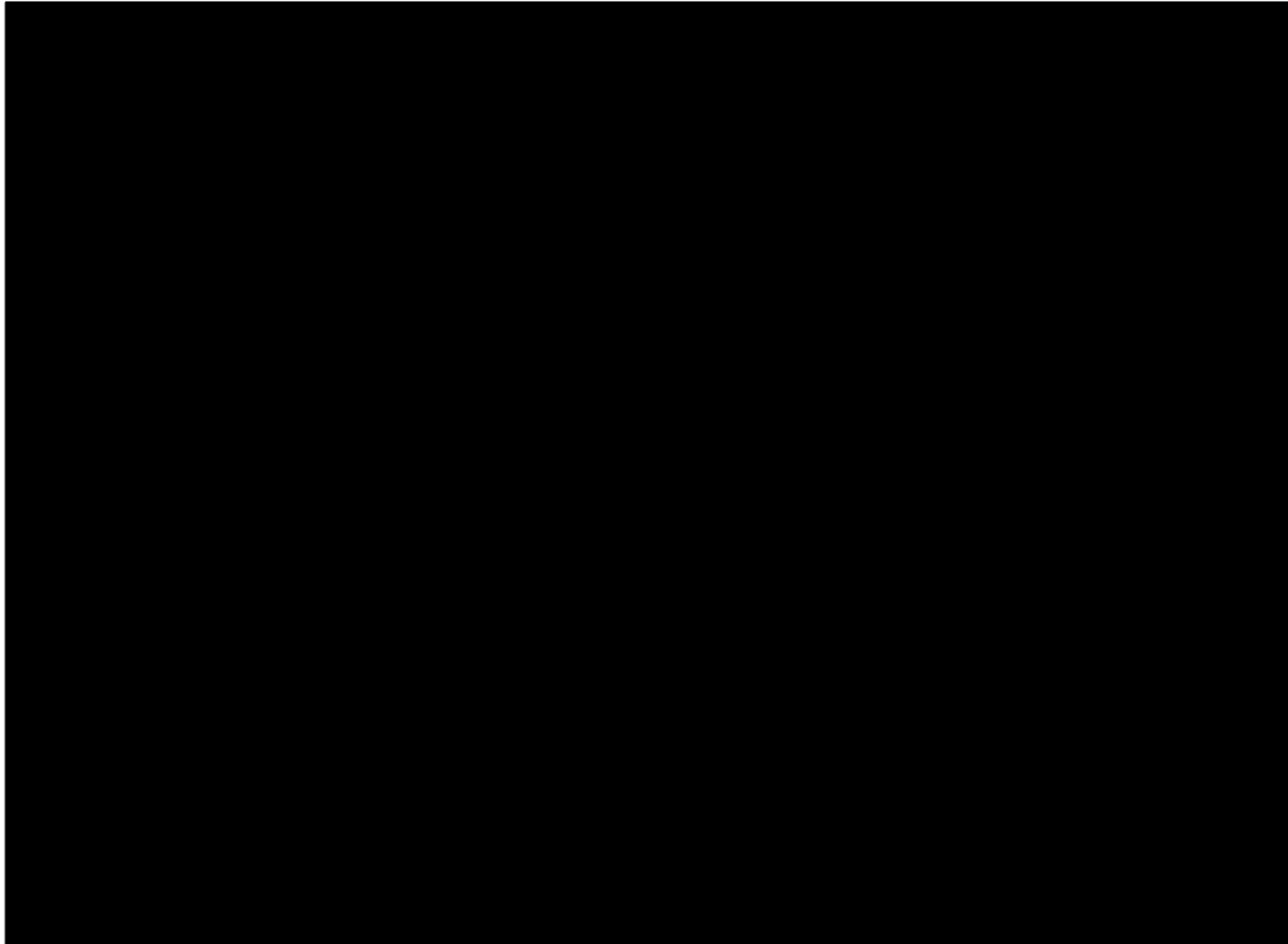


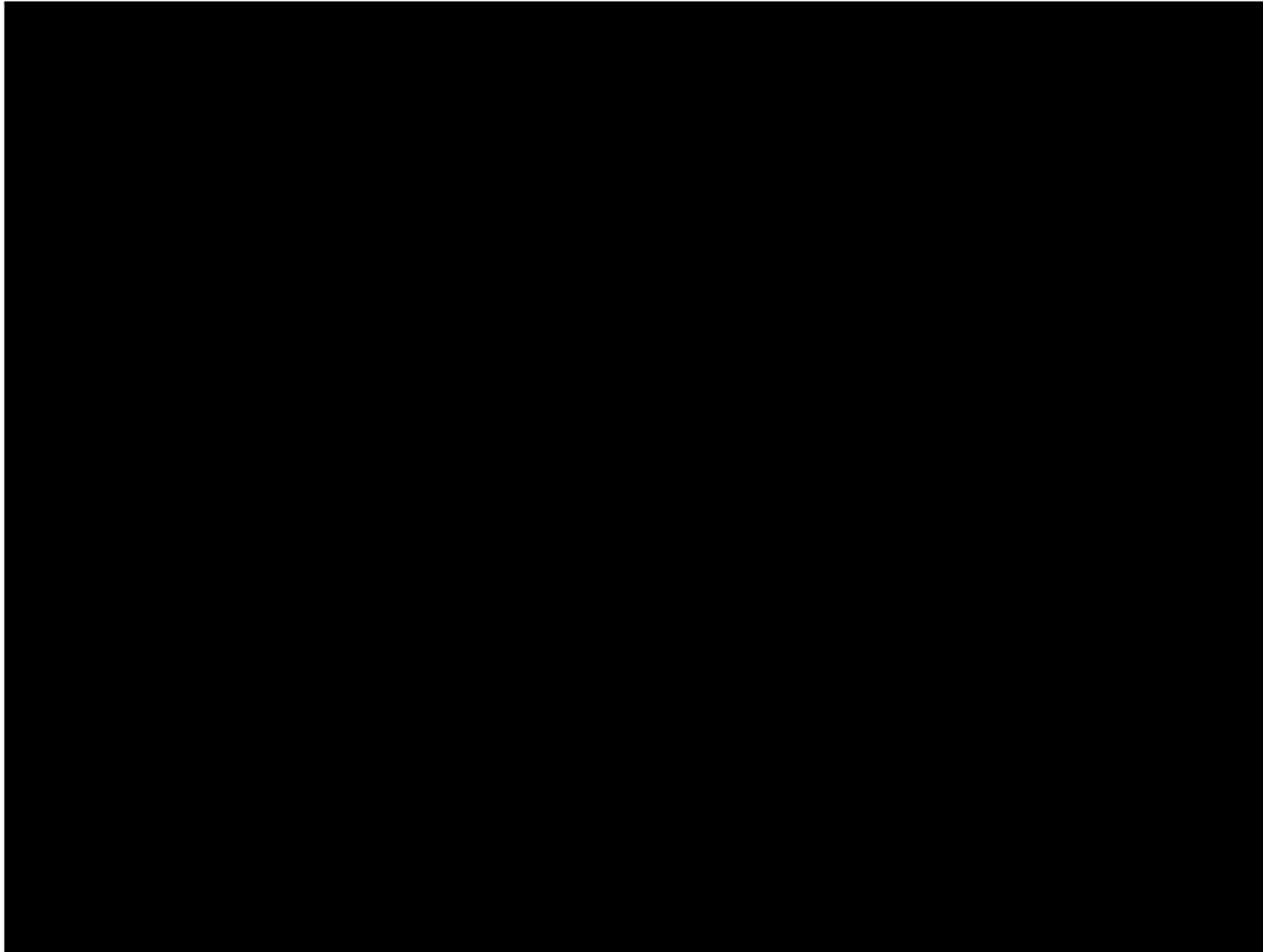


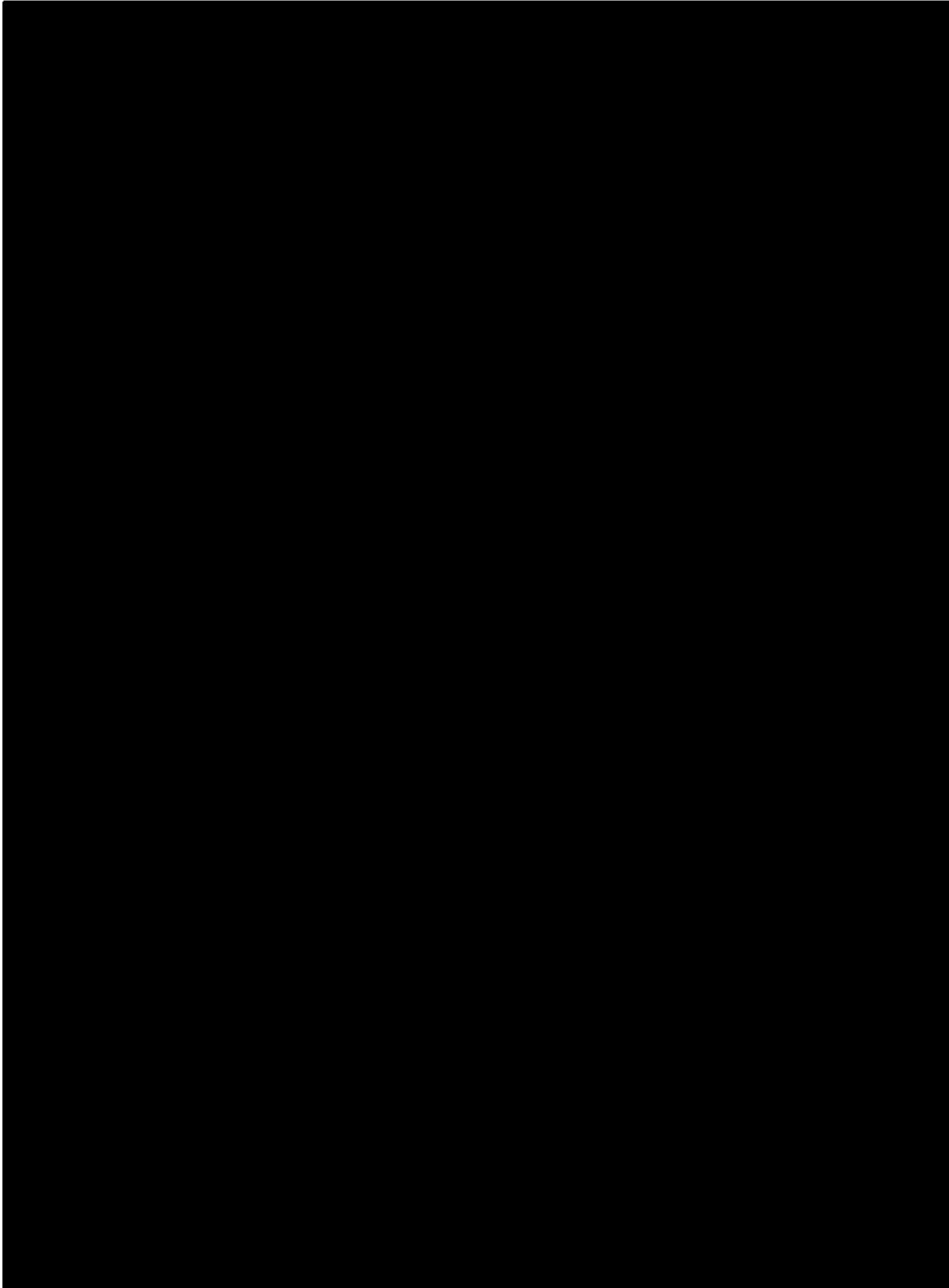






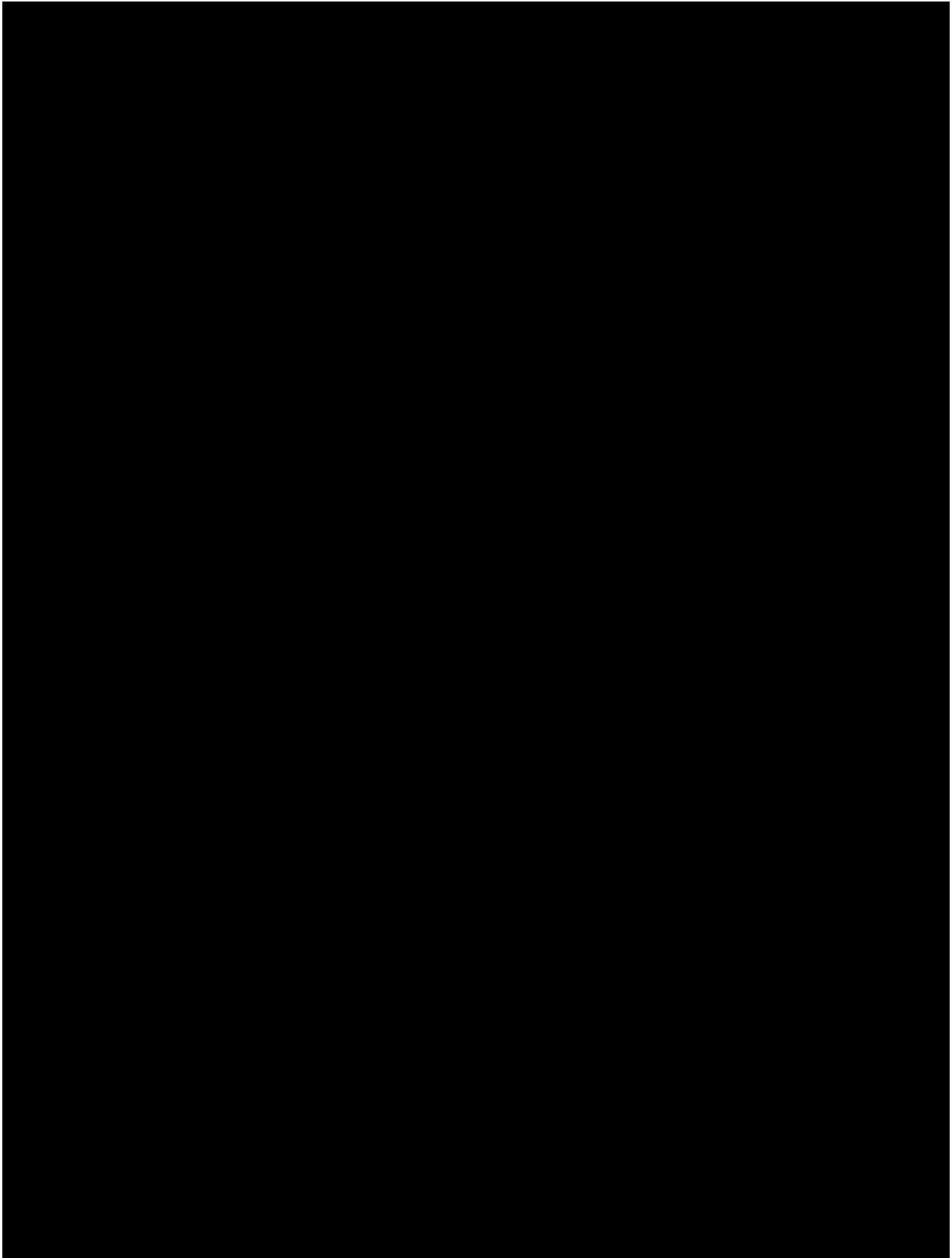


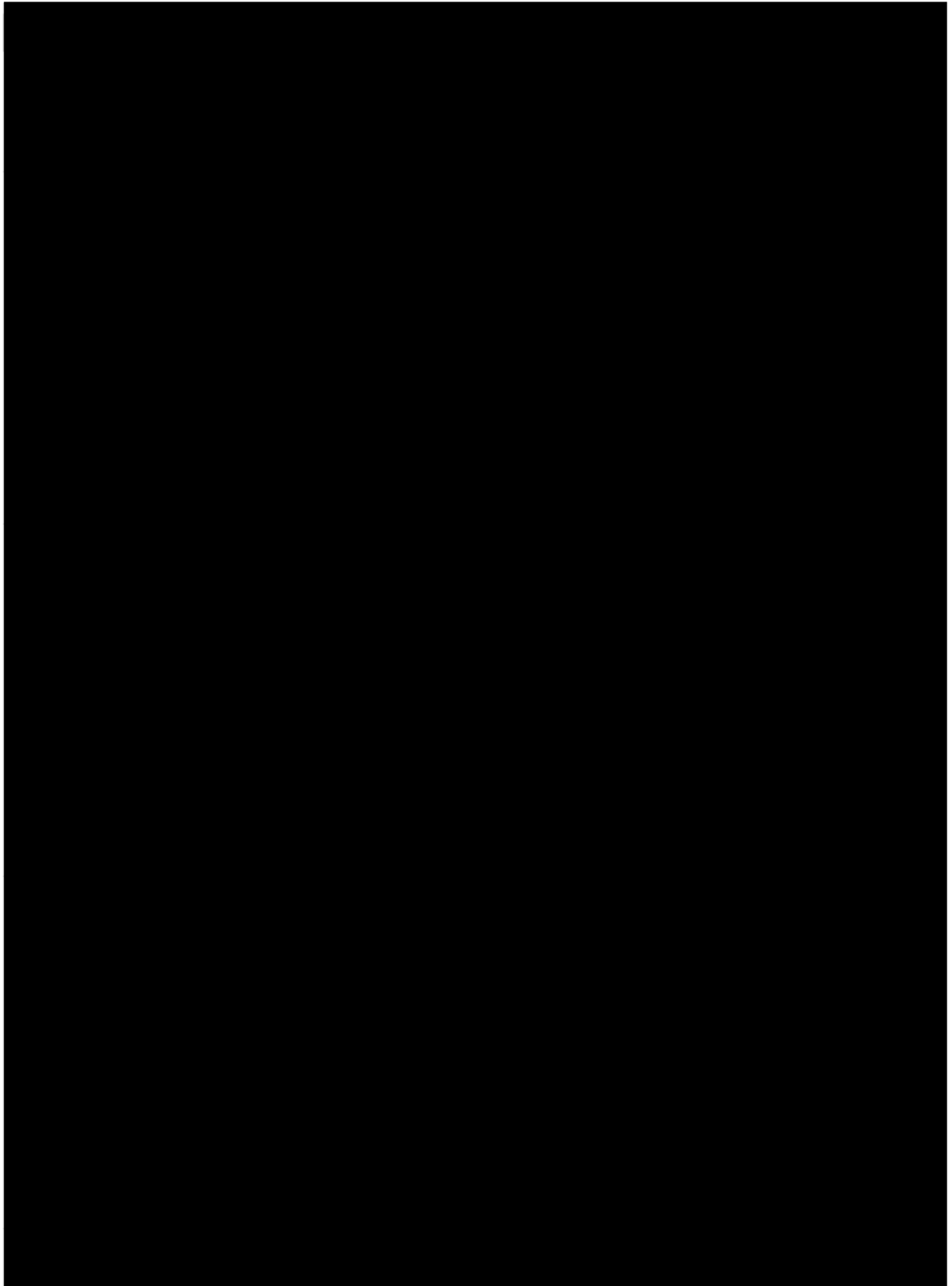


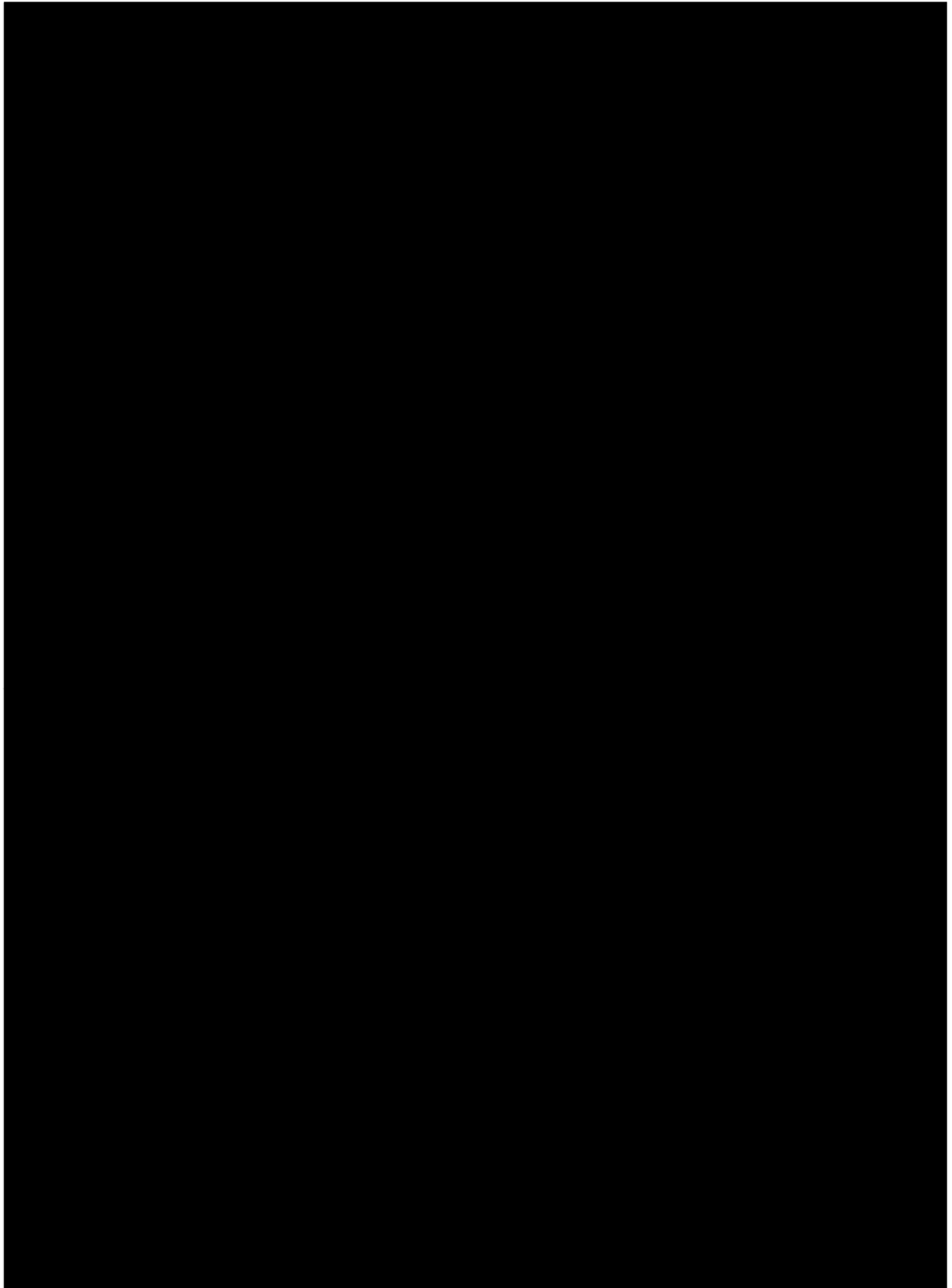


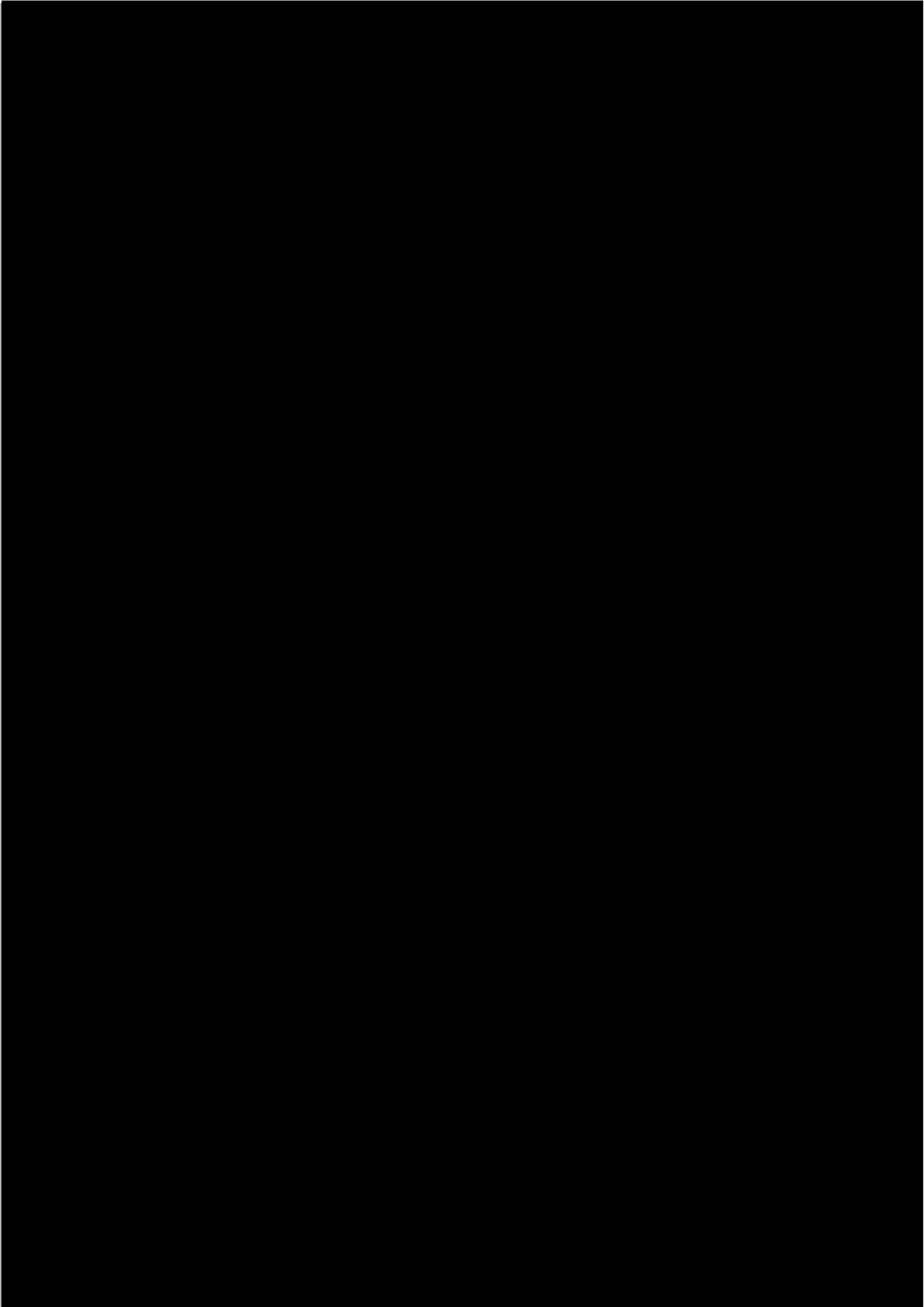


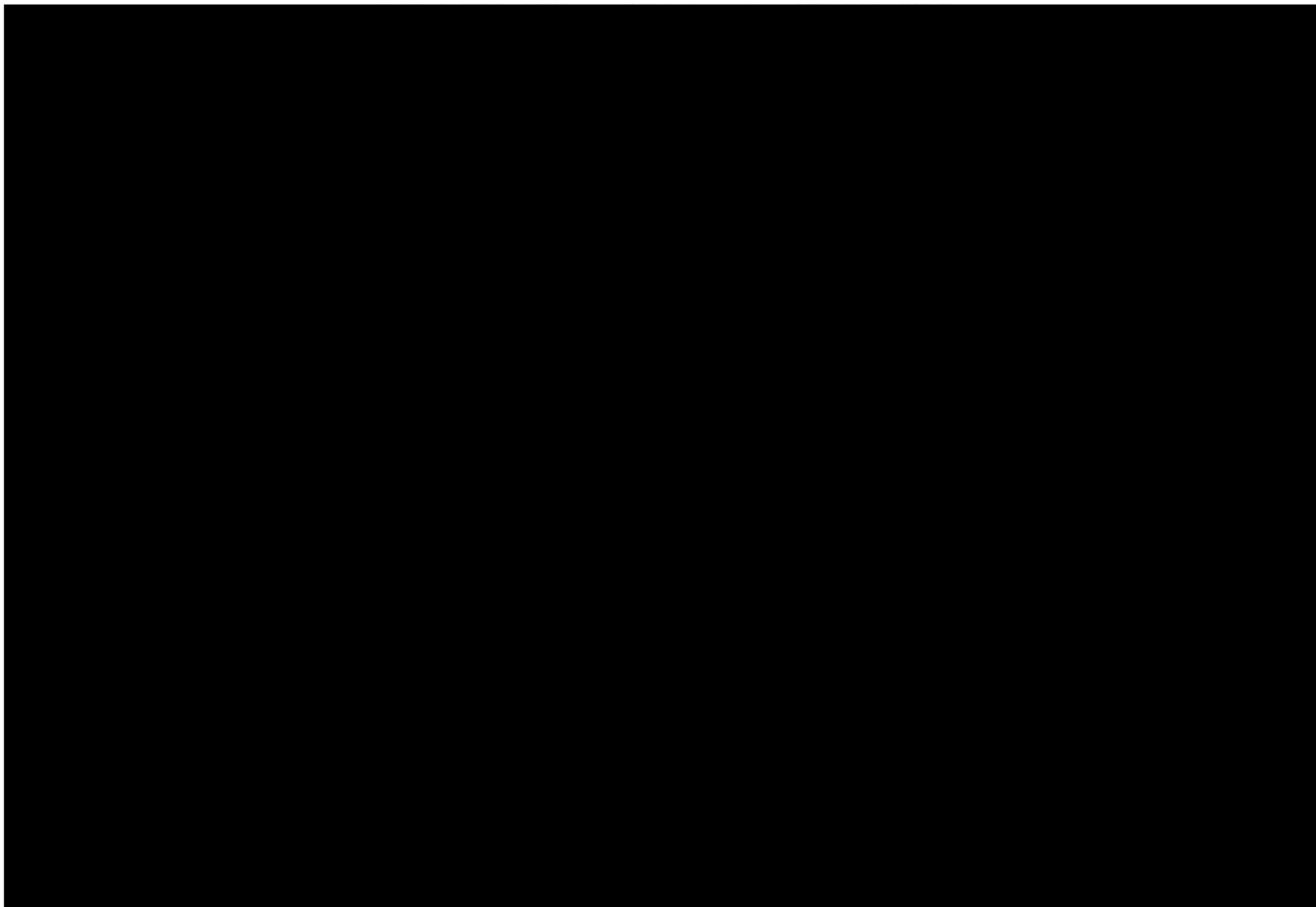
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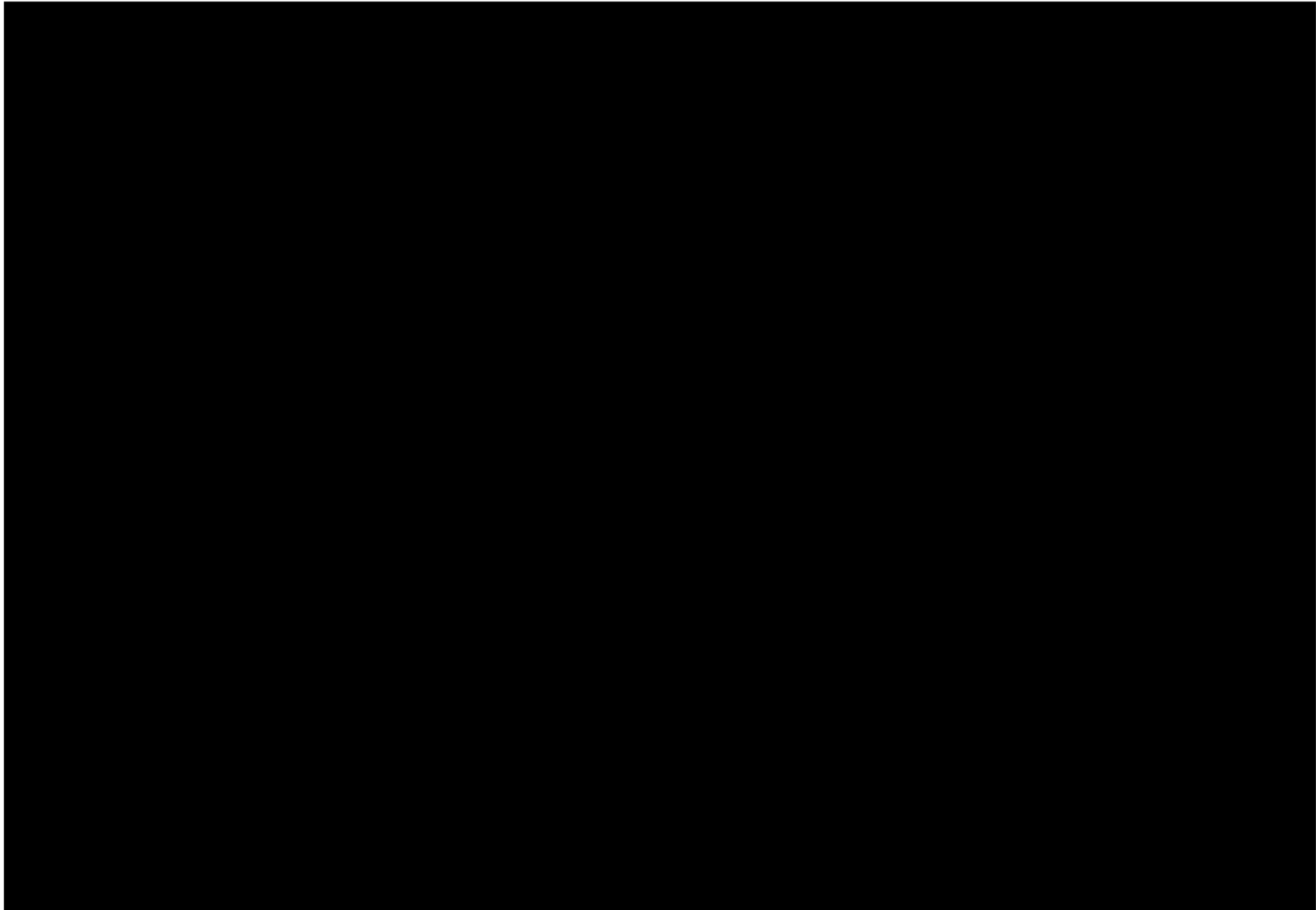


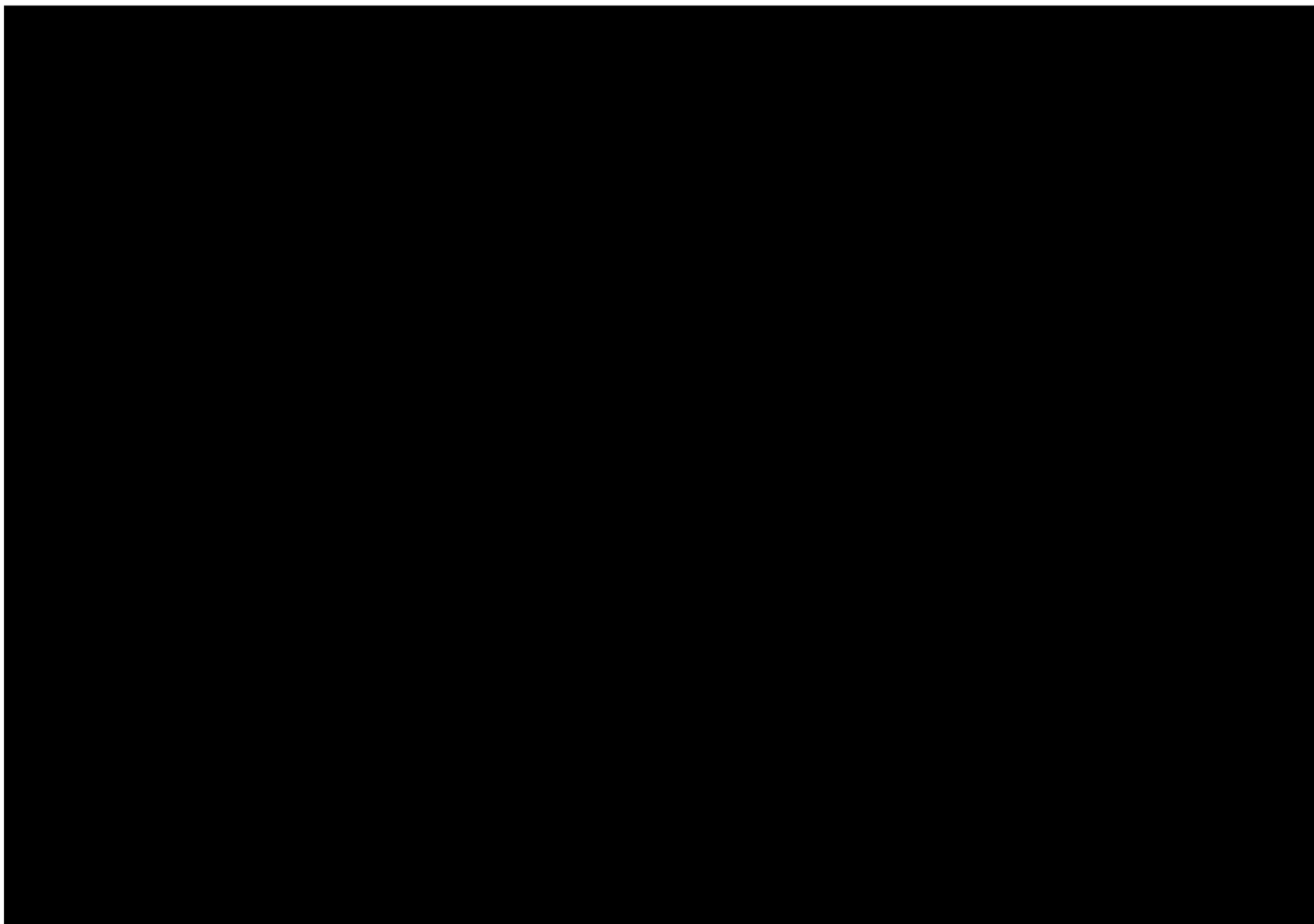


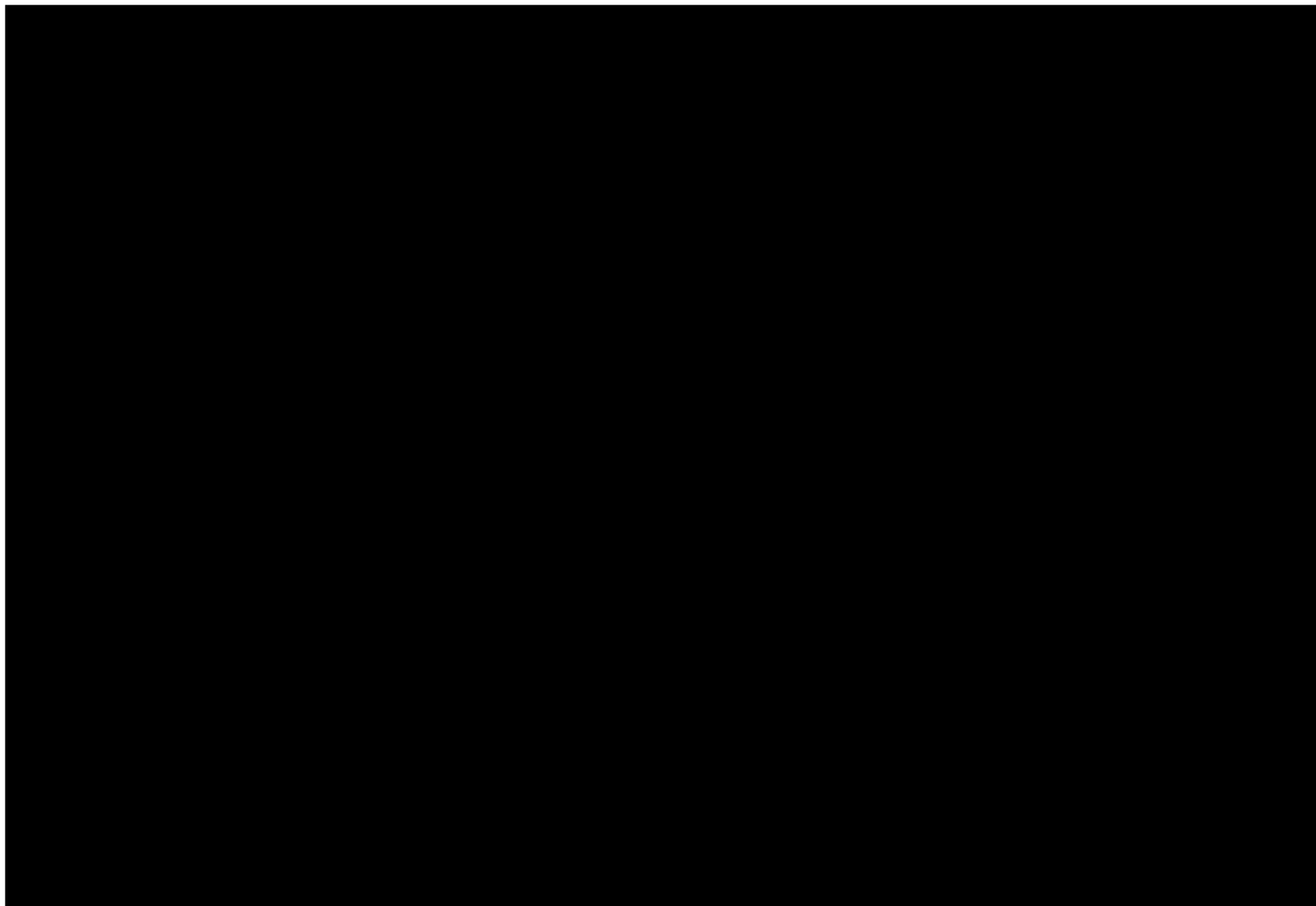


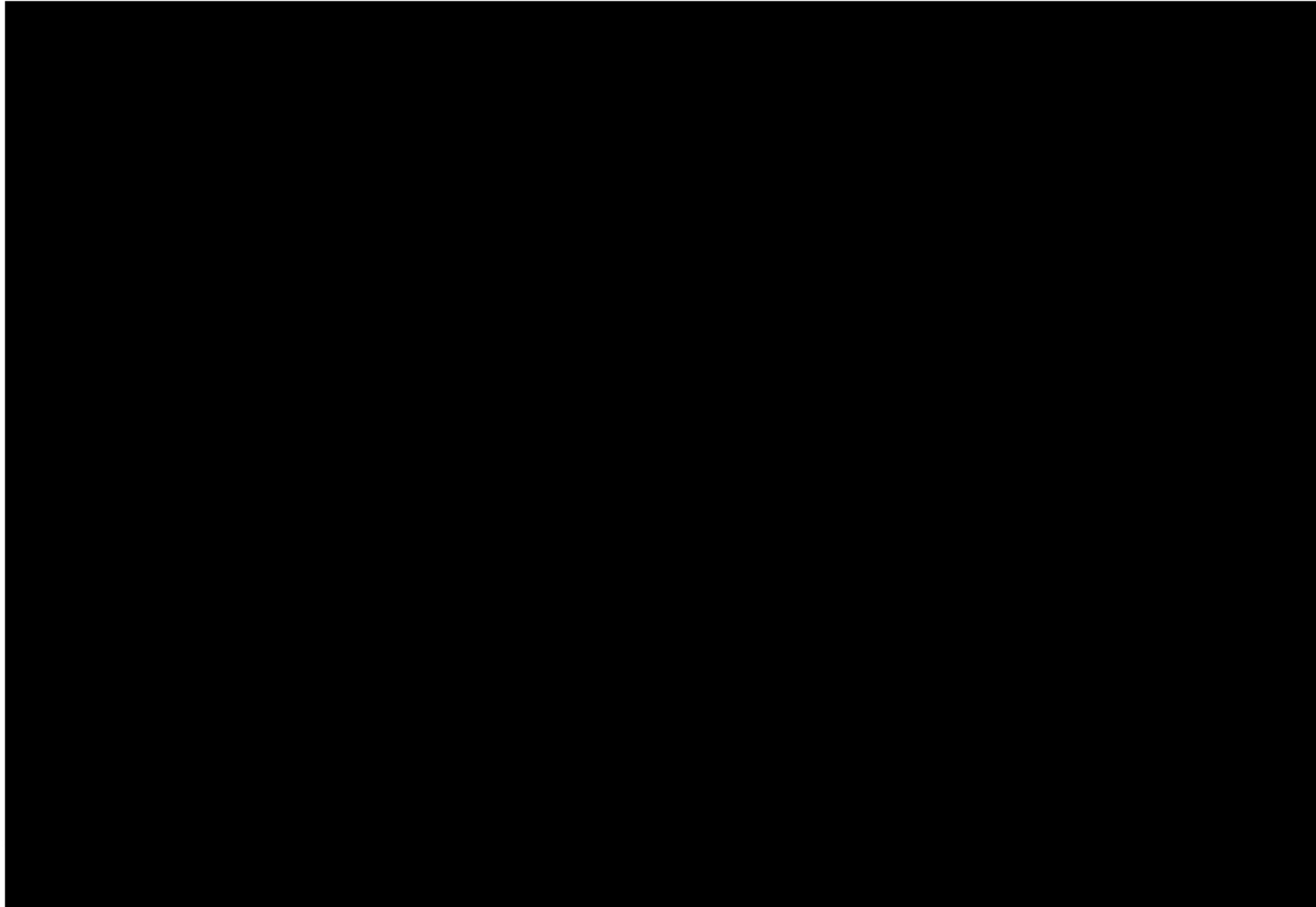


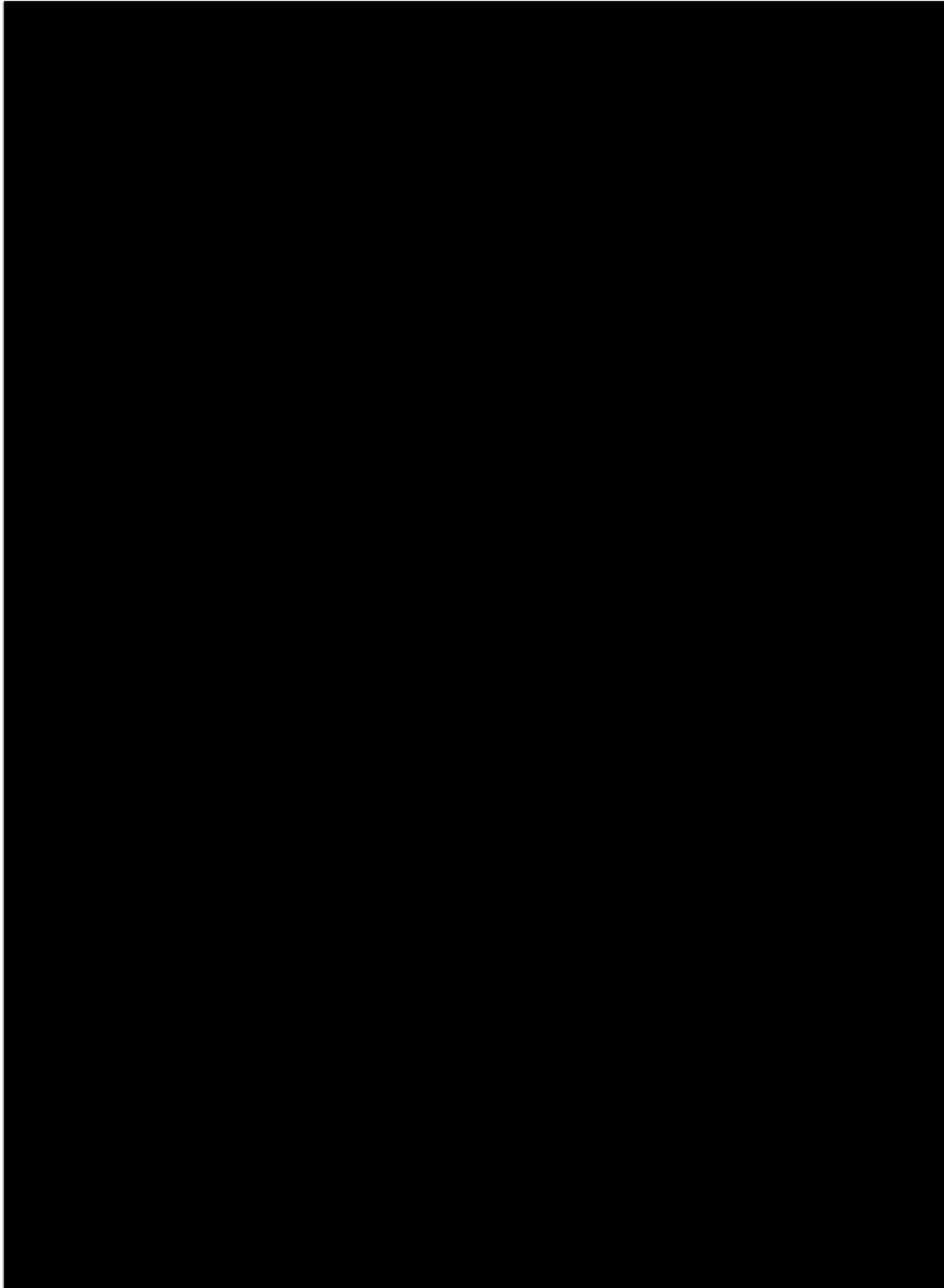


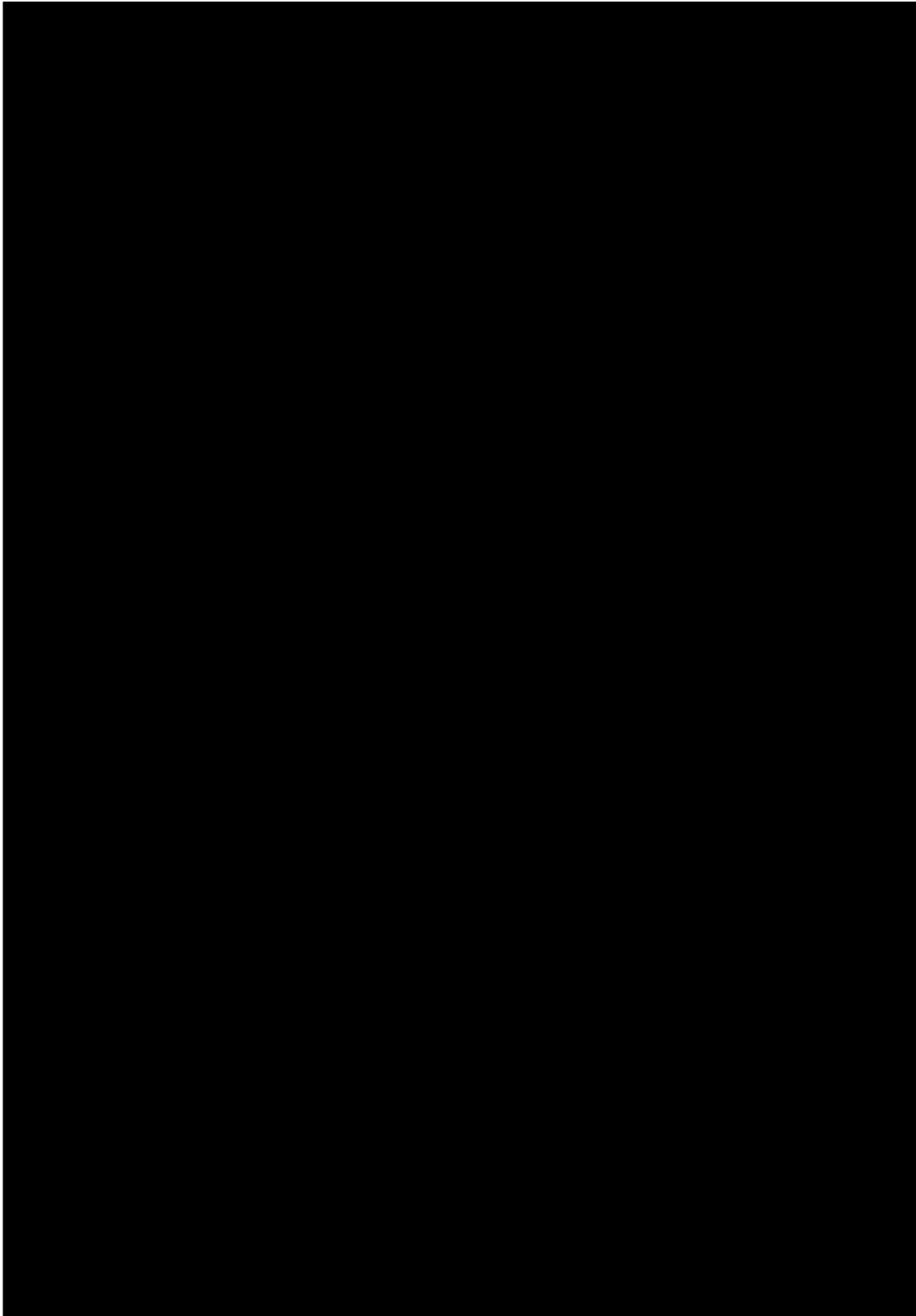


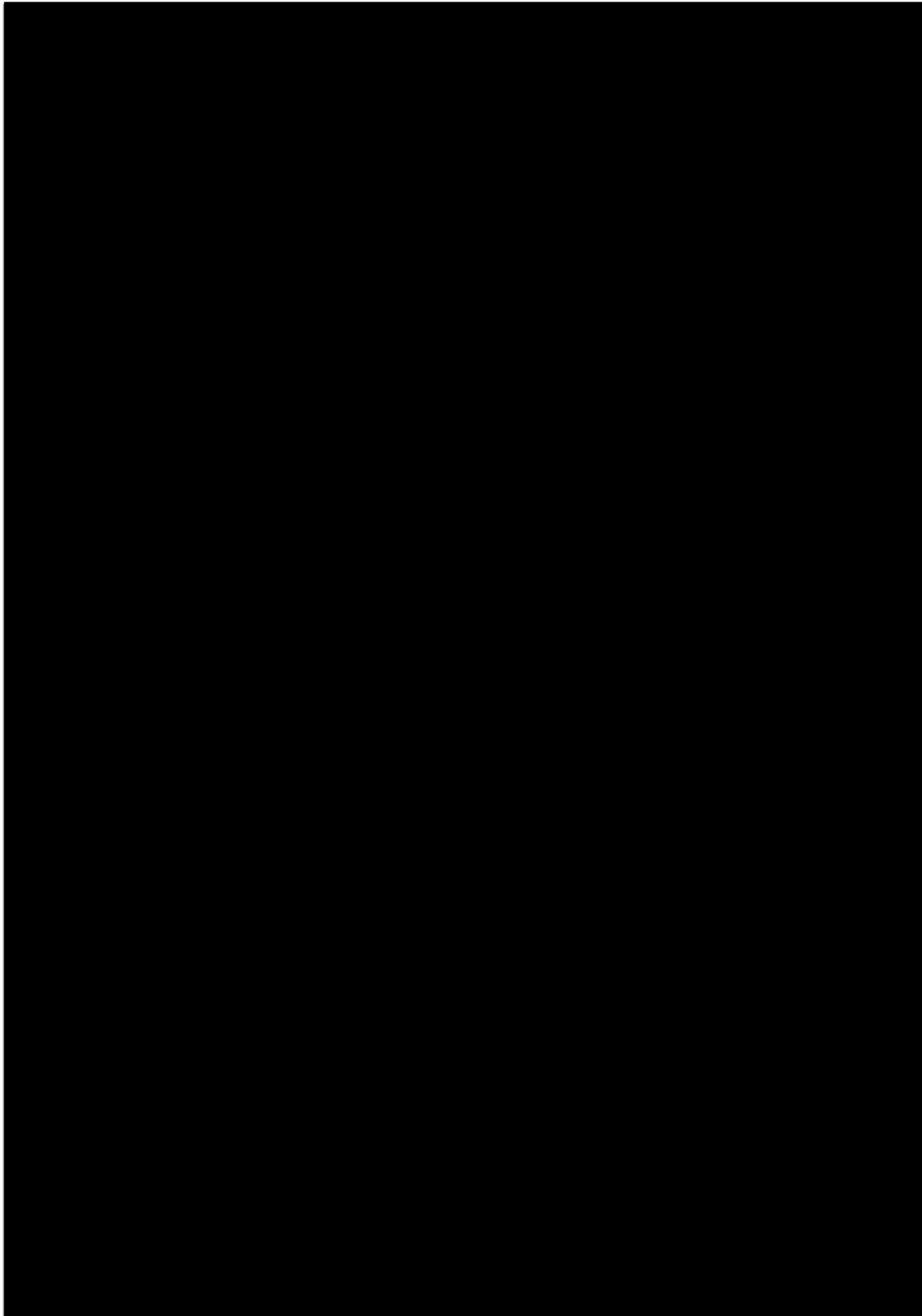


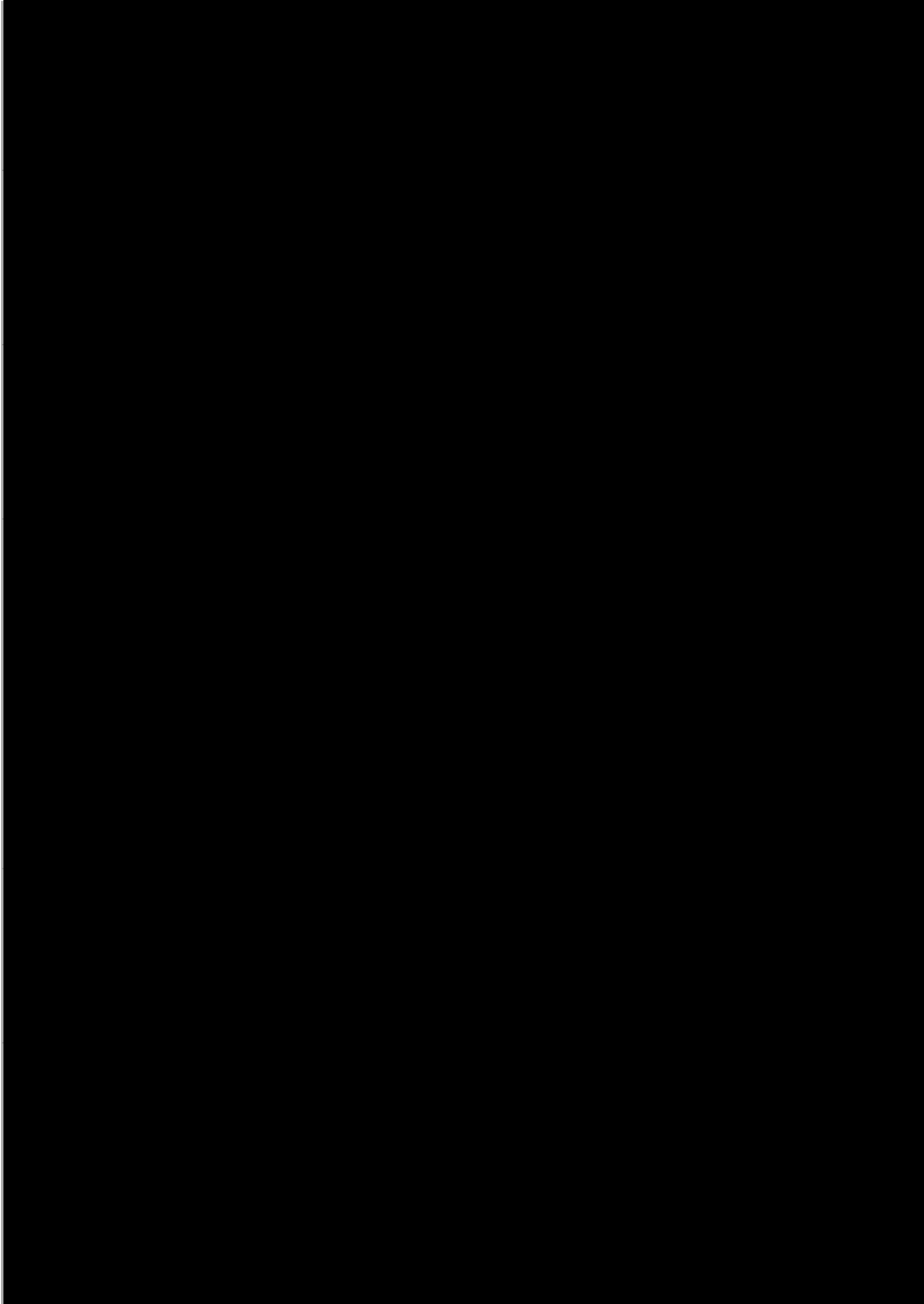


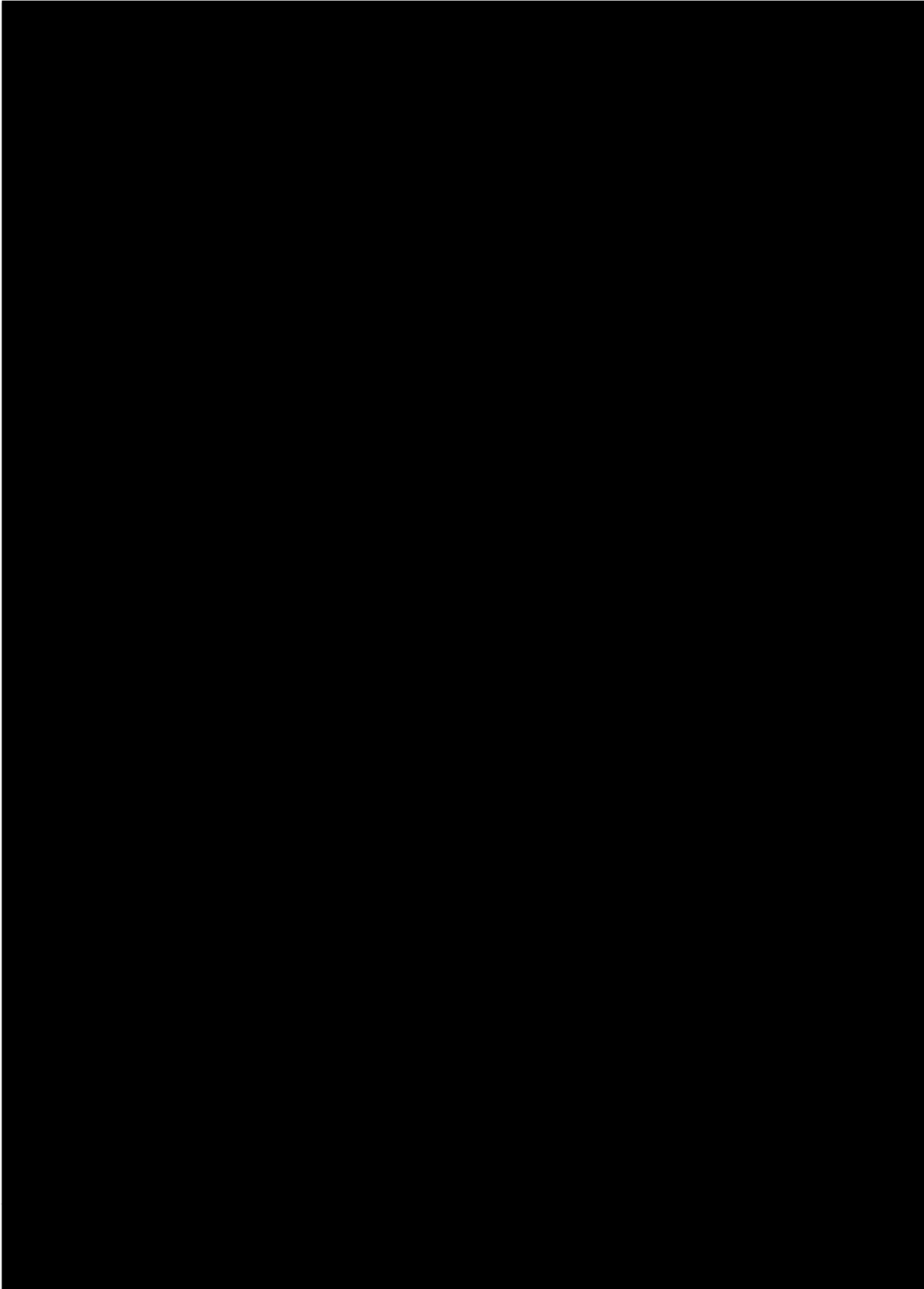


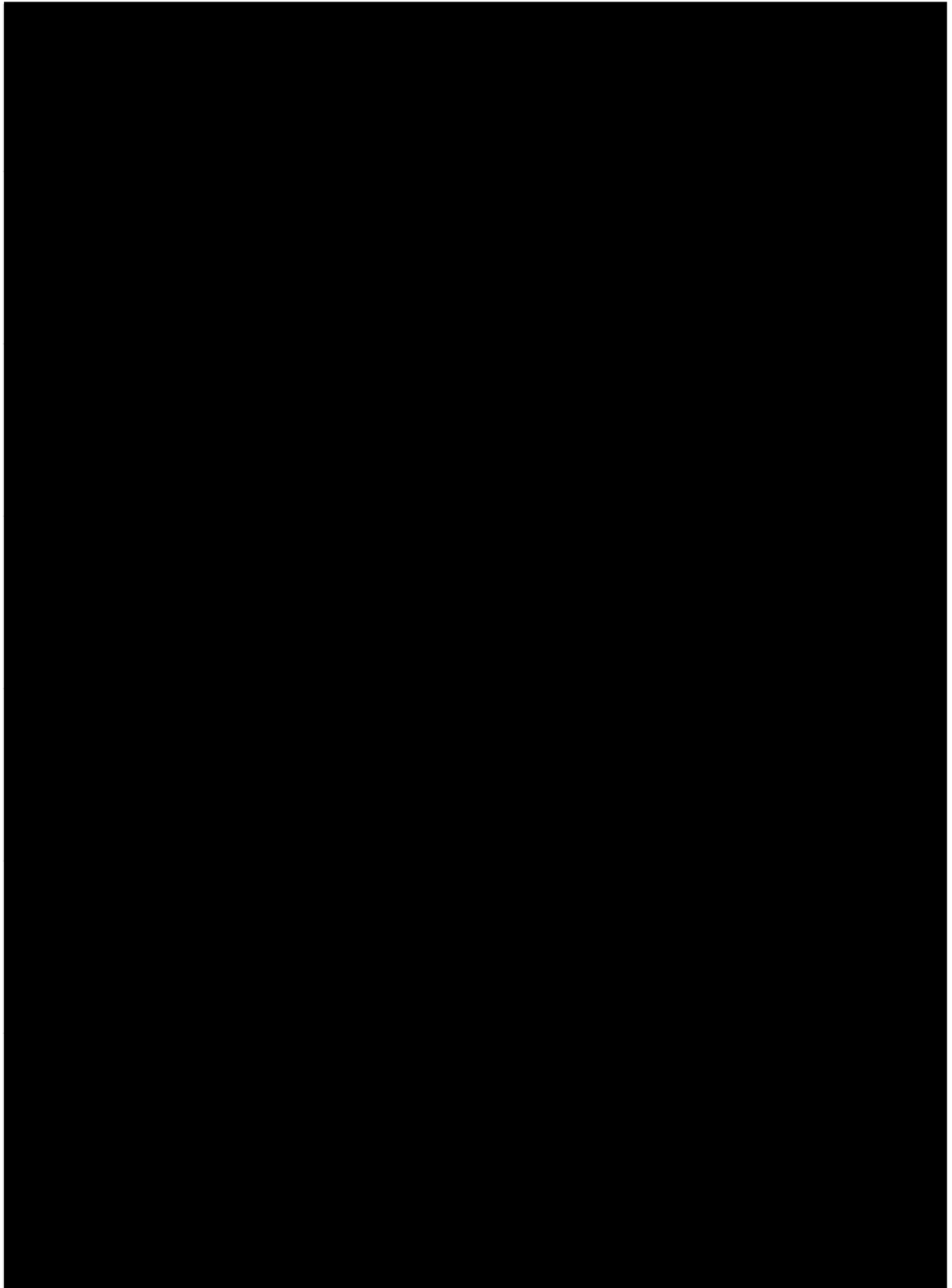


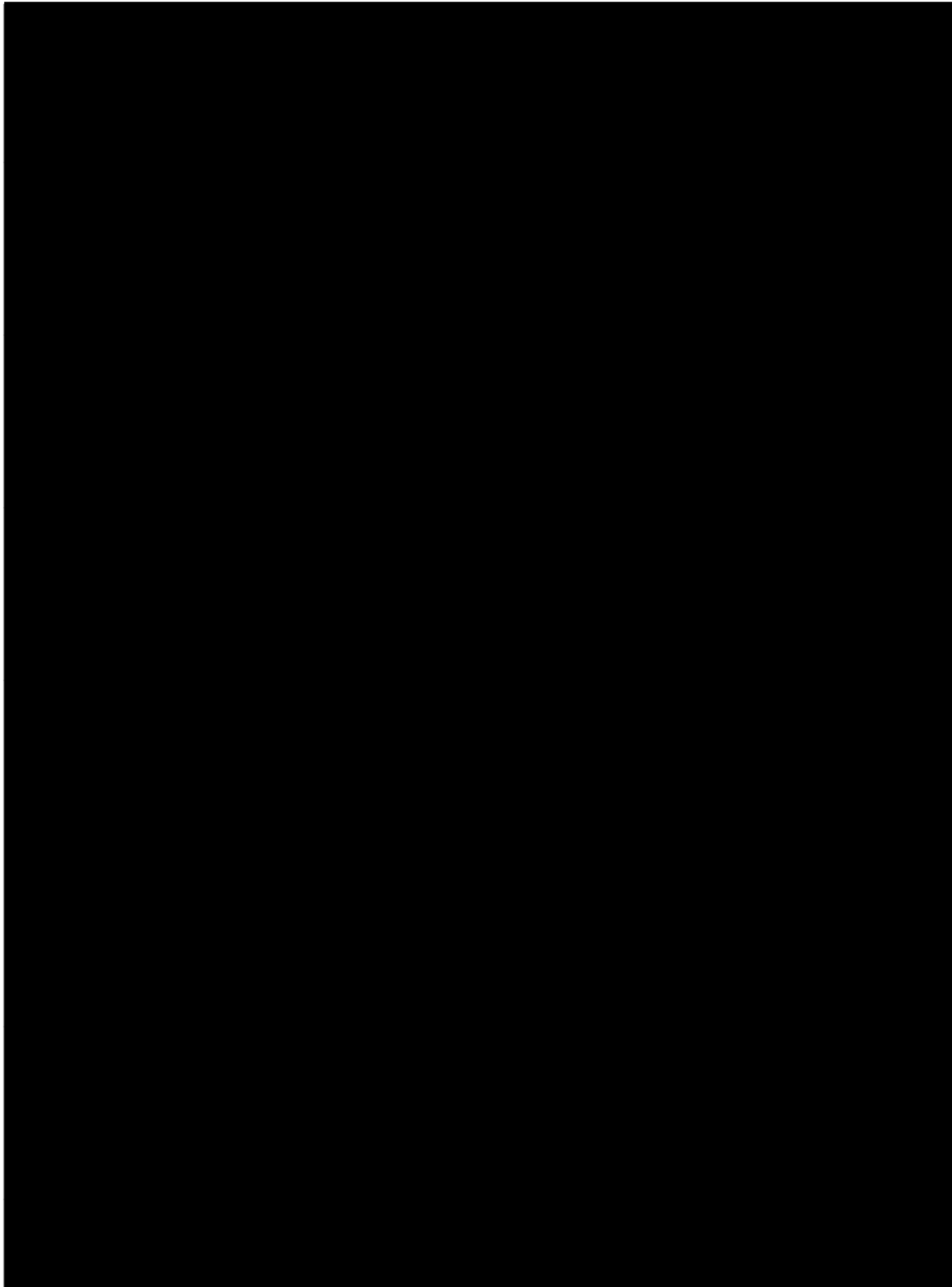


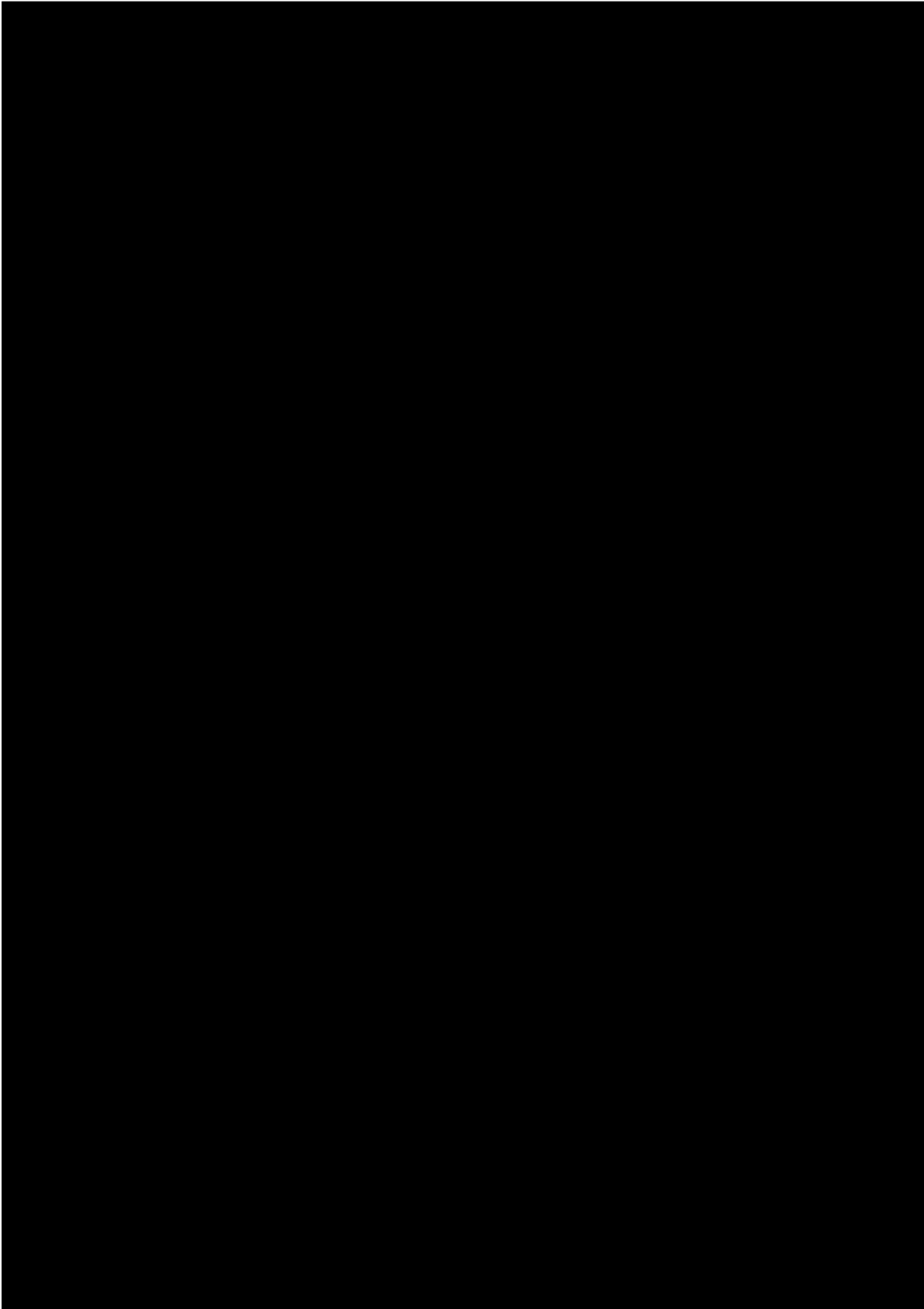


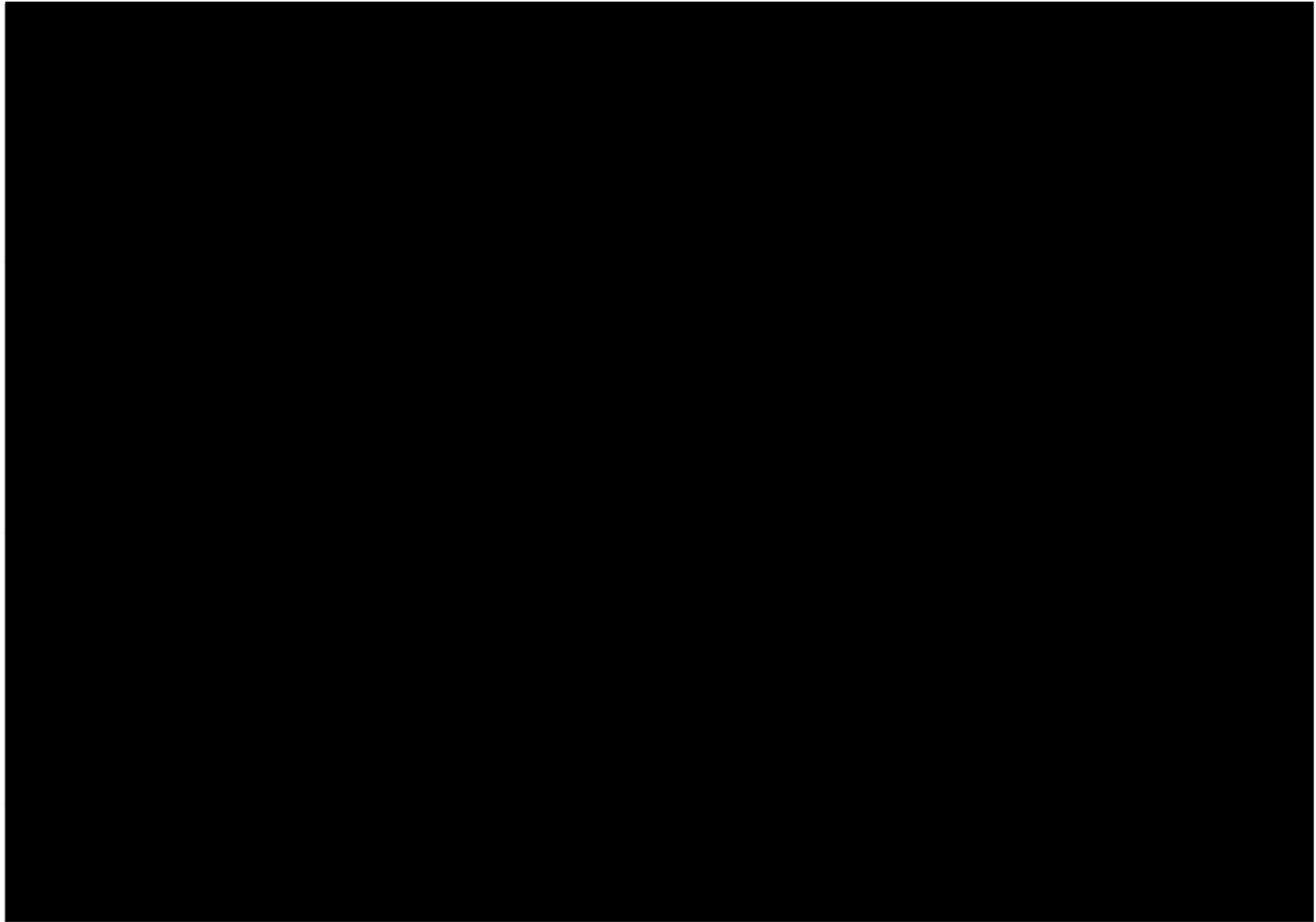


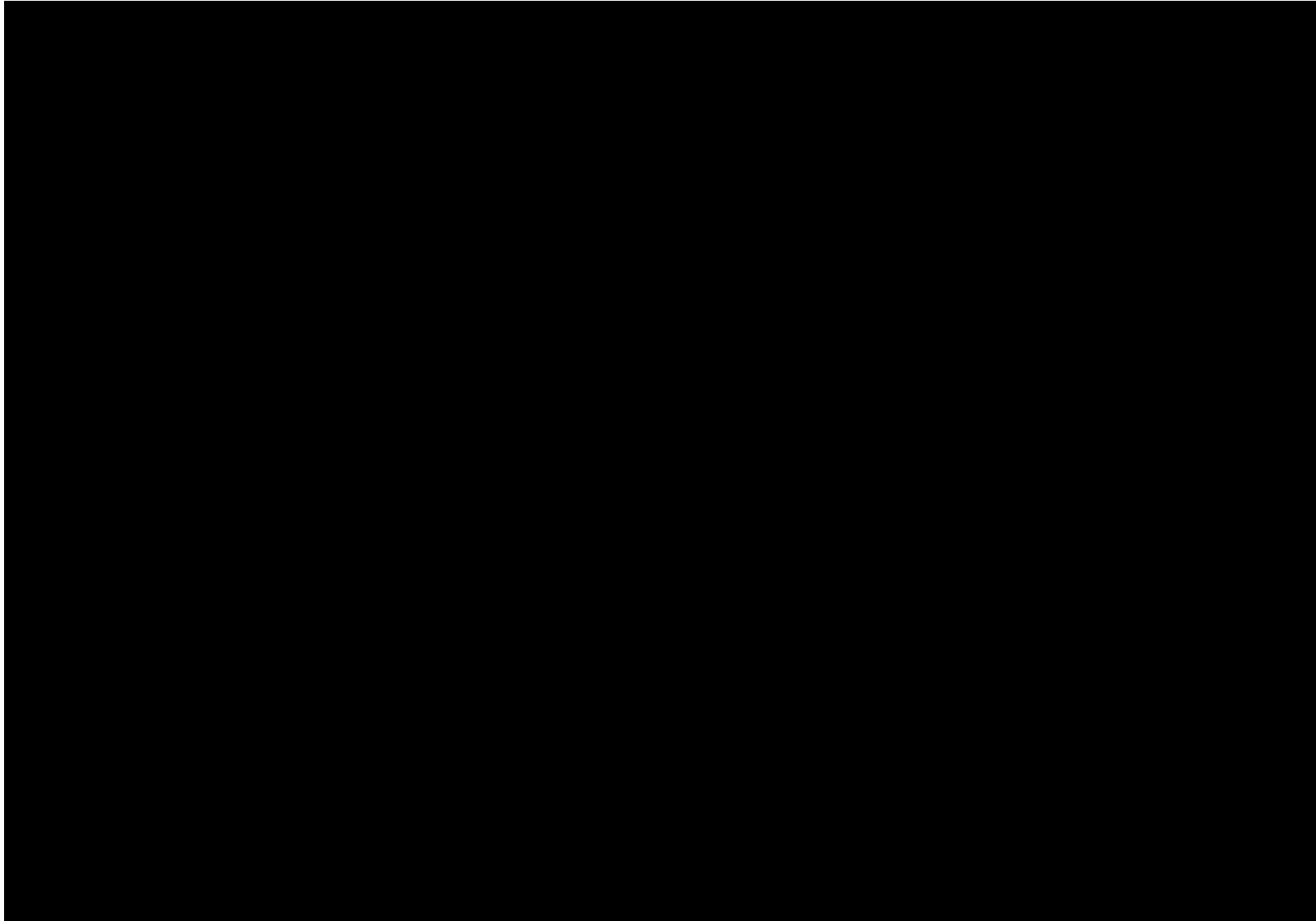


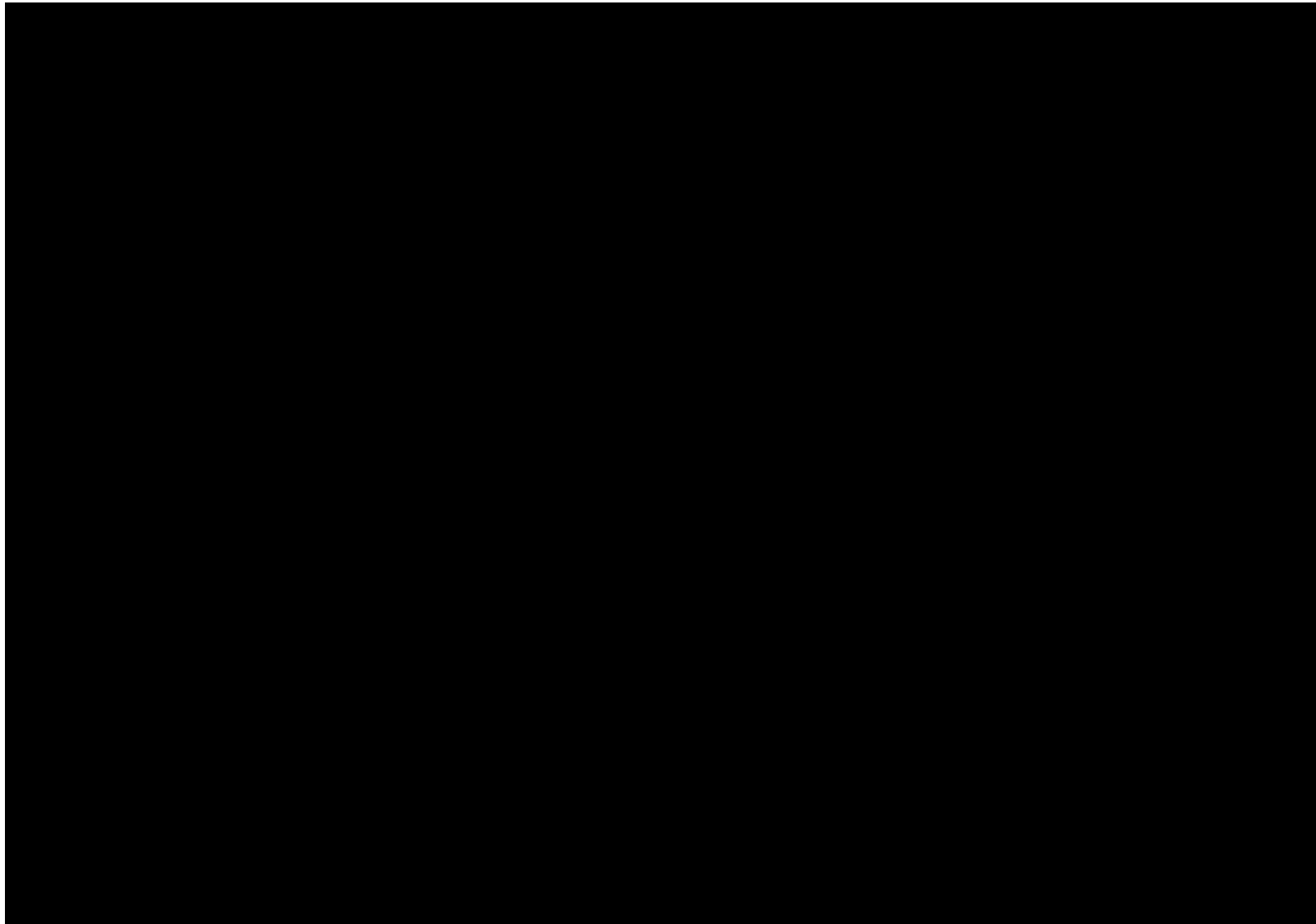


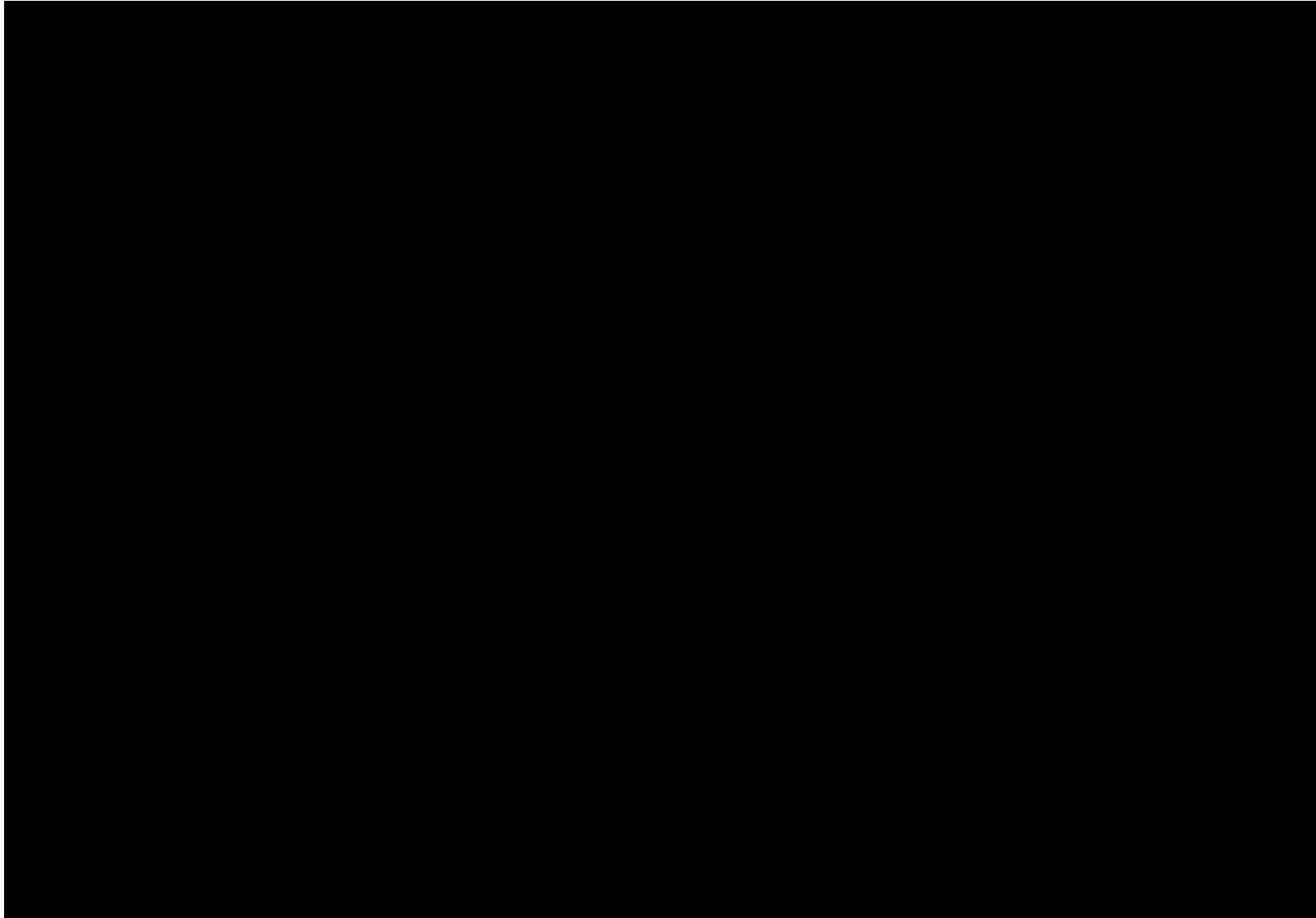


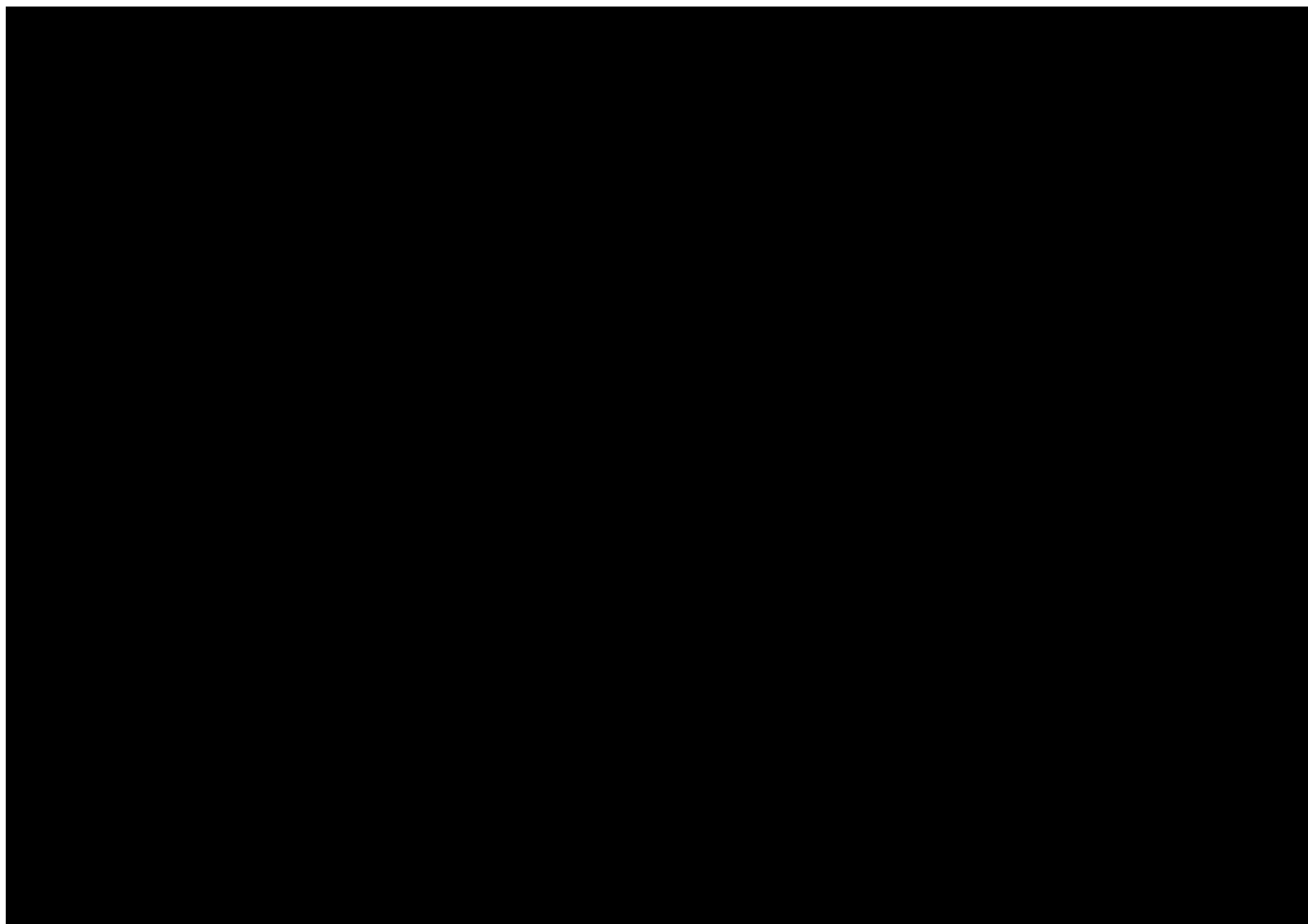


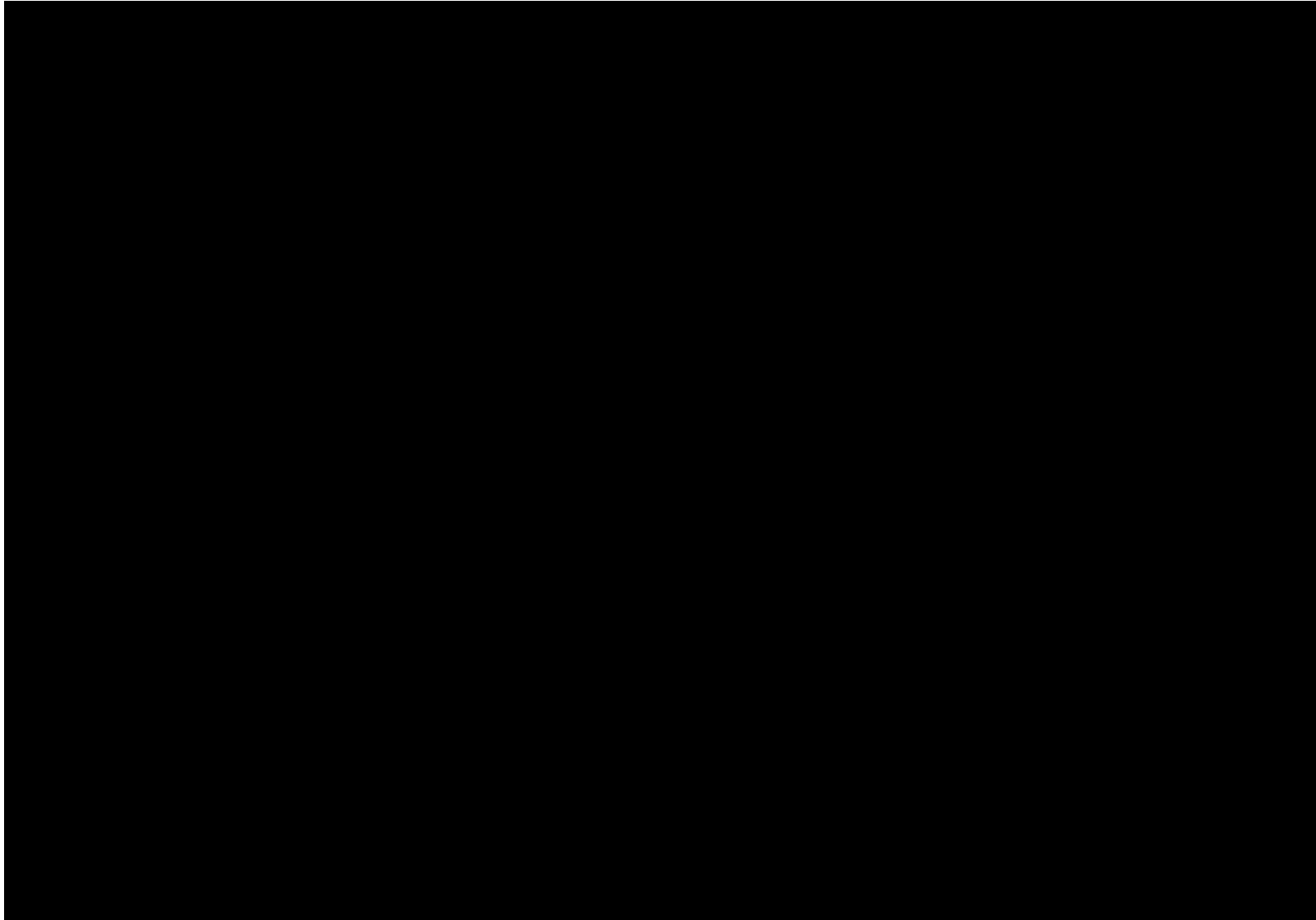


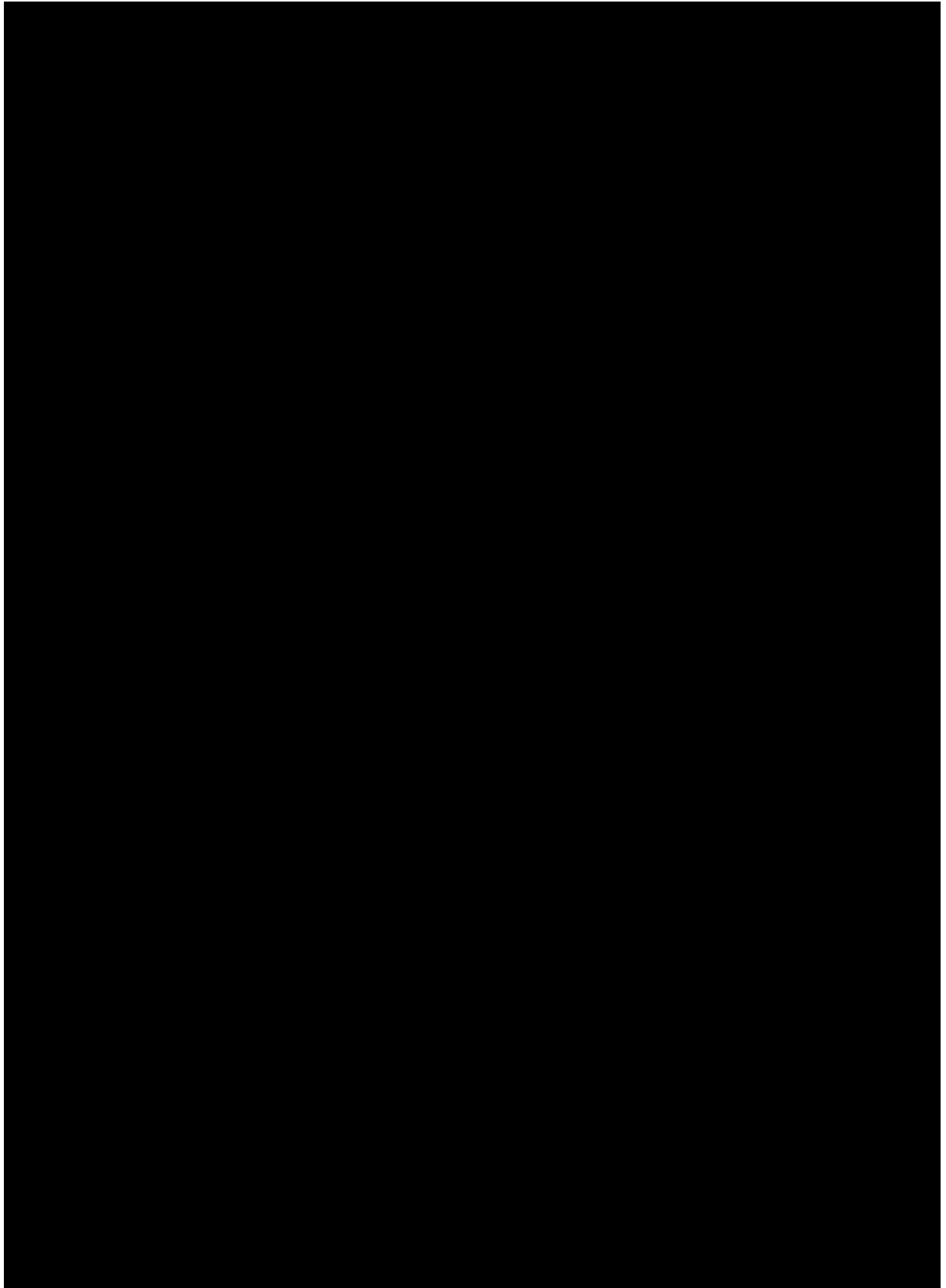


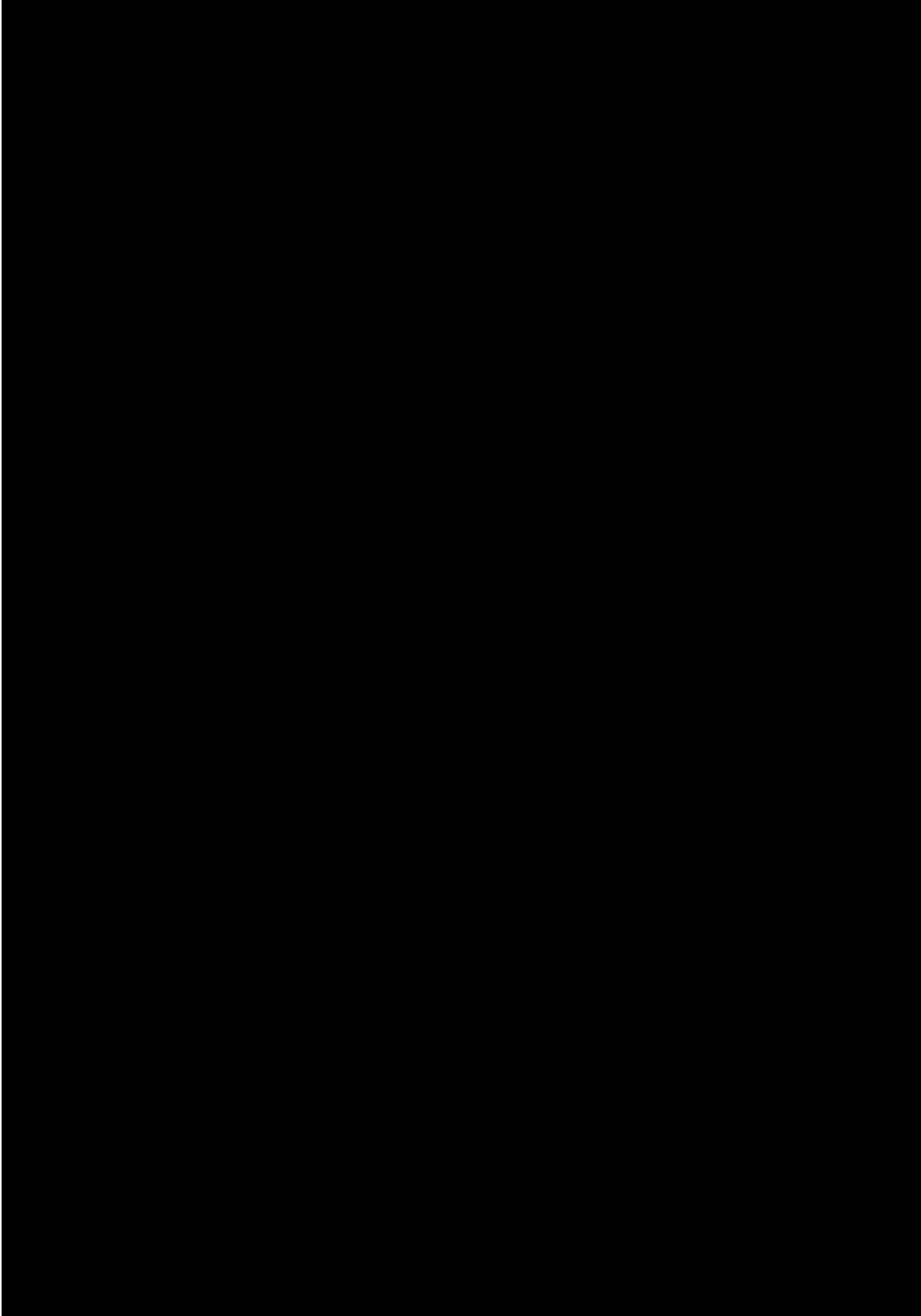












3.	Bookmark Title: MSQ3 – Utilization Management Program Approach Bookmark Title for Supporting Material: <u>MS3.1 – QLL Utilization Management Criteria</u> Narrative description is limited to four (4) pages, not including the required supporting material.
Describe your experience, ability, and method (both administrative and clinical) for providing support to the State Advisory Board as described in Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.2 State Advisory Board.	

Utilization Management (UM) is a critical component of any Medicaid program. It requires both clinical knowledge and extensive experience to craft a bespoke solution to ensure appropriate prescribing and prevent excessive medication use within a State's unique provider and patient population. NorthStar HealthCare Consulting (NHC)'s suite of UM offerings includes:

- Prior Authorization (PA) criteria,
- Step Edits,
- Quantity Level Limits (QLLs), and
- Preferred Drug List (PDL) development and maintenance.

These elements are designed to promote appropriate clinical usage, contain costs, and avoid waste and diversion. Collectively, this is NHC's Stepwise Approach to UM – as depicted in Figure MSQ3.

Stepwise Approach to Utilization Management

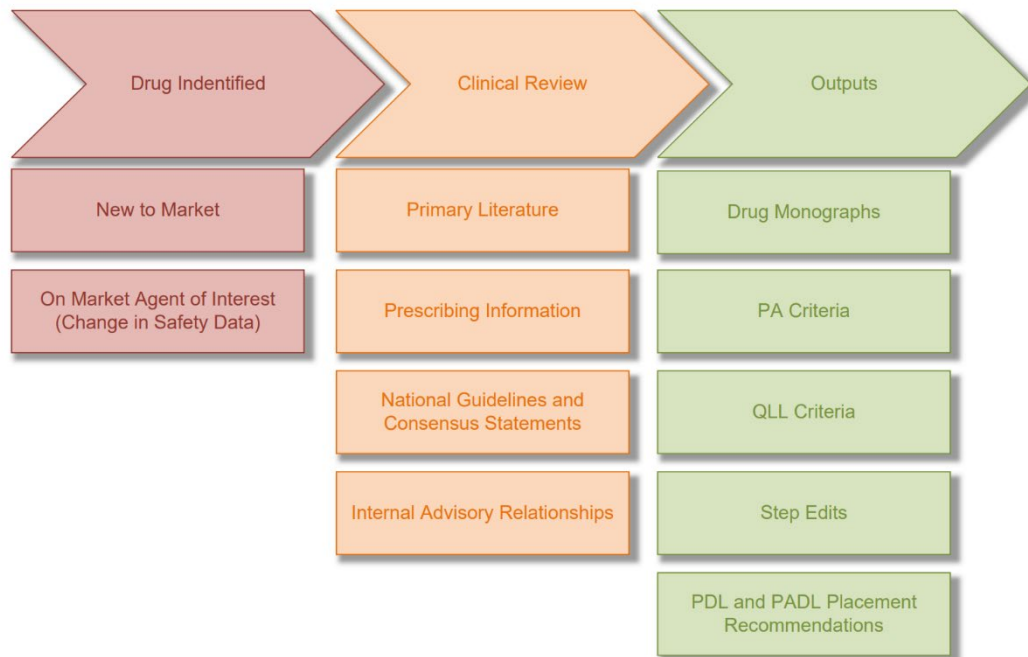


Figure MSQ3: NHC offers a suite of service offerings that support appropriate usage, cost containment, and waste avoidance/diversion.

Clinical Approach

NHC's robust clinical approach to UM criteria development starts with our team of experienced clinicians. Their development of a customized UM approach involves:

- review, analysis, and synthesis of primary clinical literature;
- clinical trial design;
- prescribing information;
- product monographs;
- nationally recognized guidelines;
- expert consensus statements; and
- internal advisory relationships with State-approved specialists.

Equipped with this information – and our experience and clinical training – NHC drafts clinically appropriate criteria for review by the State and the State Advisory Board (SAB). This process is performed for each new product, when new indications are approved for existing products, and often occurs concurrently with drug monograph



development for PDL review and inclusion. When appropriate, our comprehensive review includes QLLs, Step Edits, and PDL placement to ensure appropriate utilization.

NHC provides recommendations for quantity limits for all new products as well as existing products with changes to dosage regimens or formulations, if appropriate. QLL recommendations are made based on:

- FDA-approved package labeling,
- medical compendia, and
- current peer-reviewed medical literature.

Quantity limits reflect:

- FDA-approved maximum recommended dosage,
- frequency of administration,
- duration of therapy,
- available dosage strengths,
- available package sizes, and
- dose modifications due to drug interactions or adverse effects.

State Policy & Partners

NHC adheres to the State's policy regarding the length of time a product is required to be on the market prior to its eligibility for review by the SAB. On a rolling annual basis, NHC reviews and updates criteria as needed or more frequently in response to significant developments within a drug class or disease state. Additionally, NHC has experience fostering collaborative relationships with states' rebate vendors – assisting the State with financial modeling including for example, break even analyses. Partnering with a state's rebate vendor allows us to make certain that criteria recommendations align with supplemental rebate contracting, thus ensuring recommendations to the State are prudent from both a clinical and a fiscal perspective. More recently, NHC has assisted the State with ensuring Value Based Contracting language is consistent with and free from conflict with UM criteria.

State Review

Once an in-depth product review taking all the above into consideration is complete, NHC submits the proposed UM criteria to the State and the SAB, if applicable. Typically, included in our proposal are draft prior authorization criteria incorporating any FDA-approved indications as well as off label indications, if applicable, clinical study results and inclusion criteria, and other pertinent clinical information that demonstrates the



justification and rationale for our recommendation. All criteria and UM recommendations are referenced when possible.

If applicable, quantity level limits are embedded within prior authorization criteria or may be recommended even if a product does not require pre-approval. Step edits may also be proposed and will be developed and detailed in a format similar to the creation of prior authorization criteria. Depending upon the structure of the review and approval process for each state, NHC may present our recommendations during SAB meetings or directly to the State. To facilitate this portion of the process, NHC provides an automated workflow tool wherein the State conducts its review and final approval of any additions or updates as part of the UM program.

Once a final decision and approval of proposed UM criteria has been made by the State, NHC crafts web-based prior authorization criteria (if applicable) for upload to the State's website. The purpose of the web-based criteria is to provide a general overview of the clinical rationale and approval requirements. This high-level summary serves as a guide to stakeholders, including providers, to assist with optimization of therapy. Additionally, the web-based criteria may serve as a contractual requirement for supplemental rebate purposes. NHC can also provide criteria in a decision tree format to assist with decision making and ensure fidelity and consistency across prior authorization reviewers. Any approved or updated QLLs and/or step edits will be communicated to the Pharmacy Benefits Administrator (PBA) for notation on the PDL and system coding. Specific QLL criteria will be updated and included within a document for reference by providers.

State Specific Customization

NHC clinicians have experience with multiple Medicaid programs and are aware that all programs have unique characteristics reflective of the state and its population. As such, we customize our approach to UM development and management to meet each State's requirements and will maintain and adhere to State-specific policies and procedures for the development, implementation, and execution of UM programs.

Based on our efforts with other states, applying our methodology for UM program design has resulted in the successful implementation and execution of effective UM strategies for rebateable products typically covered under the outpatient drug benefit – whether existing or new-to-market products. However, we offer additional experience and expertise in crafting effective UM strategies to address:

- durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS);
- provider administered drugs (PAD);
- compliance with early and periodic screening, diagnosis, and treatment (EPSDT) requirements; and



- products subject to “white” or “brown” bagging which are at increased risk for duplicative claims to the State.

For example, NHC has successfully reviewed utilization data and available information in drafting proposed UM criteria for:

- continuous glucose monitors,
- ventilation devices,
- leg stretchers,
- metabolic formulas, and
- gene therapies.

Our efforts do not stop upon approval of a UM approach. NHC ensures the presence of qualified members of our team, who have been intimately involved in developing the UM criteria, at any meetings as required by the State. We further assist the State with fielding and responding to inquiries and complaints from stakeholders.



MSQ3.1 – QLL Utilization Management Criteria

Policy and Procedure: Quantity Level Limit (QLL) Exception

Requestor: State

Creation Date: December 22, 2022

Last Reviewed: January 2023

Approved Date: February 2023

Created By: Lead Pharmacist

Policy Type: Prior Authorization Criteria

Policy Name: Quantity Level Limit (QLL) Exception

Requestor: State Fee-For-Service Medicaid

Length of Authorization: 12 months; 3 months for loading dose or titration

Description:

Quantity Level Limits (QLL) are established based on:

- Dosage recommendations from FDA-approved product labeling or CMS-approved compendia for off-label use
- Commercially available dosage strengths and duration of therapy in clinical practice
- Dose efficiency, which advises the use of a single higher strength drug rather than multiple lower strength drugs

The prior authorization process allows prescribers to submit exception requests for review if there is sufficient clinical justification to exceed established quantity limits. These requests will be reviewed based on the criteria below.

Criteria for Exceeding Quantity Level Limit (QLL):

- ❖ Requests to exceed established Quantity Level Limits (QLL) are approvable when *all* of the following conditions are met:



- i. The patient has an FDA-labeled indication or an off-label indication that is supported in CMS approved compendia for the requested medication
- ii. One of the following:
 - a. The requested dose cannot be achieved with a lower quantity of a higher strength that does not exceed the plan quantity limit
 - b. The patient is being prescribed a drug dosed by weight or body surface area and requires a greater quantity to achieve the appropriate dose
 - c. The patient has a documented history of treatment failure with the requested drug being prescribed within plan quantity limits
 - d. The request is for continuation of therapy on the requested dose where patient is stable and not experiencing any adverse side effects
 - e. The request is for a temporary loading dose or dose titration
- iii. The prescriber has provided clinical literature in support of therapy with a higher dose for the requested indication

4. **Bookmark Title: MSQ4 – Utilization Management Criteria Structure**

Bookmark Title for Supporting Material:

- **MSQ4.1 – Utilization Management Process Visual**
- **MSQ4.2 – Utilization Management Algorithm Examples**
- **MSQ4.3 – QLL Override Criteria**

Narrative description is limited to two (2) pages, not including the required supporting material.

Describe in detail how Utilization Management criteria will be structured as outlined, but not limited to, the requirements stated in Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program.

Provide the following supporting material:

- a. Visual of Utilization Management Process that supports the State's requirements as described in the SOW.
- b. Examples of Utilization Management criteria developed for HIV atypical anti-psychotics and GLP-1 antagonists.
- c. Examples of quantity level limit (QLL) override criteria for four (4) classes of drugs of therapeutic categories that should require a QLL.

As a part of NorthStar HealthCare Consulting's (NHC) approach to the Utilization Management (UM) Program, the structure of the UM criteria provides a foundational guideline for the provision of the most appropriate utilization of included products. Our approach was crafted based on post-doctoral training in drug literature evaluation and formulary management coupled with decades of Medicaid Fee-for-Service and Managed Care experience. Included in this training were principles derived from Primers in Formulary Management from the American Academy of Managed Care Pharmacy and the Principles of a Sound Drug Formulary System from the American Society of Health-System Pharmacists. As such, our approach to UM criteria development and presentation is stepwise and incremental and is displayed in a logical format that has been standardized over the years based on best practices derived from our clinical engagements from other Medicaid programs and clients.

Our approach to UM criteria development and presentation is stepwise and incremental and is displayed in a logical format that has been standardized based on best practices.

The development of UM criteria commences with the identification of new medications or new indications of existing products, which typically occur during weekly meetings with the Pharmacy Benefits Administrator (PBA) Vendor and the client.



Upon identification, new products will be evaluated comprehensively to provide a robust and inclusive recommendation to the State and the State Advisory Board (SAB) regarding the product's place in therapy and its appropriate utilization. As a part of our evaluation, NHC will conduct a total class review to assess comparator products for the following:

- efficacy
- medical appropriateness
- quality of life
- safety
- cost

After completing the above assessment, NHC will craft a new drug monograph. The monograph will be presented to the State and SAB to facilitate discussions and inform decisions regarding:

- Preferred Drug List (PDL) placement,
- Provider Administered Drug List (PADL) placement,
- Quantity Level Limits (QLL),
- Step Edits, and
- UM criteria.

The structure of our drug monographs, and by extension any resulting UM criteria, follow a stepwise approach. The structure of the monograph can be divided into three main sections:

- 1. Background Information:** may include the brand and generic name of the product, FDA approval and market availability dates, the manufacturer, indication, and available strengths and formulations.
- 2. Safety and Clinical Efficacy:** focuses on clinical and safety data and typically begins with a disease state review followed by the safety data which is often summarized from the package labeling and pivotal trials. The clinical efficacy is presented in a tabular format and relies on primary literature that meet the pre-determined criteria for monograph inclusion. Summaries of selected randomized controlled clinical trials will focus on study design including primary outcomes and statistical outcomes.
- 3. Interpretation and Application:** focus on interpretation and application of the previous information including place in therapy, recommendations for UM criteria (PA criteria, QLLs, step edits), and a summary paragraph referencing PDL placement.

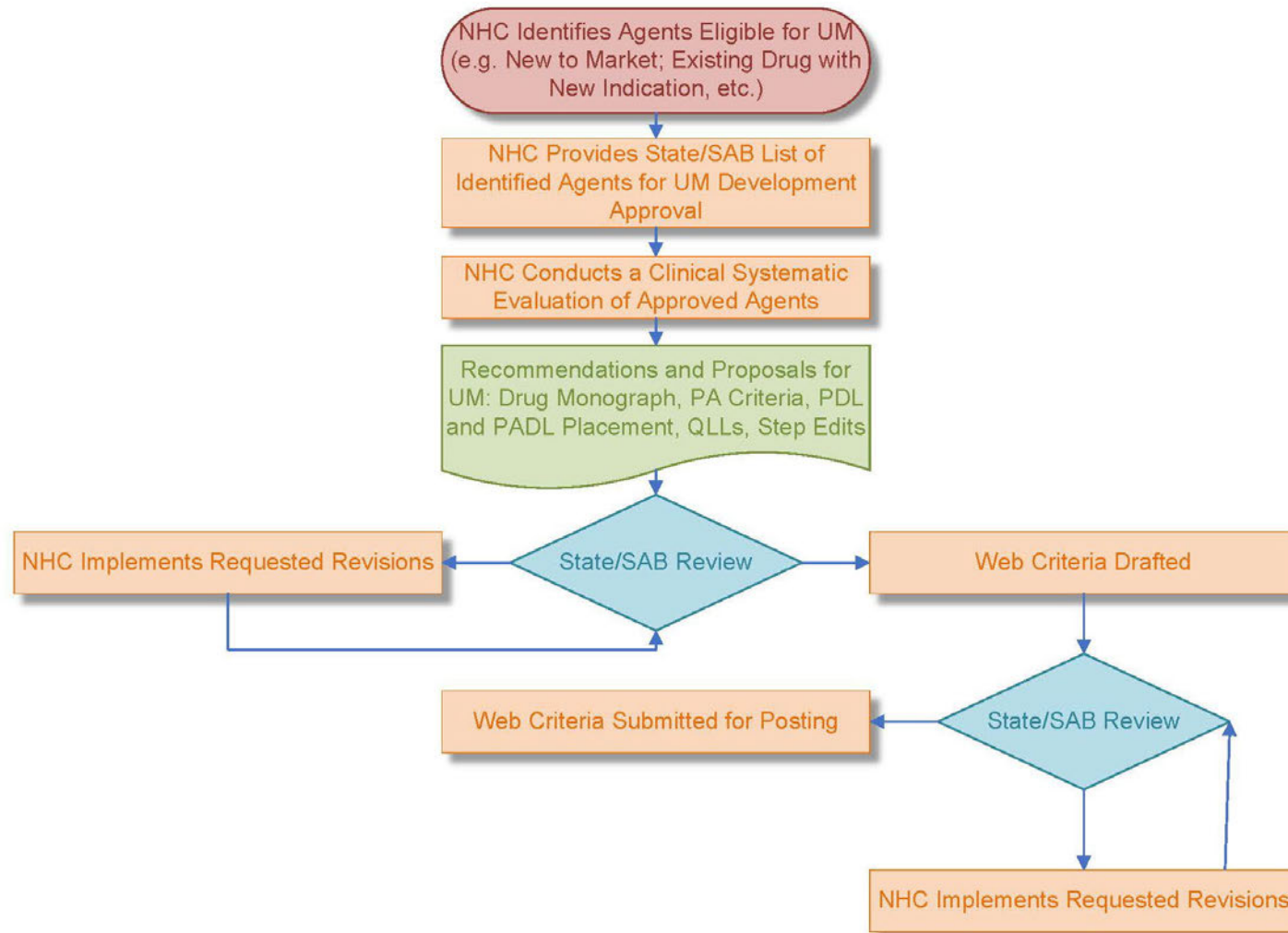
As UM criteria is determined for new products, existing criteria for comparator products should be simultaneously reevaluated and updated as needed. All UM criteria will be



developed and submitted for approval to the State in two formats. One version will be formatted for posting on the State's website to provide stakeholders with a general idea of how the product is managed by the State. The other will be formatted as an algorithm-based criteria for use in coverage determinations by the PBA's call center.

Throughout the life of the contract, NHC will review all UM criteria on a rolling annual basis. The annual review will include, as needed, updating UM algorithm criteria for each therapeutic class, any UM form, and web-based UM criteria. Any resulting updates will be finalized and submitted to the State for review, approval, and posting.

MSQ4.1 – Utilization Management Process Visual





MSQ4.2 – Utilization Management Algorithm Examples

This document begins on the following page.



PA Criteria Category/Drug: HIV-AIDS

Length of authorization: Varies

Medications

PDL Status	
Preferred (may not be all inclusive)	Non-Preferred
Abacavir generic	Abacavir/lamivudine/zidovudine generic
Abacavir/lamivudine generic	Aptivus (tipranavir)
Atazanavir capsules generic	Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)	Fuzeon (enfuvirtide)
Cimduo (lamivudine/tenofovir disoproxil fumarate)	Intelence (etravirine)
Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate)	Invirase (saquinavir)
Descovy (emtricitabine/tenofovir alafenamide)	Lexiva (fosamprenavir)
Dovato (dolutegravir/lamivudine)	Nevirapine extended-release generic
Edurant (rilpivirine)*	Norvir Solution (ritonavir)
Efavirenz tablets generic	Pifeltro (doravirine)
Efavirenz/emtricitabine/tenofovir disoproxil fumarate generic	Reyataz Powder (atazanavir)
Emtriva (emtricitabine)	Rukobia (fostemsavir)
Epivir solution (lamivudine)	Selzentry (maraviroc)
Evotaz (atazanavir/cobicistat)*	Stavudine generic^
Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)	Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate)
Isentress and Isentress HD (raltegravir)*	Sunlenca tablets (lenacapavir)
Juluca (dolutegravir/rilpivirine)	Symfi (efavirenz 600 mg/lamivudine/tenofovir disoproxil fumarate)
Lamivudine generic	Symfi Lo (efavirenz 400 mg/lamivudine/tenofovir disoproxil fumarate)
Lamivudine/zidovudine generic	Temixys (lamivudine/tenofovir disoproxil fumarate)
Lopinavir/ritonavir generic	Viracept (nelfinavir)
Nevirapine immediate-release tablets generic	
Norvir Powder (ritonavir)	
Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)*	
Prezcobix (darunavir/cobicistat)*	
Prezista (darunavir)*	
Ritonavir tablets generic	
Sustiva capsules (efavirenz)	
Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)	
Tenofovir disoproxil fumarate generic	
Tivicay (dolutegravir tablets)	



Tivicay PD (dolutegravir tablets for oral suspension)*	
Triumeq (dolutegravir/abacavir/lamivudine)	
Triumeq PD (dolutegravir/abacavir/lamivudine tablets for oral suspension)	
Trizivir (abacavir/lamivudine/zidovudine)	
Emtricitabine/tenofovir disoproxil fumarate generic	
Tybost (cobicistat)*	
Viramune Suspension (nevirapine)	
Viread Powder and Tablets 150 mg, 200 mg, 250 mg (tenofovir disoproxil fumarate)	
Ziagen Solution (abacavir)	
Zidovudine generic	

*preferred but requires PA; ^non-preferred but does not require PA

- **Note:** Edurant, Evotaz, Isentress, Odefsey, Prezcoibix, Prezista, Tivicay PD and Tybost are preferred but require prior authorization.
- **Grandfathering:** For all prior authorized products except Isentress chewable (25 mg and 100 mg) for patients 12 years of age and older and Sunlenca tablets, look back 365 days in claims history for same product (not specific to strength) to bypass reject 75.
- **Step Edit:** Aptivus, Invirase and Viracept - For ages 2 years and older, look back 365 days for 2 protease inhibitor claims to bypass reject 75.
- **Step Edit:** Evotaz and Prezcoibix – For ages 12 years and older, look back 365 days for a claim from the antiretroviral drug class to bypass reject 75.
- **Step Edit:** Fuzeon - For ages 6 years and older, look back 365 days for 2 claims from the antiretroviral drug class to bypass reject 75.
- **Step Edit:** Intencele – For ages 6 years and older, look back 365 days for 2 non-nucleoside transcriptase inhibitor claims to bypass reject 75.
- **Step Edit:** Lexiva - For ages 6 months and older, look back 365 days for 2 protease inhibitor claims to bypass reject 75.
- **Step Edit:** Prezista - For ages 3 years and older, look back 365 days for a protease inhibitor claim to bypass reject 75.
- **Step edit:** Tybost – For ages 18 years and older, look back 365 days for a claim for atazanavir or darunavir to bypass reject 75.
- **Note:** Emergency override allowed for generic abacavir/lamivudine/zidovudine if brand Trizivir is unavailable—go to the following criteria: Emergency Override for Non-Preferred Generics.

Criteria

Abacavir/Lamivudine/Zidovudine Generic

1. Inform the caller that brand Trizivir is preferred.

If caller agrees = CANCEL the PA request.

If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, brand Trizivir, is not appropriate for the member.



Aptivus

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.
If NO = Go to next question.

2. What is the member's age?

If 2 years or older = Go to next question.
If less than 2 years = DENY and refer to RPH.

3. Is the member resistant to at least 2 other protease inhibitors (PIs)?

Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir (Prezista, Prezcofix), fosamprenavir (Lexiva), lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), and saquinavir (Invirase).

If YES = Go to next question.
If NO = DENY and refer to RPH.

4. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medications but will not be used in combination with efavirenz (Intelence)?

Efavirenz concentration may be significantly reduced by ritonavir-boosted tipranavir and coadministration is not recommended in the DHHS guidelines.

If YES = APPROVE for 1 year.
If NO = DENY and refer to RPH.

Complera

1. What is the member's age?

If 12 years or older = Go to next question.
If less than 12 years = DENY and refer to RPH.

2. What is the member's weight in kilograms (kg)?

If 35 kg or greater = Go to next question.
If less than 35 kg = DENY and refer to RPH.

3. Is the member using this medication for prophylaxis following exposure to HIV?

If YES = APPROVE for 1 month.
If NO = Go to next question.

4. Is the member HIV treatment-naïve (has not used other antiretrovirals previously)?

If YES (treatment-naïve) = Go to next question.
If NO (treatment-experienced) = Go to question 7.

5. What is the member's baseline HIV-RNA level?

If less than or equal to 100,000 copies/ml = Go to next question.
If greater than 100,000 copies/ml = DENY and refer to RPH.

6. What is the member's baseline CD4+ cell count?

If less than 200 cells/mm³ = DENY and refer to RPH. If greater than or equal to 200 cells/mm³ = Go to question 8. 7. Has the member experienced consistent viral suppression (HIV RNA <50 copies/mL) for ≥6 months with no history of virologic failure? If YES = Go to next question. If NO = DENY and refer to RPH. 8. In all calls, inform caller that Odefsey and Edurant taken with Descovy or emtricitabine/tenofovir disoproxil fumarate generic are preferred. If caller agrees = CANCEL this request and APPROVE Odefsey or Edurant (Descovy and emtricitabine/tenofovir disoproxil fumarate generic do not require PA) for 1 year. If caller disagrees = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, Odefsey and Edurant taken with Descovy or emtricitabine/tenofovir disoproxil fumarate generic, are not appropriate for the member.

Edurant

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program? If YES = APPROVE for 1 year. If NO = Go to next question. 2. What is the member's age? If 12 years or older = Go to next question. If less than 12 years = DENY and refer to RPH. 3. What is the member's weight in kilograms (kg)? If 35 kg or greater = Go to next question. If less than 35 kg = DENY and refer to RPH. 4. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more antiretroviral medications? If YES = APPROVE for 1 month. If NO = Go to next question. 5. Is the member HIV treatment-naïve (has not used other antiretrovirals previously)? If YES (treatment-naïve) = Go to next question. If NO (treatment-experienced) = Go to question 8. 6. What is the member's baseline HIV-RNA level? If less than or equal to 100,000 copies/ml = Go to next question. If greater than 100,000 copies/ml = DENY and refer to RPH. 7. What is the member's baseline CD4+ cell count? If less than 200 cells/mm³ = DENY and refer to RPH. If greater than or equal to 200 cells/mm³ = Go to question 9. 8. Has the member experienced consistent viral suppression (HIV RNA <50 copies/mL) for ≥6 months with no history of virologic failure? If YES = Go to next question.



If NO = DENY and refer to RPH.

9. Will the medication be used in combination with one or more antiretroviral medications?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Evotaz and Prezcofix

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.

If NO = Go to next question.

2. What is the member's age?

If 12 years or older = Go to next question.

If less than 12 years = DENY and refer to RPH.

3. Will the medication be used in combination with one or more antiretroviral medications?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH

Fuzeon and Intelence

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.

If NO = Go to next question.

2. What is the member's age?

If 6 years or older = Go to next question.

If less than 6 years of age = DENY and refer to RPH.

3. Has the member used antiretroviral medications previously (i.e. Is the member treatment-experienced)?

If YES = Go to question 5.

If NO = Go to next question.

4. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more antiretroviral medications?

If YES = APPROVE for 1 month.

If NO = DENY and refer to RPH.

5. Which medication is being requested?

If Fuzeon = Go to next question.

If Intelence = Go to question 8.

6. Is the member resistant to at least 2 HIV treatments?

If YES = Go to next question.

If NO = DENY and refer to RPH.

7. Will the medication be used in combination with one or more antiretroviral medications?

If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
8. Is the member resistant to at least 2 other non-nucleoside reverse transcriptase inhibitors (NNRTIs)? <i>Other NNRTIs may include but not limited to delavirdine (Rescriptor), efavirenz (Sustiva, Atripla), nevirapine (Viramune, Viramune XR), rilpivirine (Edurant, Complera, Odefsey).</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
9. Will the medication be used in combination with one or more antiretroviral medications but will not be used in combination with tipranavir (Aptivus), atazanavir (Reyataz) or fosamprenavir (Lexiva)? <i>Concentrations of etravirine, tipranavir, atazanavir or fosamprenavir may be altered when etravirine is used in combination with tipranavir, atazanavir or fosamprenavir and coadministration is not recommended in the DHHS guidelines.</i>
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Invirase

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 2 years or older = Go to next question. If less than 2 years = DENY and refer to RPH.
3. Is the member resistant to at least 2 other protease inhibitors (PIs)? <i>Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir (Prezista, Prezcoibix), fosamprenavir (Lexiva) lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), and tipranavir (Aptivus).</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medications?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Isentress, Isentress HD and Selzentry

1. Are Isentress chewable tablets (25 mg or 100 mg) or powder being requested?
If YES = Go to question 10. If NO = Go to next question.
2. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?



If YES = APPROVE for 1 year. If NO = Go to next question.
3. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more antiretroviral medications?
If YES = APPROVE for 1 month. If NO = Go to next question.
4. Which medication is being requested?
If Isentress 400 mg tablets = Go to question 6. If Isentress HD 600 mg tablets = Go to question 16. If Selzentry = Go to next question.
5. What is the member's age?
If 12 years or older = Go to question 7. If 2 to 11 years = Go to question 7. If less than 2 years = DENY and refer to RPH.
6. What is the member's age?
If 6 years or older = Go to question 9. If less than 6 years = DENY and refer to RPH.
7. Does the member have CCR5-tropic HIV-1 as indicated by tropism testing?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Will the medication be used in combination with one or more antiretroviral medications?
If YES = Go to question 13. If NO = DENY and refer to RPH.
9. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE Isentress 400 mg tablets for 1 year. If NO = DENY and refer to RPH.
10. What is the member's age?
If 12 years or older = Go to next question. If less than 12 years = Go to question 12.
11. Inform the caller that Isentress 400 mg Tablets should be used based on age-appropriate dosing.
If caller agrees = CANCEL this request and PROCEED to question 9. If caller refuses = DENY and refer to RPH. Inform prescriber that in addition to meeting the criteria for Isentress 400 mg Tablets above, a written letter of medical necessity must be submitted stating the reason(s) that Isentress 400 mg Tablets cannot be used.
12. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE Isentress chewable tablets or powder for 1 year. If NO = DENY and refer to RPH.
13. Which formulation is being requested?
If tablets = APPROVE for 1 year. If oral solution and member is aged 2 to 11 years (provided in question 5) = APPROVE for 1 year. If oral solution and member is aged 12 years or older (provided in question 5) = Go to next question.
14. Is the member unable to swallow solid oral dosage formulations (i.e., capsules, tablets)?
If YES = APPROVE for 1 year.



If NO = Go to next question.
15. Inform the caller that Selzentry tablets should be used.
If caller agrees = CANCEL this request and APPROVE Selzentry tablets for 1 year. If caller refuses = DENY and refer to RPH. Inform prescriber a written letter of medical necessity must be submitted stating the reason(s) that Selzentry tablets are not appropriate for the member.
16. What is the member's age?
If 18 years or older = Go to question 18. If less than 18 years = Go to next question.
17. What is the member's weight?
If 40 kg or greater = Go to next question. If less than 40 kg = DENY and refer to RPH.
18. Is the member treatment-naïve or virologically suppressed on Isentress 400 mg twice daily?
If YES = Go to next question. If NO = DENY and refer to RPH.
19. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE Isentress HD 600 mg tablets for 1 year. If NO = DENY and refer to RPH.

Lexiva

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 6 months or older = Go to next question. If less than 6 months = DENY and refer to RPH.
3. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more anti-HIV medications?
If YES = APPROVE for 1 month. If NO = Go to next question.
4. Is the member resistant to at least 2 other protease inhibitors (PIs)?
<i>Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir (Prezista, Prezcoibix), lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), saquinavir (Invirase), and tipranavir (Aptivus).</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
5. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medications but will not be used in combination with etravirine (Intelence)?
<i>Etravirine may alter the concentration of fosamprenavir and coadministration is not recommended in the DHHS guidelines.</i>



If YES = APPROVE for 1 year.
If NO = DENY and refer to RPH.

Nevirapine ER Generic

1. Inform the caller that generic nevirapine immediate-release is preferred.

If caller agrees = CANCEL the PA request.
If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, generic nevirapine immediate-release, is not appropriate for the member.

Norvir Solution

1. Is the member unable to swallow solid oral dosage formulations (i.e., tablets) and requires a dose that cannot be obtained by generic ritonavir tablets and brand Norvir Powder?

If YES = APPROVE for 1 year.
If NO = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, generic ritonavir tablets and brand Norvir Powder, are not appropriate for the member.

Odefsey

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.
If NO = Go to next question.

2. What is the member's age?

If 12 years or older = Go to next question.
If less than 12 years = DENY and refer to RPH.

3. What is the member's weight in kilograms (kg)?

If 35 kg or greater = Go to next question.
If less than 35 kg = DENY and refer to RPH.

4. Is the member using this medication for prophylaxis following exposure to HIV?

If YES = APPROVE for 1 month.
If NO = Go to next question.

5. Is the member HIV treatment-naïve (has not used other antiretrovirals previously)?

If YES (treatment-naïve) = Go to next question.
If NO (treatment-experienced) = Go to question 8.

6. What is the member's baseline HIV-RNA level?

If less than or equal to 100,000 copies/ml = Go to next question.
If greater than 100,000 copies/ml = DENY and refer to RPH.

7. What is the member's baseline CD4+ cell count?

If less than 200 cells/mm³ = DENY and refer to RPH.

If greater than or equal to 200 cells/mm³ = APPROVE for 1 year.

8. Has the member experienced consistent viral suppression (HIV RNA <50 copies/mL) for ≥6 months with no history of virologic failure?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Pifeltro

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.

If NO = Go to next question.

2. What is the member's age?

If 18 years or older = Go to next question.

If less than 18 years = DENY and refer to RPH.

3. Is the member antiretroviral treatment-naïve or is the member virologically suppressed (HIV RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the requested medication?

If YES = Go to next question.

If NO = DENY and refer to RPH.

4. Will the medication be used in combination with strong CYP 3A inducers?

Strong CYP 3A inducers may include but not limited to carbamazepine, oxcarbazepine, phenobarbital, phenytoin, enzalutamide, rifampin, rifapentine, mitotane and St John's wort.

If YES = DENY and refer to RPH.

If NO = Go to next question.

5. Will the medication be used in combination with one or more antiretroviral medications?

If YES = Go to next question.

If NO = DENY and refer to RPH.

6. Is the member resistant to bictegravir, emtricitabine or tenofovir alafenamide (Biktarvy)?

The DHHS HIV guidelines recommend HIV drug-resistance testing at entry into care for persons with HIV to guide selection of the initial antiretroviral therapy (ART) regimen.

If YES = Go to question 8.

If NO = Go to next question.

7. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to bictegravir, emtricitabine or tenofovir alafenamide (Biktarvy)?

If YES = Go to next question.

If NO = DENY and refer to RPH. Inform prescriber that a written letter of medication necessity must be submitted stating the reasons the preferred product, Biktarvy, is not appropriate for the member.

8. Is the member resistant to lamivudine or tenofovir disoproxil fumarate (in Delstrigo)?

If YES = APPROVE for 1 year.

If NO = Go to next question.

9. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to



lamivudine or tenofovir disoproxil fumarate (in Delstrigo)?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH. Inform prescriber that a written letter of medication necessity must be submitted stating the reasons the preferred product, Delstrigo, is not appropriate for the member.

Prezista

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.

If NO = Go to next question.

2. What is the member's age?

If 3 years or older = Go to next question.

If less than 3 years = DENY and refer to RPH.

3. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medication(s)?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Reyataz Powder

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.

If NO = Go to next question.

2. What is the member's age?

If 3 months or older = Go to next question.

If less than 3 months = DENY and refer to RPH.

3. What is the member's weight?

If 5 kg to less than 25 kg = APPROVE for 1 year.

If 25 kg or more = Go to next question.

If less than 5 kg = DENY and refer to RPH.

4. Is the member unable to swallow solid oral dosage formulations (i.e., capsules, tablets)?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Rukobia

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.

If NO = Go to next question.



2. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
3. Is the member heavily-treatment experienced with multidrug-resistant HIV-1 infection?
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Is the member failing their current antiretroviral regimen due to resistance, intolerance or safety considerations?
If YES = Go to next question. If NO = DENY and refer to RPH.
5. What is the member's viral load?
If ≥ 400 copies/mL = Go to next question. If < 400 copies/mL = DENY and refer to RPH.
6. How many classes of antiretroviral medications are remaining that the member can take?
If ≤ 2 classes = Go to next question. If > 2 classes = DENY and refer to RPH.
7. Will the medication be used in combination with one or more other antiretroviral medications?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Will the medication be coadministered with strong CYP3A inducers?
<i>Strong CYP3A inducers may include but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane and St John's wort.</i>
If YES = DENY and refer to RPH. If NO = APPROVE for 1 year.

Stribild

1. Inform the caller that Genvoya is preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, Genvoya, is not appropriate for the member.

Sunlenca

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 8 days. If NO = Go to next question.
2. Has the member been on Sunlenca injection, and it has been more than 28 weeks since the last injection?
If YES = APPROVE for 8 days.



If NO = Go to next question.
3. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
4. Is the member heavily-treatment experienced with multidrug-resistant HIV-1 infection?
If YES = Go to next question. If NO = DENY and refer to RPH.
5. Is the member failing their current antiretroviral regimen due to resistance, intolerance or safety considerations?
If YES = Go to next question. If NO = DENY and refer to RPH.
6. What is the member's viral load?
If ≥ 400 copies/mL = Go to next question. If < 400 copies/mL = DENY and refer to RPH.
7. How many classes of antiretroviral medications are remaining that the member can take?
If ≤ 2 classes = Go to next question. If > 2 classes = DENY and refer to RPH.
8. Will the medication be used in combination with one or more other antiretroviral medications?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. Will the medication be coadministered with strong CYP3A inducers?
<i>Strong CYP3A inducers may include but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane and St John's wort.</i>
If YES = DENY and refer to RPH. If NO = APPROVE for 8 days.

Symfi and Symfi Lo

1. Inform the caller that the individual products, efavirenz generic, lamivudine generic and tenofovir disoproxil fumarate generic, are preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, efavirenz generic, lamivudine generic and tenofovir disoproxil fumarate generic, are not appropriate for the member.

Temixys

1. Inform the caller that Cimduo and lamivudine generic with tenofovir disoproxil fumarate generic are preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, Cimduo and lamivudine generic with tenofovir disoproxil fumarate generic, are not appropriate for the member.



Tivicay PD

1. What is the member's age?

If 4 weeks to <18 years = Go to next question.
If younger than 4 weeks = DENY and refer to RPH.
If 18 years or older = DENY and refer to RPH.

2. What is the member's weight?

If 3 kg to <20 kg = APPROVE for 1 year.
If 20 kg to <25 kg = Go to next question.
If less than 3 kg = DENY and refer to RPH.
If 25 kg or more = DENY and refer to RPH.

3. Is the member unable to swallow solid oral dosage formulations (i.e., tablets, capsules)?

If YES = APPROVE for 1 year.
If NO = DENY and refer to RPH.

Tybost

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.
If NO = Go to next question.

2. What is the member's age?

If 18 years or older = Go to next question.
If less than 18 years = DENY and refer to RPH.

3. Will the medication be used in combination with atazanavir or darunavir?

If YES = APPROVE for 1 year.
If NO = DENY and refer to RPH

Viracept

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year.
If NO = Go to next question.

2. What is the member's age?

If 2 years or older = Go to next question.
If less than 2 years = DENY and refer to RPH.

3. Is the member resistant to at least 2 other protease inhibitors (PIs)?

Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir



(Prezista, PrezcoBix), fosamprenavir (Lexiva), lopinavir/ritonavir (Kaletra), saquinavir (Invirase), and tipranavir (Aptivus).

If YES = Go to next question.

If NO = DENY and refer to RPH.

4. Will the medication be used with other antiretroviral medications?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

References

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6. Centers for Disease Control and Prevention. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States – 2021 update: A Clinical Practice Guideline. U.S. Department of Health and Human Services. Available at <https://stacks.cdc.gov/view/cdc/112360>. Last accessed November 2, 2023.
7. Centers for Disease Control and Prevention. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016. U.S. Department of Health and Human Services. Available at <http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>. Last accessed November 2, 2023.
8. Centers for Disease Control and Prevention. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis – United States, Updated May 23, 2018. U.S. Department of Health and Human Services. Available at <https://stacks.cdc.gov/view/cdc/20711>. Last accessed November 2, 2023.

In the event of a denial, advise all callers of appeal rights and the reason for denial.



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PA Criteria Category/Drug: Atypical Antipsychotics

Length of authorization: 1 year

Medications

PDL Status	
Preferred	Non-Preferred
Oral Agents	
Aripiprazole tablets, oral solution generic	Abilify MyCite (aripiprazole tablets with sensor)
Asenapine sublingual tablets generic	Aripiprazole ODT generic
Clozapine tablets generic	Caplyta (lumateperone)
Fanapt (iloperidone)	Clozapine ODT generic
Lurasidone generic	Lybalvi (olanzapine and samidorphan)
Olanzapine tablets, ODT generic	Nuplazid (pimavanserin)
Paliperidone generic	Olanzapine/fluoxetine generic
Risperidone generic	Rexulti (brexpiprazole)
Quetiapine IR and ER generic	Secuado (asenapine transdermal patch)
Vraylar (cariprazine)	Versacloz (clozapine oral suspension)
Ziprasidone generic	
Injectable Agents	
Abilify Asimtufii (aripiprazole extended-release injection)*	n/a
Abilify Maintena (aripiprazole extended-release injection)*	
Aristada and Aristada Initio (aripiprazole lauroxil extended-release injection)*	
Geodon (ziprasidone short-acting injection)	
Invega Hafyera (paliperidone extended-release injection)*	
Invega Sustenna (paliperidone extended-release injection)*	
Invega Trinza (paliperidone extended-release injection)*	
Olanzapine short-acting injection generic	
Perseris (risperidone extended-release injection)*	
Risperdal Consta (risperidone long-acting injection)*	
Uzedy (risperidone extended-release injection)*	
Zyprexa Relprevv (olanzapine extended-release injection)*	

*Preferred injectable agents that require PA. *Non-preferred agent that does not require PA. IR=immediate-release; ER=extended-release; ODT=orally disintegrating tablets

- **Grandfathering:** Grandfathering in place for Abilify Asimtufii, Abilify Maintena, Aristada, Caplyta, Lybalvi, Invega Sustenna, Invega Trinza, Invega Hafyera, Nuplazid, Perseris, Rexulti, Risperdal Consta, Uzedy, Vraylar and Zyprexa Relprevv for patients within FDA-approved age indications, look back 365 days in claims history for same product (not specific to strength) to bypass reject 75.
- **Note:** For ziprasidone generic, PA is not required for members ≥ 18 yo. For risperidone/risperidone ODT/risperidone oral solution generic, PA is not required for members ≥ 5 yo with pervasive developmental disorders/autism or irritability associated with autism/PDD or for members ≥ 10 yo with other diagnoses. For quetiapine IR and ER generic, PA is not required for members ≥ 10 yo. For olanzapine/olanzapine ODT generic and lurasidone generic, PA is not required for members ≥ 13 yo. For clozapine generic, PA is not required for members ≥ 18 yo. For aripiprazole tablets and oral solution generic, PA is not required for members ≥ 6 yo with pervasive developmental disorders/autism, irritability associated with autism/PDD or Tourette's disorder or for members ≥ 10 yo with other diagnoses. For Fanapt, PA is not required for members ≥ 18 yo. For paliperidone generic, PA is not required for ≥ 12 yo
- **Automated PA Approval Process:** Risperidone/ODT/Oral Solution – Look for ages 5-9 years and diagnosis of pervasive developmental disorder (PDD)/autism or irritability associated with autism/PDD

to approve for 1 year. Vraylar – For 18 and older, look for Schizophrenia or Bipolar diagnosis to approve for 1 year OR look for MDD diagnosis and 1 antidepressant in the past 30 days to approve for 1 year.

- **Note: PAs for all atypical antipsychotics should be wildcarded at the GPI-12 EXCEPT Invega Sustenna, Invega Trinza, and Invega Haffera.**
 - Invega Sustenna, Invega Trinza, and Invega Haffera should be approved at the PA GPI List Level.
 - For Invega Sustenna approvals, use PA GPI List: GAMINVSUST
 - For Invega Trinza approvals, use PA GPI List: GAMINVTRIN
 - For Invega Haffera approvals, use PA GPI List: GAMINVHAFY
- **Note:** The Atypical Antipsychotic Prior Authorization (PA) Request Form is located on the State's website.

Criteria

Automated PA Approval Process Protocols

Drug Name	GPI	MSC
RISPERIDONE (tabs/tbdp/soln)-does not include microspheres	5907007000****	Y
VRAYLAR	5940001810****	n/a

Automated PA Approval Process CRITERIA QUESTIONS for Risperidone/ODT/oral solution generic

System Check 1: Age between 5 and 9 years (i.e. ≥ 5 to ≤ 9)

Yes = Go to SC2

No (all other ages) = Go to Manual Question 1

System Check 2: One of the following diagnosis codes: ICD-9 (299, 299.0, 299.00, 299.01, 299.1, 299.10, 299.11, 299.8, 299.80, 299.81, 299.9, 299.90, 299.91) or ICD-10 (F84.0, F84.3, F84.5, F84.8, F84.9)

Yes = APPROVE for 1 year

No = Go to Manual Question 1

Initial vs. Reauthorization Request for Aripiprazole tablets and oral solution generic (not ODT, Abilify MyCite, Abilify Maintena or Aristada), Caplyta, Clozapine generic, Clozapine ODT generic, Fanapt, Lurasidone generic, Lybalvi, Olanzapine/ODT generic (not Zyprexa Relprevv), Olanzapine/Fluoxetine generic, Paliperidone generic (not Invega Sustenna or Invega Trinza), Rexulti, Risperidone/ODT/oral solution generic (not Perseris or Risperdal Consta), Quetiapine IR and ER generic, Secuado, Versacloz, Vraylar, Ziprasidone generic

1. Is this an initial or reauthorization request?

Call center rep: Verification of prior authorization history required.

If initial = Go to appropriate criteria below based on drug being requested.

If reauthorization = Go to next question.



1. For PA Rep Only: Was the most recent prior authorization approved for a duration of therapy of 6 months or longer?
<i>Check for duration of therapy of most recent prior authorization required.</i>
If YES = Go to next question. If NO = Go to appropriate criteria below based on drug being requested.
3. Have the member's symptoms improved on therapy?
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the member continue to be routinely monitored for safety and effectiveness while on therapy?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Criteria for Oral Agents

Aripiprazole Tablets and Oral Solution Generic, Asenapine Sublingual Tablets Generic, Fanapt, Lurasidone Generic, Olanzapine/ODT Generic (not short-acting injection), Paliperidone Generic, Risperidone/ODT/Oral Solution Generic, Quetiapine IR Generic, Quetiapine ER Generic, Ziprasidone Generic

1. Which medication is being requested?
If ziprasidone generic = Go to next question. If risperidone/ODT/oral solution generic = Go to question 4. If quetiapine IR/ER generic = Go to question 3. If olanzapine/ODT generic or lurasidone generic = Go to question 6. If aripiprazole tablets or oral solution generic = Go to question 9. If Fanapt = Go to next question. If paliperidone generic = Go to question 11. If asenapine sublingual tablets = Go to question 12.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = APPROVE (PA is not required). If Ziprasidone QLL exceeds request is needed, go to the QLL criteria section for Ziprasidone below.
3. What is the member's age?
If less than 10 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 10 years or older = APPROVE (PA is not required). If a QLL exceeds or QLL low dose request is needed, go to the QLL criteria section for Quetiapine QLL Exceeded or Quetiapine Low Dose below.
4. What is the member's age?
If less than 5 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the



Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 5 to 9 years = Go to next question. If 10 years or older = APPROVE (PA is not required). If a QLL exceeds request is needed, go to the QLL criteria section for Risperidone below
5. What is the member's diagnosis?
If pervasive developmental disorder (PDD)/autism or irritability associated with autism/PDD = APPROVE (PA is not required). Please inform caller that the pharmacy can submit the claim with ICD-10 F84.0, F84.3, F84.5, F84.8, F84.9. If a QLL exceeds request is needed, go to the QLL criteria section for Risperidone below. If other diagnosis = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
6. What is the member's diagnosis?
If depressive episodes associated with bipolar disorder (bipolar depression) = Go to next question. If other diagnosis = Go to question 8.
7. What is the member's age?
If less than 10 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 10 years or older = APPROVE for 1 year. If a QLL exceeds request is needed, go to the QLL criteria section for Olanzapine or Olanzapine ODT below.
8. What is the member's age?
If less than 13 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 13 years or older = APPROVE (PA is not required). If a QLL exceeds requests needed, go to the QLL criteria section for Olanzapine or Olanzapine ODT below.
9. What is the member's age?
If less than 6 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 6 to 9 years = Go to next question. If 10 years or older = APPROVE (PA is not required).
10. What is the member's diagnosis?
If pervasive developmental disorder (PDD)/autism or irritability associated with autism/PDD = APPROVE (PA is not required). Please inform caller that the pharmacy can submit the claim with ICD-10 F84.0, F84.3, F84.5, F84.8, F84.9. If Tourette's disorder = APPROVE (PA is not required). Please inform caller that the pharmacy can submit the claim with ICD-10 F95.2. If other diagnosis = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
11. What is the member's age?



If less than 12 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 12 years or older = APPROVE (PA is not required).

12. What is the member's age?

If less than 10 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 10 to 17 years = Go to next question.

If 18 years or older = APPROVE (PA is not required).

13. What is the member's diagnosis?

If bipolar I disorder = APPROVE (PA is not required).

If other diagnosis = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

Abilify MyCite

1. What is the member's diagnosis?

If mixed or manic episodes associated with bipolar disorder = Go to question 3.

If schizophrenia or schizoaffective disorder = Go to question 3.

If adjunctive therapy for major depressive disorder (MDD, depression) = Go to question 4.

If other diagnosis = Go to next question.

2. What is the member's age?

If less than 18 years of age = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = DENY and refer to RPH.

3. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = Go to question 6.

4. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = Go to next question.

5. Is the member receiving another antidepressant to be used concurrently with Abilify MyCite?

Other antidepressants may include the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion,



mirtazapine, or trazodone.

If YES = Go to next question.
If NO = DENY and refer to RPH.

6. Inform the caller that generic aripiprazole tablets are preferred over Abilify MyCite.

If caller agrees = CANCEL this PA request and inform caller that aripiprazole tablets generic is preferred and does not require PA.
If caller refuses = Go to next question.

7. Please submit a letter of medical necessity stating the reasons generic aripiprazole tablets are not appropriate for the member.

If reasons are valid in letter of medical necessity = APPROVE for 1 year.
If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Aripiprazole ODT Generic

1. Inform the caller that generic aripiprazole tablets are preferred over aripiprazole ODT generic.

If caller agrees = CANCEL this PA request and inform caller that aripiprazole tablets generic is preferred and does not require PA.
If caller refuses = Go to next question.

2. Please submit a letter of medical necessity stating the reasons generic aripiprazole tablets are not appropriate for the member.

If reasons are valid in letter of medical necessity = APPROVE for 1 year.
If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Caplyta

1. What is the member's diagnosis?

If schizophrenia or schizoaffective disorder = Go to next question.
If depressive episodes associated with bipolar disorder (bipolar depression) = Go to question 9.
If other diagnosis = Go to question 3.

2. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = Go to question 4.

3. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = DENY and refer to RPH.

4. How long (if any time) has the member been taking the requested medication?

Faxed documentation of antipsychotic form is required.

If 2 weeks or more = Go to question 8 upon review of faxed antipsychotic form.
If <2 weeks = Go to next question.



If patient has not started requested medication = Go to question 6.
5. Have the member's symptoms improved on therapy?
<i>Faxed documentation of antipsychotic form is required.</i>
If YES = Go to question 8 upon review of faxed antipsychotic form. If NO = Go to next question.
6. Were any of the following: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, Vraylar, OR ziprasidone capsules (preferred products for same age group/diagnosis) ineffective in treating the member's condition?
If YES = Go to question 8. If NO = Go to next question.
7. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effects to at least 6 of the following: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, Vraylar, OR ziprasidone capsules (preferred products for same age group/diagnosis)?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
9. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = Go to next question.
10. How long (if any time) has the member been taking the requested medication?
<i>Faxed documentation of antipsychotic form is required.</i>
If 2 weeks or more = Go to question 8 upon review of faxed antipsychotic form. If <2 weeks = Go to next question. If patient has not started requested medication = Go to question 12.
11. Have the member's symptoms improved on therapy?
<i>Faxed documentation of antipsychotic form is required.</i>
If YES = Go to question 8 upon review of faxed antipsychotic form. If NO = Go to next question.
12. Was olanzapine given concurrently or in combination with fluoxetine, lurasidone, quetiapine, OR Vraylar ineffective in treating the member's condition?
If YES = Go to question 8. If NO = Go to next question.
13. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effect to olanzapine, fluoxetine, lurasidone, quetiapine, OR Vraylar?
If YES = Go to question 8. If NO = DENY and refer to RPH.

Clozapine Tablets Generic, Clozapine ODT Generic, Versacloz

1. What is the member's diagnosis?
If suicidal behavior associated with schizophrenia or schizoaffective disorder = Go to next question. If treatment-resistant (refractory) schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. Which medication is being requested?
If generic clozapine tablets = APPROVE (PA is not required). If a QLL exceeds request is needed, go to the QLL criteria section below. If generic clozapine ODT or Versacloz = Go to next question.
5. Inform the caller that generic clozapine tablets are preferred over generic clozapine ODT and Versacloz.
If caller agrees = CANCEL this PA request and inform caller that clozapine tablets generic is preferred and does not require PA. If caller refuses = Go to next question.
6. Please submit a letter of medical necessity stating the reasons generic clozapine tablets are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Lybalvi

1. What is the member's diagnosis?
If manic or mixed episodes associated with bipolar disorder = Go to next question. If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the



Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = DENY and refer to RPH.
4. How long (if any time) has the member been taking the requested medication?
<i>Faxed documentation of antipsychotic form is required.</i>
If 2 weeks or more = Go to question 10 upon review of faxed antipsychotic form. If <2 weeks = Go to next question. If patient has not started requested medication = Go to question 6.
5. Have the member's symptoms improved on therapy?
<i>Faxed documentation of antipsychotic form is required.</i>
If YES = Go to question 10 upon review of faxed antipsychotic form. If NO = Go to next question.
6. Is the member currently established on olanzapine/ODT as confirmed by claims history?
If YES = DENY and refer to RPH. Current evidence base for Lybalvi is limited to reduction of weight gain in people who are starting olanzapine as opposed to producing weight loss in people who have already gained weight on olanzapine. If NO = Go to next question.
7. Is the member expected to experience undesirable weight gain attributable to treatment with olanzapine/ODT?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Were ANY of the following: aripiprazole, Fanapt, lurasidone, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis), as confirmed by claims history, ineffective in treating the member's condition?
If YES = Go to question 10. If NO = Go to next question.
9. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effect (such as weight gain) to ANY of the following: aripiprazole, Fanapt, lurasidone, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis)?
If YES = Go to next question. If NO = DENY and refer to RPH.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Nuplazid

1. Has the member been started and stabilized on the requested medication from outside the plan (samples do not count)?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's diagnosis?
If hallucinations and/or delusions associated with Parkinson's disease psychosis = Go to next question. If dementia-related psychosis = DENY and refer to RPH. If other diagnosis = DENY and refer to RPH.

3. What is the member's age?
If 40 years or older = Go to next question. If less than 40 years = DENY and refer to RPH.
4. Does the member have QT prolongation or is the member taking a medication that can prolong the QT interval?
<i>Drugs known to prolong QT interval include Class 1A antiarrhythmics (e.g., quinidine, procainamide), Class 3 antiarrhythmics (e.g., amiodarone, sotalol), certain antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine) and certain antibiotics (e.g., gatifloxacin, moxifloxacin).</i>
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Has the prescribing physician attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms?
If YES = Go to next question. If NO = DENY and refer to RPH.
6. Will the member be on a concomitant antipsychotic while taking Nuplazid?
<i>Concomitant indicates that Nuplazid will be taken continuously with another antipsychotic medication. If an antipsychotic medication will be taken continuously with Nuplazid, the answer should be 'YES' and the PA request should be denied. If an antipsychotic medication is being tapered for discontinuation while starting Nuplazid, the answer should be 'NO.'</i>
If YES = DENY and refer to RPH. If NO = Go to next question.
7. Is the medication being prescribed by or in consultation with a geriatrician, neurologist or psychiatrist?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Olanzapine/Fluoxetine Generic

1. Inform the caller to use a preferred atypical antipsychotic and a preferred antidepressant as two separate products.
If caller agrees = CANCEL this PA request and inform caller that several atypical antipsychotics and antidepressants (including olanzapine and fluoxetine) are preferred and do not require PA. If caller refuses = Go to next question.
2. Please submit a letter of medical necessity stating the reasons a preferred atypical antipsychotic and a preferred antidepressant, used as two separate products, are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Rexulti

1. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If adjunctive therapy for major depressive disorder (MDD, depression) = Go to question 9. If agitation associated with dementia due to Alzheimer's disease = Go to question 13. If other diagnosis = Go to question 3.
2. What is the member's age?



If less than 13 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 13 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. How long (if any time) has the member been taking the requested medication? <i>Faxed documentation of antipsychotic form is required.</i>
If 2 weeks or more = Go to question 8 upon review of faxed antipsychotic form. If <2 weeks = Go to next question. If patient has not started requested medication = Go to question 6.
5. Have the member's symptoms improved on therapy? <i>Faxed documentation of antipsychotic form is required.</i>
If YES = Go to question 8 upon review of faxed antipsychotic form. If NO = Go to next question.
6. Were ANY of the following medications: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis) ineffective in treating the member's condition?
If YES = Go to question 8. If NO = Go to next question.
7. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effect to ANY of the following medications: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis)?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If a QLL exceeds request is needed, go to the QLL criteria section for Rexulti below. If NO = DENY and refer to RPH.
9. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to next question.
10. Has the member had an inadequate response to at least 1 antidepressant, aripiprazole or quetiapine extended release (preferred products for same age group/diagnosis)? <i>Antidepressants may include the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine,</i>

<i>fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion, mirtazapine, or trazodone.</i>
If YES = Go to next question. If NO = DENY and refer to RPH. Note: A prescriber may wish to submit an appeal (with letter of medical necessity, medical history, PA form, etc) to PBA vendor for a new member or a recently discharged (from inpatient care) member on a non-preferred medication for less than 2 weeks who is responding well and not appropriate for conversion.
11. Is the member receiving another antidepressant to be used concurrently with Rexulti?
<i>Other antidepressants may include but not limited to the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion, mirtazapine, or trazodone.</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
12. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If a QLL exceeds request is needed, go to the QLL criteria section for Rexulti below. If NO = DENY and refer to RPH.
13. What is the member's age?
If 40 years or older = Go to next question. If less than 40 years = DENY and refer to RPH.
14. Did the member have an inadequate response, allergy, contraindication, drug-drug interaction or intolerable side effect to at least one selective serotonin reuptake inhibitor (SSRI) or one preferred atypical antipsychotic (see table above)?
<i>SSRIs may include but not limited to citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline,</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
15. Is the medication being prescribed by or in consultation with a geriatrician, neurologist or psychiatrist?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Secuado

1. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the

Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = DENY and refer to RPH.
4. Inform the caller that generic asenapine sublingual tablets are preferred over Secuado.
If caller agrees = CANCEL this PA request and inform caller that asenapine sublingual tablets generic are preferred and do not require PA.
If caller refuses = Go to next question.
5. Please submit a letter of medical necessity stating the reasons generic asenapine sublingual tablets are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year.
If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Vraylar

1. What is the member's diagnosis?
If manic or mixed episodes associated with bipolar disorder = Go to next question.
If schizophrenia or schizoaffective disorder = Go to next question.
If depressive episodes associated with bipolar disorder (bipolar depression) = Go to question 4.
If adjunctive therapy for major depressive disorder (MDD, depression) = Go to question 5.
If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = APPROVE (PA is not required if Automated PA Approval Process criteria is met).
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = DENY and refer to RPH.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = APPROVE (PA is not required if Automated PA Approval Process criteria is met).
5. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = Go to next question.
6. Has the member had an inadequate response to at least 1 antidepressant, aripiprazole, OR quetiapine extended-release (preferred products for same age group/diagnosis)?
<i>Other antidepressants may include the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion,</i>

mirtazapine, or trazodone.
If YES = Go to next question. If NO = DENY and refer to RPH. Note: A prescriber may wish to submit an appeal (with letter of medical necessity, medical history, PA form, etc) to PBA vendor for a new member or a recently discharged (from inpatient care) member on a non-preferred medication for less than 2 weeks who is responding well and not appropriate for conversion.
7. Is the member receiving another antidepressant to be used concurrently with Vraylar?
<i>Other antidepressants may include but not limited to the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion, mirtazapine, or trazodone.</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Criteria for Injectable Agents

- Note:** For a listing of Community Service Board health centers, go to the website.

Abilify Asimtufii and Abilify Maintena

1. Where is the medication being administered?
If medication will be administered in the home = Go to next question. If medication will be administered in a long-term care facility = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If bipolar disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = DENY and refer to RPH.



5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Has the member been started and stabilized on the requested medication?
If YES = Go to question 10. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral aripiprazole?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Aristada and Aristada Initio

1. Where is the medication being administered?
If medication will be administered in the home = Go to next question. If medication will be administered in a long-term care facility = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the



Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Has the member been started and stabilized on Aristada?
If YES = Go to question 12. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral aripiprazole?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Which product is being requested?
If Aristada = Go to question 14. If Aristada Initio = Go to next question.
11. Is Aristada being initiated?
If YES = APPROVE Aristada Initio for one dose only. If NO = DENY and refer to RPH.
12. Which product is being requested?
If Aristada = Go to question 14. If Aristada Initio = Go to next question.
13. Is Aristada being re-initiated following a missed dose of Aristada?
If YES = APPROVE Aristada Initio for one dose only. If NO = DENY and refer to RPH.
14. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE Aristada only for 1 year. If NO = DENY and refer to RPH.

Invega Hafyera, Invega Sustenna and Invega Trinza

1. Where is the medication being administered?
If medication will be administered by a trained healthcare professional in the home, in a long-term care facility or other outpatient pharmacy setting = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question.



If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Which medication is being requested?
If Invega Sustenna = Go to next question. If Invega Trinza = Go to question 11. If Invega Hafyera = Go to question 12.
7. Has the member been started and stabilized on Invega Sustenna?
If YES = Go to question 13. If NO = Go to next question.
8. Has the member been noncompliant after a trial of oral paliperidone (Invega) or oral risperidone (Risperdal)?
If YES = Go to question 13. If NO = Go to next question.
9. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
10. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to question 13.
11. Has Invega Sustenna been established as adequate treatment for the member for at least 4 months?
<i>The member's last 2 doses of Invega Sustenna must be the same dosage strength to substantiate established, adequate treatment.</i>
If YES = Go to question 13. If NO = DENY and refer to RPH.



12. Has Invega Sustenna been established as adequate treatment for the member for at least 4 months or has Invega Trinza been established as adequate treatment for the member for at least 3 months?

The member's last 2 doses of Invega Sustenna must be the same dosage strength to substantiate established, adequate treatment.

If YES = Go to next question.

If NO = DENY and refer to RPH.

13. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Perseris and Uzedry

1. Where is the medication being administered?

If medication will be administered by a trained healthcare professional in the home, in a long-term care facility or other outpatient pharmacy setting = Go to next question.

If medication will be administered in a CSB (community service board health center) = Go to next question.

If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)

2. What is the member's diagnosis?

If schizophrenia or schizoaffective disorder = Go to next question.

If other diagnosis = Go to question 4.

3. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = Go to question 5.

4. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = DENY and refer to RPH.

5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?

If medication is being prescribed by or in consultation with a psychiatrist = Go to next question.

If other provider specialty = DENY and refer to RPH.

6. Has the member been started and stabilized on Perseris?

If YES = Go to question 10.

If NO = Go to next question.

7. Has the member been noncompliant after a trial of oral risperidone (Risperdal) or oral paliperidone (Invega)?

If YES = Go to question 10.

If NO = Go to next question.

8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?

If YES = Go to next question.

If NO = DENY and refer to RPH.

9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?

If YES = DENY and refer to RPH.

If NO = Go to next question.

10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Risperdal Consta

1. Where is the medication being administered?

If medication will be administered by a trained healthcare professional in the home, in a long-term care facility or other outpatient pharmacy setting = Go to next question.

If medication will be administered in a CSB (community service board health center) = Go to next question.

If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)

2. What is the member's diagnosis?

If schizophrenia or schizoaffective disorder = Go to next question.

If bipolar disorder = Go to next question.

If other diagnosis = Go to question 4.

3. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = Go to question 5.

4. What is the member's age?

If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

If 18 years or older = DENY and refer to RPH.

5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?

If medication is being prescribed by or in consultation with a psychiatrist = Go to next question.

If other provider specialty = DENY and refer to RPH.

6. Has the member been started and stabilized on Risperdal Consta?

If YES = Go to question 10.

If NO = Go to next question.



7. Has the member been noncompliant after a trial of oral risperidone (Risperdal) or oral paliperidone (Invega)?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Zyprexa Relprevv

1. Where is the medication being administered?
If medication will be administered in the home = DENY and refer to RPH. If medication will be administered in a REMS-certified long-term care facility = Go to next question. If medication will be administered in a REMS-certified CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.



6. Has the member been started and stabilized on Zyprexa Relprevv?
If YES = Go to question 10. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral olanzapine (Zyprexa)?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Quantity Level Limit Criteria

Clozapine Tablets Generic, Clozapine ODT Generic, Rexulti or Versacloz Quantity Level Limit (QLL) Criteria

1. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month authorization only). If NO = DENY and refer to RPH. Offer higher tablet strength if available.

Ziprasidone (Geodon) Quantity Level Limit (QLL) Criteria

1. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month authorization only). If NO = DENY and refer to RPH. Offer higher capsule strength if available.

Risperidone (Risperdal) Tablet or Risperidone ODT tablet (Risperdal M-Tablet) Quantity Level Limit (QLL) Criteria

1. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month for all diagnoses except pervasive developmental disorder)



(PDD)/autism or irritability associated with autism/PDD in which QLL authorization may be for two months if necessary).
If NO = DENY and refer to RPH. Offer higher tablet strength if available.

Quetiapine IR (Seroquel IR) Quantity Level Limit (QLL) Criteria

- Note:** Use of low dose quetiapine IR (Seroquel) 25mg (at doses of 1 or 2 tablets per day) or quetiapine IR (Seroquel) 50 mg (at dose of 1 tablet per day) not in conjunction with another strength of quetiapine (Seroquel), an antidepressant or other antipsychotic will be reviewed upon appeal only (see below).

Quetiapine IR (Seroquel) Low Dose - 25 mg (at doses of 1 or 2 tablets per day) or 50 mg (at dose of 1 tablet per day) (see below for max quantity limits exceeded)

In all calls, DENY and refer to RPH. Inform caller of the appeals process and that the prescriber must submit a written letter of medical necessity for the use of quetiapine IR (Seroquel) 25mg (one or two tablets per day) or 50 mg (one tablet per day) without the concomitant use of another strength of quetiapine IR (Seroquel), an antidepressant or other antipsychotic.

Quetiapine IR (Seroquel) Max Quantity Limits Exceeded – All Strengths

1. What formulation of quetiapine (Seroquel) is being requested?

Quetiapine immediate release generic (Seroquel) = Go to next question.
Quetiapine extended release generic (Seroquel XR) = DENY and refer to RPH.

2. Is the member's dose being titrated due to initiation of therapy?

If YES = APPROVE enough for initial titration only (one month authorization only).
If NO = DENY and refer to RPH. Offer higher tablet strength if available.

Olanzapine (Zyprexa) or Olanzapine ODT (Zyprexa Zydis) tablets Quantity Level Limit (QLL) Criteria

1. What strength of medication is being requested?

If 2.5 mg = Go to next question.
If 5 mg = Go to question 3.
If 20 mg = Go to question 4.
If other strength = DENY and refer to RPH. QLL of 60 tablets/30 days applies. Offer higher tablet strength if available.

2. Is the member's dose being titrated due to initiation of therapy?

If YES = APPROVE enough for up to 10 mg/day for the first month of therapy (initiation of therapy) only.
If NO = DENY and refer to RPH. QLL of 60 tablets/30 days applies.

3. Is the member's dose being titrated due to initiation of therapy?

If YES = APPROVE enough for up to 20 mg/day for the first month of therapy (initiation of therapy) only.
If NO = DENY and refer to RPH. QLL of 60 tablets/30 days applies.

4. What is the member's diagnosis?

If schizophrenia or schizoaffective disorder = Go to next question.



If other diagnosis = DENY and refer to RPH. QLL of 30 tablets/30 days applies.

5. Is this an initial or reauthorization QLL request?

If initial = Go to next question.

If reauthorization = Go to question 7.

6. Does the member have refractory schizophrenia (failure of 2 or more antipsychotics at adequate doses for at least 6 weeks)?

If YES = Go to next question.

If NO = DENY and refer to RPH. QLL of 30 tablets/30 days applies.

7. Is the member being monitored for increases in weight, blood glucose, and lipid panel?

If YES = APPROVE up to 90 tablets per 30 days for 3 months (renewals may be approved for 1 year).

If NO = DENY and refer to RPH. QLL of 30 tablets/30 days applies.

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In the event of a denial, advise all callers of appeal rights and the reason for denial.



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PA Criteria Category/Drug: GLP-1 Agonists
Length of authorization: 1 Year Unless
Otherwise Noted

Medications

PDL Status	
Preferred	Non-Preferred
Byetta (exenatide) Victoza (liraglutide)	Adlyxin (lixisenatide) Bydureon BCise (exenatide ER) Mounjaro (tirzepatide) Ozempic (semaglutide injection) Rybelsus (semaglutide tablets) Trulicity (dulaglutide)

Criteria

Adlyxin

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 11.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
4. Does the member have ESRD (end-stage renal disease)?
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Does the member have a history of pancreatitis or gastroparesis?
If YES = DENY and refer to RPH. If NO = Go to next question.
6. Has the member tried the preferred medications, Byetta AND Victoza, for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal)?
If YES = Go to next question. If NO = Go to question 8.
7. What is the member's hemoglobin A1c (HbA1c) level after therapy with Byetta AND Victoza?
If 7% or higher = Go to question 10. If less than 7% = DENY and refer to RPH.
8. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Byetta AND Victoza, which are not expected to occur with Adlyxin?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?



If 7% or higher = Go to next question. If less than 7% = DENY and refer to RPH.
10. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?
<i>For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.</i>
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
11. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?
<i>For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
12. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels) from the requested medication?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Bydureon BCise

1. What is the member's age?
If 10 to 17 years = Go to next question. If 18 years or older = Go to question 3. If less than 10 years = DENY and refer to RPH.
2. Inform the caller that Victoza is preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, Victoza, is not appropriate for the member.
3. Inform the caller that Byetta and Victoza are preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, Byetta and Victoza, are not appropriate for the member.

Mounjaro and Ozempic

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 15.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. What is the member's age?
If 18 years or older = Go to next question.



If less than 18 years = DENY and refer to RPH.
4. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?
If 7% or higher = Go to next question. If less than 7% = DENY and refer to RPH.
5. Does the member have a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN2)?
If YES = DENY and refer to RPH. If NO = Go to next question.
6. Does the member have a history of pancreatitis?
If YES = DENY and refer to RPH. If NO = Go to next question.
7. Which product is being requested?
If Mounjaro = Go to question 11. If Ozempic = Go to next question.
8. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = Go to next question. If NO = Go to question 11.
9. Has the member tried the preferred medication, Victoza, for 3 months and failed therapy?
If YES = APPROVE for 1 year. If NO = Go to next question.
10. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to the preferred medication, Victoza, which is not expected to occur with the requested medication?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
11. Has the member tried the preferred medications, Byetta AND Victoza, for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal) as confirmed by claims history?
If YES = Go to next question. If NO = Go to question 13.
12. What is the member's hemoglobin A1c (HbA1c) level after therapy with Byetta AND Victoza?
If 7% or higher = Go to question 14. If less than 7% = DENY and refer to RPH.
13. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Byetta AND Victoza, which are not expected to occur with the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
14. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione as confirmed by claims history?
<i>For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table.</i>
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
15. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = APPROVE for 1 year.



If NO = Go to next question.
16. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?
<i>For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
17. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Rybelsus

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 11.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
4. Does the member have a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN2)?
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Does the member have a history of pancreatitis?
If YES = DENY and refer to RPH. If NO = Go to next question.
6. Has the member tried the preferred medications, Farxiga, Jardiance or Invokana AND Byetta or Victoza, for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal)?
If YES = Go to next question. If NO = Go question 8.
7. What is the member's hemoglobin A1c (HbA1c) level after therapy with Farxiga, Jardiance or Invokana AND Byetta or Victoza?
If 7% or higher = Go to question 10. If less than 7% = DENY and refer to RPH.
8. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Farxiga, Jardiance, Invokana, Byetta and Victoza, which are not expected to occur with the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?
If 7% or higher = Go to next question.

If less than 7% = DENY and refer to RPH.

10. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?

For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.

If YES = APPROVE for 6 months.

If NO = DENY and refer to RPH.

11. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?

For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.

If YES = Go to next question.

If NO = DENY and refer to RPH.

12. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels)?

If YES = APPROVE for 1 year.

If NO = DENY and refer to RPH.

Trulicity

1. Is this an initial or reauthorization request?

If initial = Go to next question.

If reauthorization = Go to question 16.

2. What is the member's diagnosis?

If Type 2 diabetes mellitus = Go to next question.

If other diagnosis = DENY and refer to RPH.

3. Does the member have a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN2)?

If YES = DENY and refer to RPH.

If NO = Go to next question.

4. Does the member have a history of pancreatitis?

If YES = DENY and refer to RPH.

If NO = Go to next question.

5. What is the member's age?

If 10 to 17 years = Go to question 7.

If 18 years or older = Go to next question.

6. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?

If YES = Go to question 9.

If NO = Go to question 11.

7. Has the member tried the preferred medication, Victoza, for 3 months and failed therapy?

If YES = APPROVE for 1 year.

If NO = Go to next question.

8. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to the preferred medication, Victoza, which is not expected to occur with the requested medication?



If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
9. Has the member tried the preferred medications, Victoza and Ozempic (NP/PA), for 3 months each and failed therapy?
If YES = APPROVE for 1 year. If NO = Go to next question.
10. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Victoza and Ozempic (NP/PA), which is not expected to occur with the requested medication?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
11. Has the member tried the preferred medications, Byetta, Victoza and Ozempic (NP/PA), for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal)?
If YES = Go to next question. If NO = Go to question 13.
12. What is the member's hemoglobin A1c (HbA1c) level after therapy with Byetta, Victoza and Ozempic?
If 7% or higher = Go to question 15. If less than 7% = DENY and refer to RPH.
13. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Byetta, Victoza and Ozempic (NP/PA), which are not expected to occur with the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
14. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?
If 7% or higher = Go to next question. If less than 7% = DENY and refer to RPH.
15. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?
<i>For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.</i>
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
16. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = APPROVE for 1 year. If NO = Go to next question.
17. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione?
<i>For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.</i>
If YES = Go to next question. If NO = DENY and refer to RPH.
18. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

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In the event of a denial, advise all callers of appeal rights and the reason for denial.



MSQ4.3 – QLL Override Criteria

This document begins on the following page.

PA Criteria Category/Drug: Antimigraine Agents, Triptans

Length of authorization: 1 year

Medications

PA Status	
Preferred	Non-Preferred
Rizatriptan tablet, ODT generic Sumatriptan nasal spray, tablet generic Zomig Nasal Spray (zolmitriptan)	Almotriptan generic Cafergot (ergotamine with caffeine 1/100 mg tablet)* Dihydroergotamine (DHE) nasal spray generic Eletriptan generic Ergomar (ergotamine sublingual) Frova (frovatriptan) Migergot (ergotamine with caffeine 2/200 mg suppository) Migranal Nasal Spray (dihydroergotamine) Naratriptan generic Onzetra Xsail (sumatriptan nasal powder) Sumatriptan injection generic Tosymra (sumatriptan nasal spray) Treximet (sumatriptan/naproxen) Trudhesa (dihydroergotamine nasal spray) Zembrace SymTouch (sumatriptan for injection) Zolmitriptan tablet, ODT generic Zomig (zolmitriptan tablet) Zomig ZMT (zolmitriptan ODT)

ODT=orally disintegrating tablets; *non-preferred but does not require PA

- **Note:** The triptan tablets are limited to 9 total tablets per 30 days. See quantity level limit (QLL) authorization criteria below for QLL requests.
- **Step Edit:** For generic almotriptan, generic eletriptan, brand Frova, generic naratriptan and brand Zomig, look back 60 days in claims history for two of the following: rizatriptan tablet/orally disintegrating tablet and sumatriptan tablet to bypass reject 75.
- **Step Edit:** For Ergomar and Zomig ZMT, look back 60 days in claims history for rizatriptan orally disintegrating tablet and sumatriptan tablet to bypass reject 75.
- **Note:** If brand Migranal Nasal Spray is approved, notify the caller that the generic is preferred over the brand and the PA is approved for generic dihydroergotamine nasal spray.
- **Note:** If generic zolmitriptan is approved, notify the caller that the brand is preferred over the generic and the PA is approved for brand Zomig; enter the PA for brand Zomig at the NDC level.
- **Note:** If generic zolmitriptan ODT is approved, notify the caller that the brand is preferred over the generic and the PA is approved for brand Zomig ZMT; enter the PA for brand Zomig ZMT at the NDC level.

Quantity Level Limit Authorization Criteria

Triptans

1. How many moderate to severe headache days does the member experience each month?
If >8 days per month = Go to next question. If ≤8 days per month = DENY and refer to RPH.
2. Is the triptan being used for migraine prophylaxis?
If YES = DENY and refer to RPH. If NO = Go to next question.

3. Is the member receiving prophylactic (preventative) therapy for migraine headaches such as an anticonvulsant, antidepressant, beta-blocker, calcium channel blocker, or NSAID?

Examples of prophylactic therapy may include but not limited to the medications in Table 1 below.

If YES = Go to next question.

If NO = DENY and refer to RPH.

4. Is the member taking this triptan in combination with another triptan or an ergotamine (ex. Migranal, dihydroergotamine, Cafergot, Ergomar, Migergot)?

If YES = DENY and refer to RPH.

If NO = APPROVE for 1 year.

Table 1

Prophylactic Drug Class	Example of medication
Anticonvulsants	Divalproex sodium/sodium valproate, gabapentin, topiramate (Topamax)
Tricyclic Antidepressants	Amitriptyline, nortriptyline, protriptyline, doxepin, imipramine
Selective serotonin reuptake inhibitors (caution: co-administration with triptans can cause serotonin syndrome)	fluoxetine, fluvoxamine, paroxetine, sertraline
Other antidepressants (caution: co-administration of venlafaxine with triptans can cause serotonin syndrome)	Bupropion, mirtazapine, trazodone, venlafaxine
Beta Blockers	Atenolol, metoprolol, nadolol, propranolol, timolol
Calcium Channel Blockers	Diltiazem, nimodipine, verapamil
NSAIDs	Aspirin, fenoprofen, flurbiprofen, mefenamic acid, ibuprofen, ketoprofen, naproxen

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PA Criteria Category/Drug: Diabetic supplies, Insulin pens or cartridges

Length of authorization: 1 year

Medications

PA Status	
Preferred	Non-Preferred
Apidra pens/cartridges (insulin glulisine)* Baqsimi (glucagon nasal powder) Glucagon injection generic EXCEPT kit by Fresenius (NDC 63323-0582-82)* Glucagen (glucagon injection)* Humalog 100 units/mL pens/cartridges (insulin lispro) Humalog Mix 50/50 pens/cartridges (insulin lispro/lispro protamine) Humalog Mix 75/25 pens/cartridges (insulin lispro/lispro protamine) Humulin 70/30 pens/cartridges Humulin R U-500 pens/cartridges (insulin regular concentrate) Insulin aspart pens/cartridges generic Insulin glargine 100 units/mL pens/cartridges generic* Insulin aspart/aspart protamine mix 70/30 pens/cartridges generic Insulin lispro 100 units/mL pens/cartridges generic Insulin syringes Ketone test strips Lancet devices and lancets Lantus pens/cartridges (insulin glargine 100 units/mL)* Levemir pens/cartridges (insulin detemir)* Novolin N pens/cartridges (insulin NPH) Novolin R pens/cartridges (insulin regular) Novolog pens/cartridges (insulin aspart) Novolog Mix 70/30 pens/cartridges (insulin aspart/aspart protamine) Pen needles True Metrix blood glucose test strips	Basaglar pens/cartridges (insulin glargine 100 units/mL) Fiasp pens/cartridges (insulin aspart with niacinamide) Gvoke (glucagon injection) Humalog 200 units/mL pens/cartridges (insulin lispro) Humulin N pens/cartridges (insulin NPH) Insulin lispro/lispro protamine mix 75/25 pens/cartridges generic Lyumjev pens/cartridges (insulin lispro-aabc) Novolin 70/30 pens/cartridges (insulin NPH/regular) Semglee pens/cartridges (insulin glargine 100 units/mL) Toujeo pens/cartridges (insulin glargine 300 units/mL) Tresiba pens/cartridges (insulin degludec) Zegalogue (dasiglucagon)

*Does not require PA; The drug names above include all available pen/cartridge/syringe formulations under the same primary name unless otherwise stated.

- **Note:** Please refer to the covered diabetic supplies listing for covered NDCs located at the State's website
- **Note:** Please see end of document for quantity level limit (QLL) criteria for test strips, lancets, pen needles and insulin syringes.
- **Note:** Glucagon, Glucagen, Lantus and Levemir pens/cartridges do not require PA. Other preferred insulin pens/cartridges do not require PA for members younger than 21 years of age. Non-preferred insulin pens/cartridges require PA for all ages.
- **Note:** All lancet devices, lancets, pen needles and insulin syringes will be covered at a flat MAC rate.
- **Note:** For True Metrix Test Strips, enter approvals at the PA list level using the following: PA NDC list-TRUE and PA Reason Code-XC. Do not enter approvals at NDC-9 level.
- **Grandfathering:** For all preferred and non-preferred products, look back 365 days for same product to bypass reject 75.
- **Step Edit:** Preferred test strips and lancets: Claims history reviewed for 1 antidiabetic medication in the past 90 days to bypass reject 75. Claims history also reviewed for 1 prenatal vitamin in the past 90 days or an ICD-10 code submitted on claim for gestational diabetes (O24.410, O24.414, O24.419, O24.420, O24.424, O24.429, O24.430, O24.434, O24.439, O99.810, O99.814, or

O99.815) to bypass reject 75. Insulin syringes: Claims history reviewed for desmopressin/DDAVP vial, insulin vial, enoxaparin/Lovenox vial, Epogen, Granix, Leukine, Neupogen, Nivestym or growth hormone vial claim in the past 90 days to bypass reject 75. Pen needles: Claims history reviewed for 1 claim of insulin pen/cartridge, Forteo, Byetta, Victoza, SymlinPen or growth hormone pen/cartridge in the past 90 days to bypass reject 75. Baqsimi: Claims history reviewed for 1 claims of generic glucagon injection in the past 90 days to bypass reject 75.

Quantity Level Limit Criteria

Quantity Level Limit (QLL) Criteria for Blood Glucose Test Strips and Lancets

1. On average, how many times per day does the member test his or her blood glucose?
If >5 = Go to next question. If ≤5 = DENY and refer to RPH.
2. What is the member's hemoglobin A1C (HbA1c)?
If ≥7 = APPROVE for 1 year. If <7 = Go to next question.
3. Please submit a letter of medical necessity stating the reasons that testing blood glucose more than 5 times per day is required.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Quantity Level Limit (QLL) Criteria for Insulin Syringes

1. How many insulin syringes does the member use each day?
If >4 = APPROVE for 1 year. If ≤4 = DENY and refer to RPH.

Quantity Level Limit (QLL) Criteria for Pen Needles

1. How many pen needles does the member use each day?
If >4 = APPROVE for 1 year. If ≤4 = DENY and refer to RPH.

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In the event of a denial, advise all callers of appeal rights and the reason for denial.



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PA Criteria Category/Drug: Biologic
Immunomodulators
Length of authorization: Varies

Medications

PA Status	
Preferred	Non-Preferred
Adbry (tralokinumab)	Actemra subcutaneous (tocilizumab)
Arcalyst (rilonacept)	Amjevita (adalimumab-atto)
Dupixent (dupilumab)	Cibinqo (abrocitinib)
Enbrel (etanercept)	Cimzia (certolizumab)
Fasenra Pen (benralizumab autoinjector)	Cosentyx (secukinumab)
Humira (adalimumab)	Enspryng (satralizumab-mwge)
Ilaris (canakinumab)	Kineret (anakinra)
Kevzara (sarilumab)	Olumiant (baricitinib)
Nucala Pen (mepolizumab autoinjector)	Orencia subcutaneous (abatacept)
Otezla (apremilast)	Rezurock (belumosudil)
Taltz (ixekizumab)	Rinvoq (upadacitinib)
Xeljanz (tofacitinib tablets)	Siliq (brodalumab)
Xeljanz Oral Solution (tofacitinib)	Simponi (golimumab)
Xeljanz XR (tofacitinib extended-release tablets)	Skyrizi (risankizumab)
	Sotyktu (deucravacitinib)
	Stelara (ustekinumab)
	Tremfya (guselkumab)

The drug names above include all available oral or subcutaneous formulations under the same primary name unless otherwise noted.

- **Note:** All preferred and non-preferred agents require prior authorization. Intravenous (IV) formulations of the biologic immunomodulators are not covered under Pharmacy Services. Only Fasenra and Nucala autoinjector pen formulations are covered under Pharmacy Services.
- **Note:** If the provider is calling for authorization for administration in a physician's office or clinic, please instruct them to go to the State website to request coverage from Physician Services.
- **Note:** PAs for Enbrel should be entered at the GPI-10 (6629003000****)
- **Note:** All starter or titration kits/packs/packages should be approved one time only – one per lifetime limit.
- **Step Edit:** For Kineret and Cimzia, look back 365 days for 3 months use of each Enbrel and Humira to bypass reject 75.
- **Grandfathering:** For Arcalyst, Ilaris and Otezla, look back 180 days in claims history for same product (not specific to strength) to bypass reject 75.

QLL Criteria

Quantity Level Limit (QLL) Criteria for Cimzia

1. Is the patient initiating therapy with Cimzia for any diagnosis below or renewing therapy with Cimzia for Plaque Psoriasis?

Crohn's Disease

- 400 mg initially and at weeks 2 and 4. If response occurs, follow with 400 mg every four weeks.

Rheumatoid Arthritis

- 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.

Psoriatic Arthritis

- 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4

weeks can be considered.

Ankylosing Spondylitis

- 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.

Non-Radiographic Axial Spondyloarthritis

- 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.

Plaque Psoriasis

- 400 mg every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week may be considered.

If YES = May APPROVE 2 kits (400 mg each) per 30 days for the initial month of therapy only. For Plaque Psoriasis, may APPROVE 2 kits (400 mg each per 30 day for initial requests and renewal requests if member is dosing 400 mg every other week.

If NO = DENY and refer to RPH (max of 1 kit [400 mg each] per 30 days allowed for maintenance dosing).

Quantity Level Limit (QLL) Criteria for Humira

1. What is the member's diagnosis?

Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis

- Adults: 40 mg every other week. Some patients with rheumatoid arthritis not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week.

Juvenile Idiopathic Arthritis or Pediatric Uveitis

- Pediatric Patients 2 Years of Age and Older: Depending on weight, 10 mg, 20 mg or 40 mg every other week.

Crohn's Disease

- Adults: 160 mg on Day 1 (given in one day or split over two consecutive days), 80 mg on Day 15, followed by 40 mg every other week starting on Day 29.
- Pediatric Patients 6 Years of Age and Older: Depending on weight, 80 mg or 160 mg (single dose or split over two consecutive days) on Day 1, 40 mg or 80 mg on Day 15, followed by 20 mg or 40 mg every other week starting on Day 29.

Ulcerative Colitis

- Adults: 160 mg on Day 1 (given in one day or split over two consecutive days), 80 mg on Day 15, followed by 40 mg every other week starting on Day 29. Discontinue in patients without evidence of clinical remission by eight weeks (Day 57).
- Pediatric Patients 5 Years of Age and Older: Depending on weight, 80 mg or 160 mg (single dose or split over two consecutive days) on Day 1, 40 mg or 80 mg on Day 8, 40 mg or 80 mg on Day 15, followed by 40 mg or 80 mg every other week or 20 mg or 40 mg every week starting on Day 29.

Plaque Psoriasis and Adult Uveitis

- 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

Hidradenitis Suppurativa

- Adults: 160 mg (given in one day or split over two consecutive days) on Day 1, 80 mg on Day 15, followed by 40 mg every week or 80 mg every other week starting on Day 29.
- Adolescents 12 Years of Age and Older: Depending on weight, 80 mg on Day 1 followed by 40 mg every other week starting on Day 8 or 160 mg (given in one day or split over two consecutive days) on Day 1, 80 mg on Day 15, followed by 40 mg every week or 80 mg every other week starting on Day 29.

If plaque psoriasis = May APPROVE 4 syringes per 28 days for the initial month of therapy only or may APPROVE one psoriasis starter pack per lifetime.

If uveitis = May APPROVE 4 syringes per 28 days for the initial month of therapy only.

If Crohn's disease = May APPROVE 6 syringes per 28 days for the initial month of therapy only or may APPROVE one Crohn's disease starter pack per lifetime.

If ulcerative colitis = May APPROVE 6 syringes per 28 days for the initial month of therapy only.

If hidradenitis suppurativa = May APPROVE 6 syringes per 28 days for the initial month of therapy only and APPROVE 4 syringes per 28 days thereafter.

If rheumatoid arthritis = Go to next question.

If other diagnosis = DENY and refer to RPH (max of 2 syringes per 28 days allowed for other diagnoses).

2. Is the member currently taking or will the member begin taking methotrexate?

The dosing for rheumatoid arthritis is 40 mg every other week. Patients not taking concomitant methotrexate may benefit from a dosage of 40 mg every week.

If YES = DENY and refer to RPH (max of 2 syringes per 28 days allowed).

If NO = May APPROVE 4 syringes per 28 days.

Quantity Level Limit (QLL) Criteria for Enbrel

1. What is the member's diagnosis?

The dosing for plaque psoriasis is: 50 mg dose given twice weekly for 3 months, followed by a reduction to a maintenance dose of 50 mg weekly.

If plaque psoriasis = APPROVE a maximum of 8 syringes per 28 days for 3 months only.

If other diagnosis = DENY and refer to RPH.

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In the event of a denial, advise all callers of appeal rights and the reason for denial.



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PA Criteria Category/Drug: Hepatitis C Agents

Length of authorization: Varies

Medications

PA Status	
Preferred	Non-Preferred
Direct Inhibitors	
Mavyret (glecaprevir/pibrentasvir)* Sofosbuvir/velpatasvir 400/100 mg tablets generic* Vosevi (sofosbuvir/velpatasvir/voxilaprevir)*	Epclusa Paks (sofosbuvir/velpatasvir 200/50 mg, 150/37.5 mg pellets) Harvoni 45/200 mg and Paks (ledipasvir/sofosbuvir) Ledipasvir/sofosbuvir 90/400 mg generic Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
Ribavirin	
Ribavirin generic	n/a)
Pegylated Interferons	
Pegasys (peginterferon alfa-2a)	
Interferons	
Intron-A (interferon alfa-2b)	

*Preferred but requires PA

- **Note:** Mavyret, sofosbuvir/velpatasvir 400/100 mg generic and Vosevi are preferred but require prior authorization.
- **Note:** For all repeat authorization/retreatment requests, faxed documentation of the Hepatitis C Retreatment Form is required. The Hepatitis C Retreatment Form must be completed and signed by the physician to be accepted. This Form is located at the State website

Table 1: Quantity of Medication for Sofosbuvir/Velpatasvir 400/100 mg Generic Therapy

Patient Population	Treatment	Total Quantity (Duration)
Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	sofosbuvir/velpatasvir	84 tablets (for 12 weeks)
With decompensated cirrhosis (Child-Pugh B or C) who are ribavirin ineligible	sofosbuvir/velpatasvir	168 tablets (for 24 weeks)
With decompensated cirrhosis (Child-Pugh B or C) who are ribavirin eligible	sofosbuvir/velpatasvir + ribavirin	84 tablets (for 12 weeks)

Table 2: Quantity of Medication for Harvoni 45/200 mg and Pak and Ledipasvir/Sofosbuvir 90/400 mg Generic Therapy

Patient Population	Treatment	Total Quantity (Duration)
Genotype 1 treatment-naïve adults without cirrhosis who have pre-treatment HCV RNA < 6 million IU/mL	Harvoni/ledipasvir-sofosbuvir	56 tablets (for 8 weeks)
Genotype 1 treatment-naïve adults without cirrhosis who have pre-treatment HCV RNA ≥ 6 million IU/mL	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)
Genotype 1 treatment-naïve adults who have HIV or compensated cirrhosis (Child-Pugh A), or treatment-naïve	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)

adolescents without cirrhosis or with compensated cirrhosis (Child-Pugh A)		
Genotype 1 treatment-experienced adults without cirrhosis and without liver transplant or adolescents without cirrhosis	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)
Genotype 1 treatment-experienced adults with compensated cirrhosis (Child-Pugh A) and without liver transplant who are ribavirin ineligible or adolescents with compensated cirrhosis (Child-Pugh A)	Harvoni/ledipasvir-sofosbuvir	168 tablets (for 24 weeks)
Genotype 1 treatment-experienced adults with compensated cirrhosis (Child-Pugh A) and without liver transplant who are ribavirin eligible	Harvoni/ledipasvir-sofosbuvir + ribavirin	84 tablets (for 12 weeks)
Genotype 1, 4, 5 or 6 adults with decompensated cirrhosis (Child-Pugh B or C) without liver transplant who are ribavirin ineligible	Harvoni/ledipasvir-sofosbuvir	168 tablets (for 24 weeks)
Genotype 1, 4, 5 or 6 adults with decompensated cirrhosis (Child-Pugh B or C) without liver transplant who are ribavirin eligible	Harvoni/ledipasvir-sofosbuvir + ribavirin	84 tablets (for 12 weeks)
Genotype 1, 4, 5 or 6 adults with liver transplant	Harvoni/ledipasvir-sofosbuvir + ribavirin	84 tablets (for 12 weeks)
Genotype 4, 5 or 6 treatment-naïve or treatment-experienced adults or adolescents without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)
Genotype 1, 4, 5 or 6 treatment-naïve or interferon/peginterferon-experienced pediatrics without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)

Table 3: Quantity of Medication for Sovaldi Therapy

Patient Population	Treatment	Total Quantity
Genotype 1 treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + PEG/RBV	84 tablets (for 12 weeks)
Genotype 1 treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	168 tablets (for 24 weeks)
Genotype 2 without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	84 tablets (for 12 weeks)
Genotype 3 without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	168 tablets (for 24 weeks)
Genotype 3 peginterferon/ribavirin-experienced with compensated cirrhosis (Child-Pugh A)	Sovaldi + Zepatier	84 tablets (for 12 weeks)
Genotype 4 treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + PEG/RBV	84 tablets (for 12 weeks)
Hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 336 tablets (for up to 48 weeks) or until liver transplantation, whichever occurs first

PEG/RBV=peginterferon/ribavirin

Table 4: Quantity of Medication for Zepatier Therapy

Patient Population	Treatment	Duration
Genotype 1a treatment-naïve or peginterferon/ribavirin-experienced	Zepatier	84 tablets (for 12 weeks)

without baseline NS5A polymorphisms		
Genotype 1a treatment-naïve or peginterferon/ribavirin-experienced with baseline NS5A polymorphisms	Zepatier + ribavirin	112 tablets (for 16 weeks)
Genotype 1b treatment-naïve or peginterferon/ribavirin-experienced	Zepatier	84 tablets (for 12 weeks)
Genotype 1a without baseline NS5A polymorphisms	Zepatier + ribavirin	84 tablets (for 12 weeks)
Genotype 1a with baseline NS5A polymorphisms	Zepatier + ribavirin	112 tablets (for 16 weeks)
Genotype 4 treatment-naïve	Zepatier	84 tablets (for 12 weeks)
Genotype 4 peginterferon/ribavirin-experienced	Zepatier + ribavirin	112 tablets (for 16 weeks)
Genotype 3 peginterferon/ribavirin-experienced with compensated cirrhosis	Zepatier + Sovaldi	84 tablets (for 12 weeks)

Table 5: Quantity of Medication for Mavyret Therapy

Patient Population	Treatment	Total Quantity (Duration)
Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Mavyret	168 tablets (for 8 weeks)
Treatment-naïve with liver transplant or kidney transplant without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Mavyret	252 tablets (for 12 weeks)
Genotype 1, 2, 4, 5 or 6 treatment-experienced following interferon, peginterferon and/or ribavirin regimen without cirrhosis	Mavyret	168 tablets (for 8 weeks)
Genotype 1, 2, 4, 5 or 6 treatment-experienced following interferon, peginterferon and/or ribavirin regimen with compensated cirrhosis (Child-Pugh A), liver transplant or kidney transplant	Mavyret	252 tablets (for 12 weeks)
Genotype 3 treatment-experienced following interferon, peginterferon and/or ribavirin regimen without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Mavyret	336 tablets (for 16 weeks)

Table 6: Quantity of Medication for Vosevi Therapy

Patient Population	Treatment	Total Quantity (Duration)
Genotype 1, 2, 3, 4, 5 or 6 treatment-experienced	Vosevi	84 tablets (for 12 weeks)
Genotype 3 treatment-naïve	Vosevi	84 tablets (for 12 weeks)

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3. Epclusa [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised June 2021.
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6. Sovaldi [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised March 2020.
7. Vosevi [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised November 2019.
8. Zepatier [prescribing information]. Whitehouse Station, NJ: Merck Inc; December 2021.
9. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) Guidance Panel. Hepatitis C Guidance 2020 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Last updated September 29, 2021. Available at <https://www.hcvguidelines.org>. Last accessed March 17, 2022.

In the event of a denial, advise all callers of appeal rights and the reason for denial.

5.	Bookmark Title: MSQ5 – RetroDUR Narrative description is limited to six (6) pages, not including the required supporting material. Describe in detail (1) the RetroDUR programs that will be made available to the State, (2) the potential customization available to the State, (3) the methods that will be utilized to identify feasible RetroDUR opportunities and targeted providers, and (4) the plan to execute intervention and assess outcomes. Refer to Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.5 Retrospective DUR (RETRO-DUR) Services.
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Since 1993, the Centers for Medicare and Medicaid Services (CMS) has required states to develop a comprehensive Drug Utilization Review (DUR) program to optimize patient care and address safety concerns. States are allowed significant flexibility in the administration of their programs, but there are two standard requirements:

1. To prospectively review drug utilization against pre-determined criteria to identify and prevent potential safety issues; and
2. To retrospectively identify questionable prescribing patterns and target them for educational intervention.

More recently, CMS has provided guidance on specific DUR requirements including atypical anti-psychotic use in pediatric patients and opioid utilization from a fraud, misuse, or unnecessary *medical* care perspective. These targeted directives underscored the need for more than just pharmacy data in a robust DUR program.

CompassDURSM – Analytics Meets Experience

CompassDUR is NorthStar HealthCare Consulting's (NHC) solution to increasingly specific CMS requirements as well as to the uniquely complex needs of individual State programs. *CompassDUR* allows customizable clinical analytics review of both medical and pharmacy populations to identify and address suboptimal behaviors. Through our *CompassDUR* program, prescribers receive feedback on their prescribing behaviors as compared to plan-specific criteria, accepted standards of practice, and treatment guidelines established by professional medical associations (e.g., the American College of Cardiology), as well as national and global health institutes (e.g., the Centers for Disease Control and Prevention [CDC] or the World Health Organization). Our platform provides support and reinforcement when states plan to implement policy or coverage changes.

The Program

At the most basic level, the Retrospective Drug Utilization Review (RetroDUR) program provided to the State is based on initiatives to identify and monitor medical practices and medication usage for potential fraud, abuse, misuse, and inappropriate utilization or care among prescribers, pharmacies, and members.

Methods

A RetroDUR program starts with identification of an area of concern, resulting in a set of pre-determined criteria the State intends for review against claims data to identify areas for educational focus and intervention. Clinical analytics through *CompassDUR* also start with identification of an area of concern, which can originate from multiple sources including clinical literature, standard reporting plus claims review, governmental and legislative authorities, State Advisory Board (SAB) recommendations, pharmacy audit findings, and relevant, exemplary issues identified by peers in other State programs. Although vital, analysis of claims data alone is simply not enough. The importance of being able to create customized criteria that is defensible, referenced, targeted, and pre-determined, specifically for a State Medicaid program, cannot be understated. A robust RetroDUR program staffed with experienced pharmacists who are well trained to develop and deliver effective educational interventions is paramount in eliciting provider review and action.

Most RetroDUR interventions are classified based on problem type or area of concern. The interventions below are available to the State and include, but are not limited to using preset *standards* (although the *specifics* of the intervention can vary) to examine:

- Overutilization and underutilization
- Therapeutic appropriateness and duplication
- Appropriate use of generics and formulary medications
- Inappropriate duration of treatment
- Inappropriate or medically unnecessary care
- Overuse, misuse, abuse, and fraud
- Incorrect dosage
- Drug-drug interactions
- Drug-disease contraindications
- Drug-induced illness
- Drug-pregnancy risk indicators
- Use of high-cost prescription drugs
- Polypharmacy
- Agents of abuse

As an additional resource for issue identification, NHC is a member of the American Drug Utilization Review Society (ADURS). Our membership allows us to keep our ear to the ground and stay abreast of best practices on a national scale. Finally, our role and experience as a pharmacy audit vendor allows us to remain on the forefront of issue identification at the prescriber, pharmacy, and member level.

Intervention Development and Proposal Submission

NHC develops criteria for each intervention based on a multi-step process reflective of the area of interest. First, based on the results of the analyses performed during issue identification, we determine parameters against which claims data and member and/or provider behaviors are measured, and then build algorithms leveraging those parameters to find potential targets of the planned intervention.

Typically, intervention rationale is created to determine a standard or threshold by which claims data and member and/or provider behavior is measured. Intervention rationale may be based on resources such as clinical literature, FDA-approved labeling, expert consensus statements, and should be specific to the state and its patient population. Regardless of the origination, the criteria set forth must be focused, referenced, and defensible.

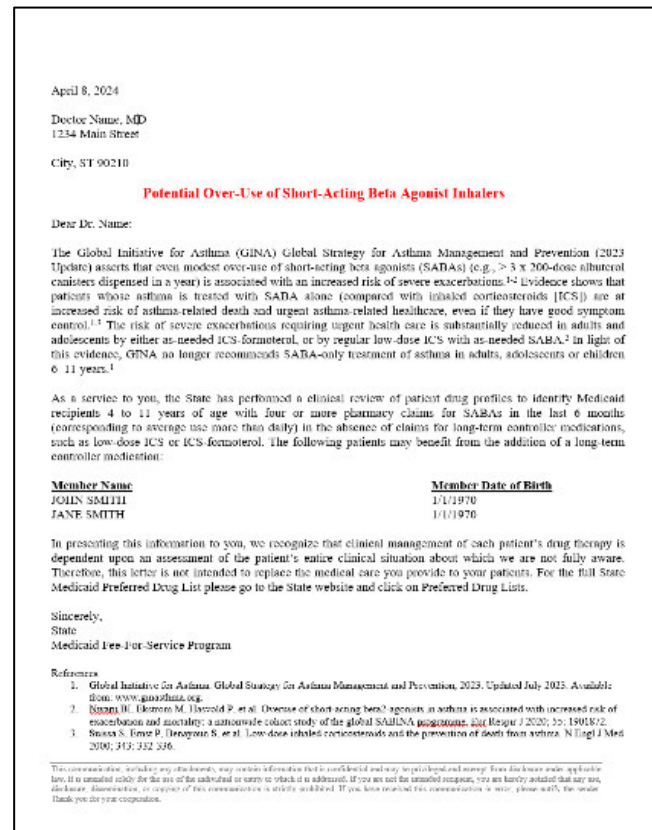


Figure 1 MSQ5.1: Sample provider letter.

We then work to create a sample of the intervention's educational material, or 'interventional collateral,' which typically includes the following documents:

- A provider communication that details the utilization problem and recommended corrective action (Figure MSQ5.1)
- 'Provider support cards' and/or patient profiles that demonstrate the provider's prescribing patterns
- A survey, questionnaire, or other tool to capture provider feedback

A summary of the **issue** identified, which includes a preliminary projection of the problem's scope and reach (based on claims data), is packaged along with the sample interventional collateral to create a formal RetroDUR proposal that is submitted to the State and/or the SAB for review, refinement, and approval. Once approved, NHC identifies the final provider targets for intervention and executes the intervention via a method agreed upon by the State.

Experience and Knowledge is Key

Compulsory data analytics of RetroDUR interventions can present a conundrum. While the power to leverage data feeds from multiple sources has increased our ability to identify complex cases, the automation has also led to identification of extensive data sets, which results in information overload to providers. NHC meets this challenge by exclusively staffing experienced clinical pharmacists with advanced education who are intimately involved in the RetroDUR process — especially criteria development and resultant case identification. For certain cases, we conduct an additional review by an experienced clinician in the field who can gauge provider response and provide us with valuable feedback on ways to mitigate perceived informatics burden to the provider community.

Identification and Initiation

Although mentioned briefly above, our process for *conducting* a RetroDUR intervention is described here. Upon identification of the area of interest or problem type, NHC compares optimal medical practice or medication use with the State's actual medical practice or medication use, per claims data, and provides the State a written proposal detailing 1) the rationale for the RetroDUR intervention, 2) member and/or provider selection criteria with necessary data fields to conduct the evaluation, 3) intervention, and 4) analysis plan.

Medical claims data provided by the State, or its medical vendor and pharmacy claims data provided by the State's Pharmacy Benefits Administrator (PBA) Vendor are reviewed to begin the identification process. We build an algorithm specifically tailored to the State and review the claims data to identify targeted members and/or providers for the intervention based on the RetroDUR proposal which delineates acceptable thresholds (e.g., percent of members or providers meeting the indicator) needed to evaluate the intervention. The RetroDUR pharmacist then assesses the claims data to measure the State's actual medical practice or medication use and compares the findings to optimal medical practice or medication use. Irregular practice patterns, inappropriate medication use, and causes for any variation between actual and optimal usages are identified and analyzed. Rather than rely solely on system-generated letters, we also employ pharmacist review to ensure the approach and intervention are appropriately and specifically targeted and stratified. While a systematic approach will generate letters that meet the identified targets and is highly efficient, the process also



must employ pharmacist review to ensure the appropriateness of the intervention and avoid burdening providers with unnecessary or irrelevant interventions.

The next step in the process is the actual intervention. NHC implements educational intervention via methods agreed upon by the State. Provider communications are drafted detailing the rationale for the intervention and recommended corrective action. Confidential communications are mailed and/or faxed to corresponding members and/or providers highlighting the changes needed to optimize outcomes based on the intervention. The number of members and providers identified, along with the drafted prescriber, member, or pharmacy letters, are provided to and approved by the State prior to distribution to the targeted population. Generally, the letters are targeted at providers, but member letters can be employed if the State desires to perform an intervention specific to compliance or Preferred Drug List (PDL) changes.

Intervention Evaluation, Measurement, and Reporting

Within three to six months, depending upon the nature and timeline of the intervention, NHC evaluates the effectiveness of RetroDUR interventions by comparing claims data three months prior to the intervention to claims data three months after the intervention. When applicable and where available, the pre- and post-intervention findings are compared to national standards or to the standards reported in other states. Clinical and financial impact and outcomes of RetroDUR interventions are assessed, the rationale and reasons for positive and negative results are documented, and both are reported to the State and its DUR Board quarterly and to CMS annually. Findings are reported to providers at the State's discretion. Finally, any findings of fraud, waste, or abuse are communicated to the State's Pharmacy Fraud, Waste, and Abuse (PWFA) Vendor or Program Integrity (PI) accordingly.

Consider a recent example of a RetroDUR intervention and resulting outcomes data over a 12-month review period shown in Figure MSQ5.2. The goal for this intervention was to encourage prescribers to gradually taper total daily Morphine Milligram Equivalents (MME) doses, where possible. In this intervention, communications were sent to prescribers whose patients were receiving high MME doses. Included in the letter were CDC resources for opioid tapering. The post-intervention analysis revealed that 76% of the patients included in the intervention had decreased their baseline average daily MME. A positive impact like this highlights the utility and importance of our *CompassDUR* solution.

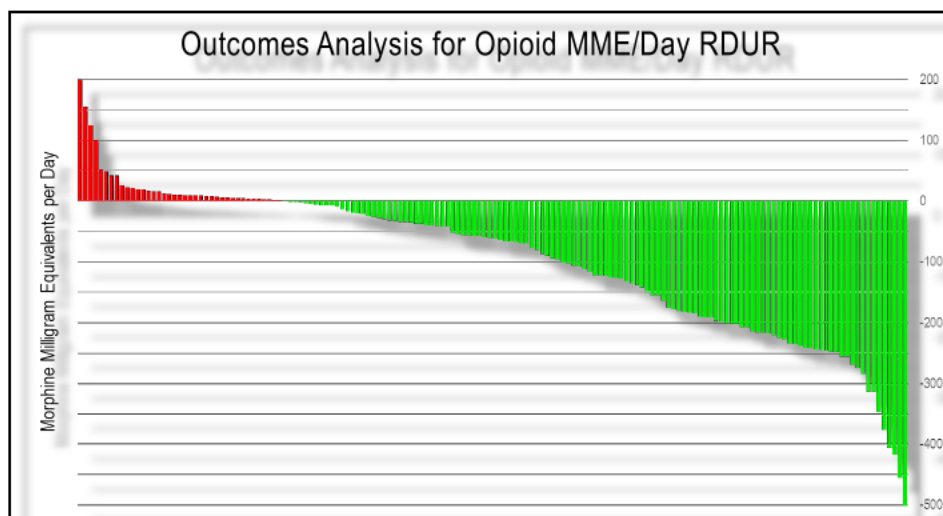


Figure MSQ5.2: Intervention to encourage the tapering of total daily MME doses resulting in a decrease from baseline MME in 76% of patients.

Customizable to Meet Our Clients' Unique Needs

NHC's *CompassDUR* program is fully customizable. Our platform intelligently incorporates the State's medical claims with its pharmacy claims to identify and address differences across the state, such as regional variations in health care access and utilization, distribution of disease state, seasonality in medication usage, as well as State utilization differences as compared to national standards. While NHC is here to guide you, all intervention criteria and collateral are subject to review and refinement at the State's discretion; it is your program after all. Our dedicated Clinical Programs Director, Chad Nicholson, PharmD., has been overseeing the RetroDUR program for nine years and brings a wealth of knowledge and familiarity to the State and the State Advisory Board.

In sum, NHC stands ready to provide you with an intelligent and customizable RetroDUR program staffed by seasoned clinical pharmacists. As your dedicated PCMS Vendor, the State can be assured that NHC will not recycle canned interventions across multiple clients. We simply do not do business that way. Our pledge to you is to provide a customizable RetroDUR program that is specific to your state, your program, and your population.



6.	Bookmark Title: MSQ6 – Approach to Appeals Narrative description is limited to four (4) pages, not including the required supporting material. Describe in detail your company’s approach to Appeals with regards to how your company will respond to inquiries and complaints about the Utilization Management criteria and review process. Include in your response, the process for sharing this information with the State. Refer to Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program.
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NorthStar HealthCare Consulting (NHC) recognizes the impact of a Clinical Management program is not limited to the quality of health care provided by the State but may also include inquiries and concerns from various stakeholders. As such, NHC is committed to responding to feedback from providers, patient advocates, manufacturers, and others affected by the program and its Utilization Management (UM) criteria. We propose several methods by which interested parties can raise questions and concerns regarding the structure and functioning of the State’s Drug Management Policies and Programs, promoting goodwill and collaboration among all participants.

With respect to Georgia Medicaid, new drug entities are not eligible for presentation to the State Advisory Board (SAB) until the product has been on the market for six months. Prior to this review, there is a pathway to coverage consistent with guidance from the Centers for Medicare and Medicaid Services (CMS).

Manufacturers, advocacy groups, providers, and other interested parties have opportunities to provide input at the SAB meeting for consideration in the development and approval process for UM criteria as discussed below. Prior to review by the SAB, interested parties may seek information regarding the general process by contacting a dedicated email box for Georgia Medicaid monitored by NHC. Those with patient specific inquiries will be referred to the Pharmacy Benefit Administrator’s (PBA) clinical call center for further follow-up.

Products Scheduled for State Review/Discussion

Manufacturers may contact NHC at any time with product specific clinical inquiries. However, when a product is up for review or discussion by the State, manufacturers may request a forum with NHC clinicians. The proposed forum protocol is as follows:

- The manufacturer must submit a one-page, factual summary of the drug in an electronic format, which will be provided to the State and SAB members.

- Manufacturers are afforded the opportunity to present clinical information on a new drug as well as clinical information relating to other drugs within the same therapeutic class as the new drug entity.
- For drugs already available in the marketplace, manufacturers may present information that has become available since previous evaluations by the SAB. This information must emphasize any changes in the drug's place in therapy and highlight comparisons with other drugs in the same therapeutic class.

Inquiries Regarding UM Criteria

Although the State employs a process by which a manufacturer can appeal an adverse recommendation by the SAB directly to the State, outside of this process, a manufacturer can submit an inquiry at any time to NHC regarding general concerns with respect to UM criteria. Such inquiries are addressed in the following way.

- NHC will review the manufacturer's concerns and respond to them directly with any questions and information.
- If NHC can resolve the issue after speaking with the manufacturer, then no further action is necessary.
- If NHC is unable to resolve the manufacturer's concerns, our clinicians research the issue further, review all available information, and contact experts within the state (if needed) for further input and recommendations.
- An analysis will be drafted and provided to the State with a summary of the issue(s) raised and recommendations, if any, for next steps.
- Upon a determination by the State, NHC can also convey this information to the manufacturer on the State's behalf.
- All inquiries and complaints will be logged and tracked so that a historical record is maintained for future reference.

Questions unrelated to UM criteria, such as rebate questions, will be referred to the appropriate vendor for follow-up and resolution.

Advocacy Groups and Provider Inquiries

In addition to manufacturers, advocacy groups and providers with general questions or concerns with the UM program, may contact NHC through an email box dedicated to the State. Alternatively, the State may forward inquiries directly to NHC for handling and disposition. If this inquiry is unrelated to a product being reviewed and discussed at the next SAB, the process that will be followed is nearly identical to the process that applies to manufacturers.



- Inquiries will be assessed and triaged by NHC, and either resolved directly (as allowed by the State) or forwarded to the State for review and direction.
- NHC will research and provide the State with a summary of the issue(s) and recommendations if applicable.

For inquiries tangentially related to UM, such as claims processing, call center, or patient specific issues, NHC may forward the inquiry to the PBA vendor for follow up and resolution. For inquiries unrelated to UM or the Fee-for-Service (FFS) Medicaid program, NHC will direct the inquirer to an alternative resource, if known. Any inquiries from the media will be referred directly to the State.

Consumer Comments for SAB Review

Interested parties regarding medications being reviewed at the next SAB, other than manufacturers, their agents, or Care Management Organization (CMO) enrollees, may contact NHC to submit consumer comments for review by the SAB.

- Consumer comments are forwarded directly to Board members and may also be included in the meeting binder for discussion.
- An additional opportunity is available to non-manufacturer stakeholders to provide testimony directly to the SAB in the form of consumer comments via a signup sheet at the meeting.
- Presenters are required to disclose any conflicts of interest, including any payments or gifts in kind from manufacturers, whether directly or indirectly.

NHC Reviews on Behalf of the State

If the State is contacted directly by a stakeholder, the State may choose to forward the pertinent information to NHC for review and follow up. Such situations are managed as follows:

- NHC's clinical team will evaluate the communication for any clinical concerns and reach out to the PBA Vendor as needed for any administrative or operational concerns.
- NHC may also collaborate with the Pharmacy Drug Rebate Services (PDRS) Vendor to confirm that any recommendations made have taken into consideration both rebate contracting and the net cost to the State.
- NHC's feedback, along with relevant clinical and economic recommendations and suggestions for revision to UM criteria, if any, will be logged and forwarded to the State for review and determination.
- The State may decide to maintain the UM criteria as it currently stands or make subsequent changes to reflect their consideration of the issues presented.



7.

Bookmark Title: MSQ7 – Document Repository

Narrative description must be uploaded as an attachment and is limited to five (5) pages, inclusive of any diagrams.

Describe in detail the design and maintenance of the document repository that will meet the requirements as outlined in Attachment C: Common Scope Requirements and Security Standards, Section 2.14.1 Document Repository and Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 3.2 Document Management.

The secure management of sensitive data is an intrinsic component of a Pharmacy Clinical Management Services (PCMS) Program. NorthStar HealthCare Consulting (NHC) is committed to maintaining industry standards for data management. To meet the document repository requirements outlined in Attachments C and G of this eRFP, NHC proposes leveraging Microsoft SharePoint to create and maintain a state-specific site, as outlined below.

SharePoint Design

Among its numerous features, SharePoint offers solutions for access control, storage, organization, tracking, dissemination, and mobile access.

- **RBAC:** Its **Role-Based Access Control** feature allows for permissions to be based on roles (e.g., project team members, stakeholders). Permissions for viewing, editing, and managing documents can be controlled throughout the contract's duration.
- **Storage, Organization, and Tracking:** SharePoint's Document Libraries provide space where project-related documents may be stored, organized, and tracked. Additionally, its Version Control feature maintains a version history, ensuring proper control over document changes. Please refer to Figure MSQ7.1 below.
- **Dissemination and Interface:** SharePoint's Web Pages serve as interfaces wherein project team members and stakeholders may access project information, view the latest documentation, and submit issues or comments to the project team. The discussion boards, notifications, and alerts enhance collaboration.
- **Mobile Access:** A mobile access feature is available to authorized users, which affords access to the document repository.

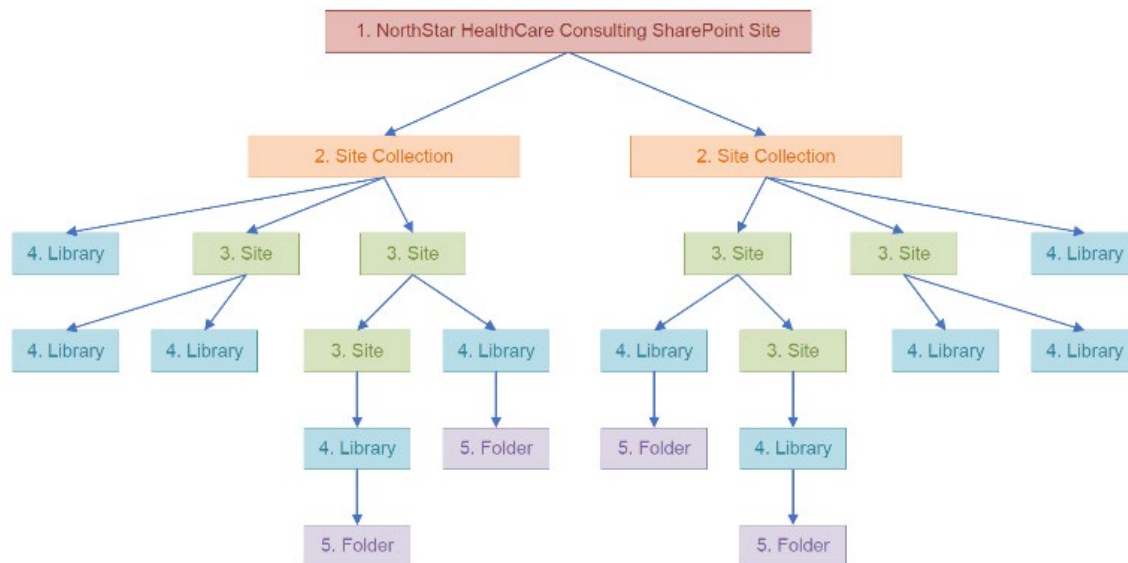


Figure 2 MSQ7.1: SharePoint Site Collection and Library Structure.

Account Manager Oversight and Authorized Users

SharePoint allows the Contractor to assign an Account Manager to oversee the document repository, ensuring smooth operations and adherence to guidelines. Permissions may be assigned at the library level. If desired, the State can own and manage access to project documentation.

In addition to its mobile device accessibility, SharePoint ensures that users who have the authorization and appropriate credentialing have 24/7 access, upload capabilities, and document linking. Users may attach new or revised versions of electronic documents and images in various formats. SharePoint may be accessed by authorized users' mobile devices, allowing real-time communication with the centralized data repository. Additionally, users may link uploaded documents or images to other system documents or cases.

Document Organization, Creation, and Tracking Features

SharePoint's Document Libraries can be used to store detailed project documentation, including process documents, procedures, and guidelines. To aid in document creation and editing of projects, SharePoint supports templates as well as collaborative editing wherein multiple team members can work on the same document simultaneously. A version history is maintained, allowing users to track changes and updates over the lifetime of a project. Additionally, metadata columns can be leveraged to categorize and organize documents by project activity or process.



Review, Modification, and Approval of Document Deliverables

SharePoint workflows can be set up to manage document approval processes. For example, when a document is modified, it can trigger an approval request and allow for designated approvers to review, modify, and approve document deliverables. Additionally, SharePoint can help manage deadlines by setting reminders and notifications, ensuring timely submission of records, documentation, reports, and data as specified in the State-approved Turnover Plan.

Operations Training and Retention

NHC will make available to the State comprehensive onsite training that may also be provided in a web-based format on SharePoint delivered by a professional with MS-900 or AZ-900 certification. Additionally, an end-user operations manual specific to the State will be provided as reference material. The manual will address the requirements in Attachment C section 2.14.1 Document Repository and will include modules on system functionality, accessing the application, role-based access, interfacing and navigating within the application, and security protocols. Further training is available from SharePoint's official website. To familiarize new users with the site, SharePoint provides instructions on using the document repository effectively via its Operations Manual feature. Additionally, its Web-based tutorial training sessions cover role-based access, navigation, document download, viewing, and confidentiality protocols. Lastly, SharePoint supports retention policies to ensure compliance with applicable ownership requirements.

SharePoint Maintenance Plan

SharePoint will be the primary access point for collaboration between the State and NHC. As such, it will be configured to meet the specific business needs of both organizations. Thus, it is imperative to this engagement that the application be well maintained, with outages limited to planned downtime.

The SharePoint operational functionality plan will include support for updates and routine maintenance to maintain a healthy environment. Critical to maintenance of the application is communication between the end user and the project manager. All users will have the ability to submit tickets when issues arise. Further, the SharePoint project manager will review user logs to identify any unreported issues with access and functionality.

Any security enhancements to SharePoint will be assessed as they are provided and promptly implemented, where applicable. SharePoint is regularly updated by Microsoft. Security patches to SharePoint published by Microsoft will be installed automatically and immediately upon availability.



NHC will work with the State to determine document retention policies to facilitate the removal of obsolete content stored within the application. Also, the project manager will review site permissions regularly to remove or delete obsolete users or immediately upon receipt of notice of termination of a user and to add or change permission settings at the user level as needed to limit access to the applications' content.

The solution can be managed by NHC, and the site will be housed in the Microsoft 365 environment. To ensure any data stored within the site will not be located offshore for any reason, the site will be set up such that it resides exclusively within the United States on the Microsoft Office 365 East Coast infrastructure. For security, the connection to the site will be made through Microsoft Office 365 Secure Socket Layer (SSL) protocols to encrypt the connection and Transport Layer Security (TLS) to encrypt the transmissions. Leveraging these security protocols ensures HIPAA-compliant transmission security for data in-transit.

Further, the SharePoint maintenance plan will include routine backups and scheduled backup testing to ensure disaster recovery.

8. Bookmark Title: MSQ8 – Staffing

Narrative description is limited to five (5) pages, exclusive of organizational chart(s) and Subcontractor contract(s) or letter(s) of agreement, if applicable.

Provide a narrative description of the proposed staffing plan that details policies, plans, and staffing strategies. The proposed plan must include the following:

- a. Organizational charts that provide a complete and detailed description of the proposed organizational structure the Supplier will use, including Subcontractors and how they fit into the Supplier's overall organizational structure.
- b. Roles and responsibilities of staff.
- c. Job titles and the requisite qualifications, skills, and credentials, including clinical licensures relevant to this Contract.

If Subcontractors will be used, provide the following:

- a. Subcontractor's name and address.
- b. Roles and responsibilities to be delegated to the Subcontractor for purposes of this Contract.
- c. Subcontractor's qualifications to perform these roles and responsibilities.
- d. Copy of the Subcontractor contract; the State will accept a letter of agreement with a prospective Subcontractor pending formalization of a final contract with details relevant to "c" in this section.

Refer to Attachment G - Pharmacy Clinical Management Services Scope of Work and Attachment C - Common Scope Requirements and Security Standards, Sections 2.15 Staff Management and 3 Staffing.

NorthStar Healthcare Consulting (NHC) is pleased to present a staffing plan that assures the same level of clinical expertise the Georgia Medicaid's Pharmacy Clinical Management Services (PCMS) program has relied upon for the last 18 years. Nothing is more critical to a clinical management program than a stellar team of experienced clinicians with firsthand experience in Medicaid pharmacy programs, as well as in the field at the pharmacy level.

NorthStar prides itself on having a flat organization structure with a reduced business hierarchy. As such, NHC employees are empowered to address our clients' needs in a nimble and flexible manner. Further, this flatter organization allows information and requests to be communicated to decision makers more promptly and increases collaboration among employees resulting in a better overall program to the State. Indeed, our employees enjoy partnering with states to develop creative solutions quickly and efficiently.

Organizational Chart

Even better than a very experienced team, is a team comprised of clinicians with an intimate understanding of the Georgia Medicaid program because they are already doing the work with documented success. The NHC team includes most of the same pharmacists serving the program today – as depicted in Figure MSQ8.1.

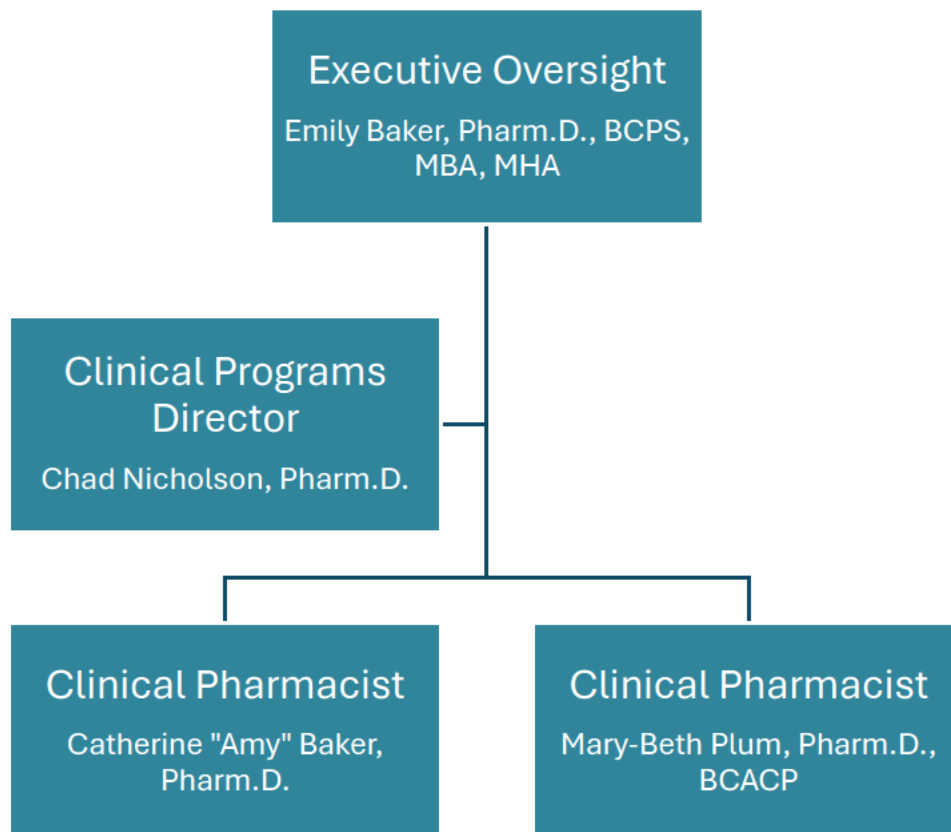


Figure MSQ8.1: NHC's Organizational Chart supporting the Pharmacy Clinical Management Services contract.



Roles and Responsibilities

Because NHC is currently providing clinical management for the State's program, we can highlight the actual individuals who are and will continue to fill each role needed for the program and shoulder the associated responsibilities.

Emily Baker, PharmD, BCPS, MBA, MHA – President and CEO

Emily Baker founded NHC in 2003 and currently serves as the company's President and CEO. She maintains hands-on oversight of all functions relative to the PCMS contract. Emily has over 25 years of experience working with Medicaid programs in both the Fee-for-Service and Managed Care spaces. Her pharmacy experience is wide ranging from prior authorization management; to fraud, waste, and abuse; to formulary and preferred drug list development. Emily has done significant work in pharmacy benefits management from a clinical as well as analytical perspective. Her experience is so wide-ranging that she served as the Interim Medicaid Pharmacy Director for Georgia Medicaid for a period in 2011. Emily is a graduate of the University of Georgia College of Pharmacy, licensed by the Georgia State Board of Pharmacy, and is also a Board-Certified Pharmacotherapy Specialist.

Chad Nicholson, PharmD – Clinical Program Director

Chad Nicholson joined NHC in 2016 as a Clinical Pharmacist supporting Georgia's PCMS Program. Today, Chad is the Director of the Clinical Management Services team. While continuing to provide hands-on clinical management services, he oversees the team's work in medication therapy management, drug utilization review programs including retrospective drug utilization review (RetroDUR), medication prior authorization, pharmacy claim data analysis, and support of the State's Drug Utilization Review Board. Prior to joining NHC, Chad had three years of retail pharmacy experience as a pharmacist and pharmacy manager. Chad is a graduate of the University of Georgia College of Pharmacy and is licensed by the Georgia State Board of Pharmacy. The Clinical Programs Director is a key staff position.

Catherine "Amy" Baker, PharmD – Clinical Pharmacist

Amy Baker is a Clinical Pharmacist providing clinical management services for Georgia's program. She has worked with the NHC team since 2012, ensuring that prior authorization decisions are consistent with covered benefits, quality of care, and medical necessity. Along with other health care providers, Amy provides independent evaluations and recommendations for appropriate therapeutic solutions and communicates clinical decisions to providers and patients. Prior to joining NHC, Amy served in a clinical capacity for a pharmacy benefit management company and was also a dispensing pharmacist for 14 years.



Mary-Beth Plum, PharmD, BCACP – Clinical Pharmacist

Mary-Beth Plum joined NHC in 2024 and is the newest member of our Clinical Management Services team. She has six years of experience working with pharmacy benefit administrators, designing, and providing clinical support for Medicaid programs involving RetroDUR, prior authorizations, and the creation of new drug monographs. Mary-Beth also has over 10 years of clinical pharmacy hospital experience and served 11 years as a preceptor and/or professor to pharmacy students. She is a graduate of Duquesne University and is licensed by the Virginia and Pennsylvania Boards of Pharmacy. Additionally, Mary-Beth is a Board-Certified Ambulatory Care Pharmacist. This clinical pharmacist position is a key staff.

As shown in our organizational chart above, and the staffing table that follows, NHC will employ two Clinical Pharmacists who will serve as key positions for this contract. With more than 80 years of combined experience in clinical services, the NHC team stands ready to continue its service to the Georgia Medicaid program. Nevertheless, NHC's Medicaid experience spans across a third of the state programs.

Job Titles/Descriptions

The following table lists our proposed positions and the required qualifications, skills, and credentials for this contract. The adequacy of our staffing plan is supported by the quality of our historical clinical oversight of the State's program – meeting and exceeding contract requirements.

Position	FTEs	Responsibilities	Qualifications/Skills/ Credentials
Executive Program Oversight	.20	Serves as a resource regarding the intersection between health care law, pharmacy practice, and fraud detection.	• PharmD • Georgia License
Clinical Program Director	1	Oversees the Clinical Management Services team's work in medication therapy management and drug utilization review programs, including retrospective drug utilization review, medication prior authorization, and pharmacy claim data analysis; while also supporting the State's Drug Utilization Review Board.	• PharmD • Georgia License
Clinical Pharmacist	2	Ensures prior authorization decisions are consistent with covered benefits,	• PharmD



		quality of care, and medical necessity. Provides independent evaluations and recommendations for appropriate therapeutic solutions and communicates clinical decisions to providers and patients.	• Georgia Licensed or Eligible
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Cross Training and Retention

All staff members at NHC receive functional cross training. Most of our pharmacists are trained to conduct audits as well as administer prior authorization determinations. Further, NHC enjoys a high rate of employee retention and longevity. At project go-live, more than half of the employees working on this account will have a minimum of 10 years of service. Two of the remaining employees will have over five years of service. Collectively, the **staff at NHC will have served the State for over 100 years in total.**

Our retention strategies include a focus on a positive work life balance including a requirement to take annual paid time off. Because all workers enjoy access to paid parental leave, all employees are willing to fill in the gaps whenever and wherever necessary. NHC also has a carefully curated group of on demand professionals that we can rely upon when needed to enhance our staffing and response times.

NHC has a plan for cross-training staff and conducting knowledge transfer to ensure that all functions can be adequately performed during the planned or unplanned absence of staff. Judicious use of processes and procedures and our internal training process assist with knowledge transfer and help mitigate the loss of institutional knowledge.

Key Staff

Per RFP Attachment C Section 3.2 Contractor Key Staff, we acknowledge that the team will be committed to the project one hundred percent of the time or as agreed upon by the State. We are dedicated to working in partnership with the State to assure that staffing levels and time commitments meet the needs of the program throughout the contract term.

Our Key Staff positions are currently filled. Therefore, our team will be ready to continue their work on day one of the contract and throughout all project phases. NHC is truly fortunate to retain team members long-term. However, should a situation arise when a resource is no longer right for the contract, we will work with the State to make the necessary modifications. We understand that the State must approve any changes to personnel serving the contract including terminations, the level of staff expertise, or reassignment.



For Key Staff, we understand that NHC must:

- notify the State within two business days of the date a Key Staff person resigns.
- obtain the State's written consent before Key Staff and other proposed project staff can be reassigned or replaced.
- name a temporary replacement acceptable to the State when Key Staff resigns or is reassigned and must do so within five business days of the position's vacancy.
- name a temporary replacement acceptable to the State prior to periods of planned leave for Key Staff positions.
- ensure a permanent replacement is working on the project within sixty (60) Calendar Days of the date a Key Staff position becomes vacant.

We acknowledge that the State may request reassignment/replacement of Key Staff at any point throughout the life of the contract.

Meeting Federal and State Requirements

NHC is fully compliant with all federal and state requirements relative to our workforce. NHC:

- has EEOC policies and procedures in place to assure fair employment and treatment of all employees without regard for race, color, religion, national origin, or physical disability.
- adheres to all federal and state laws regarding Social Security registration and legal work status of all its employed or contracted staff.
- completes criminal background checks for all employed or contracted staff prior to project participation. We will use State-accepted background check criteria and submit results to the State for review.
- is located within the United States and will not offshore any work related to this Contract for its duration.

Employees are also subject to the guidelines stipulated in the Employee Handbook, which include the requirement to disclose any potential areas of conflict and to avoid even the appearance of potential conflict.

Once approved by the State, we understand it is our responsibility to maintain compliance with the Staff Management Plan during implementation and for the duration of the contract.



9. **Bookmark Title: MSQ9 – Project Stages and Phases**

Bookmark Title for Supporting Material:

- **MSQ9.1 – Best Practices**
- **MSQ9.2 – Lessons Learned**

Narrative description is limited to five (5) pages, exclusive of required supporting material.

Demonstrate your understanding of the Project Stages, Project Phases, timeline, expectations, and responsibilities as outlined in the Attachment C: Common Scope Requirements and Security Standards, Section 2.2 Project Stages and Project Phases. If your plans for the proposed services differ from the suggested outline, please explain the differences and how the proposed plan is a better fit for the State's needs.

Include best practices and lessons learned that may be applied in the execution of these services and identify any additional proposed Milestones for the project.

NorthStar HealthCare Consulting (NHC) recognizes the State's commitment to a stepwise, incremental project management approach during this engagement while acknowledging that not all the project stages and phases are applicable to service-related scopes of work. As the incumbent Pharmacy Clinical Management Services (PCMS) Vendor for the lead State, NHC does not plan to deviate from the outline which recognizes two project stages: Design, Development, and Implementation (DDI); and Operations and Maintenance (O&M). Although the CM scope of work is largely service-related, the implementation or enhancement of our *CompassDURSM* program will follow the State's outline where applicable.

Design, Development, and Implementation Stage

The DDI stage will begin with a joint project planning kick-off meeting with the State as described in NHC's Communications Management Plan. The Project Manager will disseminate a meeting agenda to identified stakeholders and participants to facilitate the kick-off meeting. The overarching goal of the kickoff meeting is defining the scope of work and document requirements analysis for the DDI stage. During the meeting, NHC's plans and processes for Project Schedule/Project Work, Communications Management, Risk and Issue Management, Project Change Management, and Quality Assurance and Control will be reviewed and discussed. These plans will have been drafted based on our existing knowledge of the State's programs today combined with any new functionality as described within this solicitation. Further, NHC will collaborate with the State to agree on a conflict resolution process and escalation procedure. The members of the Project Core Team (PCT) will be identified plus roles and responsibilities will be

discussed and recorded. The team's fundamental approach to this engagement and resulting protocols (i.e., those for communication via electronic mail, live meetings, or phone; production of meeting minutes; team member availability; etc.) will also be established. Time will also be allowed for questions and answers as well as any other related items. Finally, a summary of the discussion will be provided to the PCT, including any decisions, actionable items, and risks. Key milestones will be State approval of the suggested timeline for implementation and submitted project management plans.

The project will then transition into the Design, Development, and Testing (DDT) phase. In this phase, NHC will modify or enhance the functionality of the *CompassDUR* system identified during the project planning phase. Key activities in this phase will include:

- Confirmation of project scope and detail via a Requirements Analysis Document (RAD);
- Initiation of any system enhancements or modifications as needed for the *CompassDUR* system or external processes based on information contained within the RAD;
- Draft and submit for approval RetroDUR related collateral including provider communications;
- Capture and subsequently draft for approval standard operating procedures for all clinical services modules;
- Collaborate with the State to determine a claims file format, frequency, and transmission method;
- Conduct quality assurance (QA) and data cleansing of claims file for ingestion; and,
- Initiate PCMS activities in a test environment for user acceptance testing.

NHC will seek client approval of the DDI plan prior to moving into a testing environment. Upon approval of the DDI approach, user acceptance will be initiated. Once the state has approved the DDI process and the completed user acceptance testing (UAT), the key milestones for this phase will have been completed and the transition to Phase III will commence.

Immediately after the conclusion of the DDT phase, NHC will enter the Operational Readiness and Production Cutover phase. Our *CompassDUR* system will be stress tested to confirm the successful ingestion of final production claims data and generation of state approved RetroDUR collateral provider communication letters. The system will then be migrated into the production environment for cut-over. The technical architecture will receive final validation while the project management staff and operations manual will be validated for operational readiness. Upon completion of parallel testing and the State's acceptance of the results is received, the final milestone for this phase of the project will be complete. NHC will submit and receive approval of

the implementation letter from the State. Once approval is secured, the operations as outlined in the letter will be deployed.

Stage Summary

Project Stage:	Design, Development, and Implementation Project Stage (DDI)		
Project Phase:	Project Phase I	Project Phase II	Project Phase III
	Project Planning and Startup	Design, Development, and Testing	Operational Readiness and Production Cutover
Purpose:	- Project planning kick-off meeting - Presentation of NHC's plans and processes for Project Schedule, Communications, Risk/Issue Management, Change Management, and QA/Control - Define conflict resolution process/escalation procedure - Clarify expectations for the Project Core Team (PCT) - Establish protocol for communications	- Completion of RAD - Initiate system modifications /enhancement - State approval of RetroDUR collateral - Memorialization of Standard Operating Procedures - NHC/State determine claims file format, transmission method, and frequency - Conduct QA and data cleansing of claims file for ingestion - User Acceptance of activities in test environment	<i>CompassDUR</i> system final testing to confirm successful ingestion of claims data/generation of communication letters - Validate technical architecture - Validate operational readiness of staff and operating manual - State approval of implementation letter. - Operations as outlined in letter deployed



Key Milestones	• State approval of implementation timeline and project management plans	• State approval of DDI process • User Acceptance Testing	• State Acceptance of parallel testing
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Operations & Maintenance Stage

The project's Operations and Maintenance (O&M) stage will be next to launch with its first phase of Initial Operations. Although the PCMS scope of work is largely service-related by design, there are go-live milestones to be met. Given the cyclical nature of some of the State's programs (e.g., RetroDUR, SAB) and their established schedule, NHC recommends a rolling initiation of the Clinical Management (CM) services including Drug Utilization Review (DUR), Utilization Management (UM), State Advisory Board (SAB) administration, and RetroDUR. Assuming a July 1, 2025 go-live date, it is anticipated that UM efforts, particularly weekly review of new additions to the drug file and drugs to market, will commence immediately. Depending on where the State is in its workflow cycle, SAB support and RetroDUR initiation will commence to avoid or minimize interruption or delay to the State's schedule for these programs. It is expected that all services will be in operational phase within three months of go-live, with the possible exception of RetroDUR outcome reporting which generally spans a period of six months.

Phase V heralds the continuation of CM services through the operations phase, with a nod to expected functionality enhancements that evolve over time. O&M will incorporate the execution of reporting tasks and management of State-approved change orders as needed including program requirements modification and any system improvements. During the O&M stage's final phase, NHC will commence tasks involving the project's turnover and contract close-out. Unless directed otherwise by the State, NHC will focus efforts into wrapping up open or ongoing CM initiatives and the provision of historical documentation and records to the incoming vendor in the final period of this engagement. Hence, new initiatives of CM services that run on a quarterly or other cyclical schedule will cease unless otherwise directed by the client after the last full cycle has been completed under the contract. At that time, efforts will be focused on closing out any remaining active initiatives and transitioning services to the incoming vendor. Included in our transition efforts will be the provision of reporting and historical data to the client or their designee as mutually agreed upon and at least as far back as necessary to facilitate the filing of the next CMS annual DUR report. Any data or documentation not transferred will be destroyed and the client will be provided with a certificate of destruction. Turnover readiness will be demonstrated with the closing out and transitioning of all CM services to the incoming vendor, and the performance of other tasks as needed to transition to the incoming vendor as outlined above.



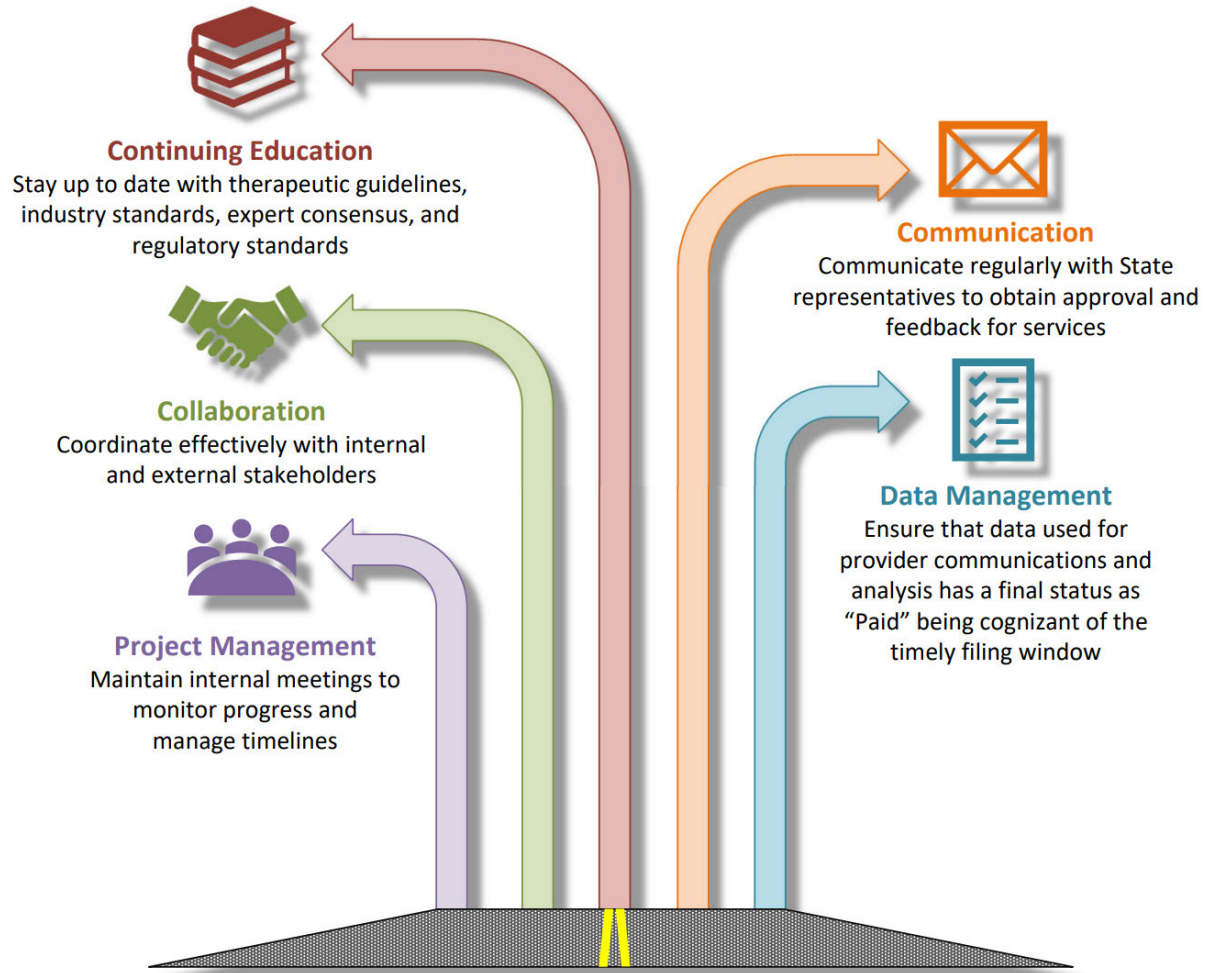
Finally, we will conduct a project wrap-up meeting wherein we will discuss lessons learned and best practices. Some observations from our previous experience implementing effective RetroDUR programs include, but are not limited to:

- RetroDUR criteria must be defensible, and this can be accomplished via a multi-disciplinary approach by leveraging the clinical literature, an experienced clinical vendor, and peers within the state including the SAB.
- RetroDUR interventions should be focused with the goal of eliminating unnecessary noise to providers. If the scope and breadth of the intervention will overwhelm providers, consider criteria refinements or performing a rolling intervention with tiering of cases based on level of concern.
- RetroDUR approach to intervention should provide actionable information and try to motivate change amongst providers while thanking them for their service to the Medicaid program in some cases.

Stage Summary

Project Stage:	Operations and Maintenance (O&M) Project Stage		
Project Phase:	Project Phase IV Initial Operations and CMS Certification	Project Phase V Operations Project	Phase VI Turnover and Contract Closeout
Purpose:	• Initiation of CM Services: DUR, UM, SAB, RetroDUR	• Incorporate execution of reporting tasks • Manage change orders	• Changeover of CM services to incoming vendor • Other tasks as needed for transition
Key Milestones	• Go-Live of Solution	• Operations and Maintenance	• Service Turnover • Project End

MSQ9.1 Best Practices



MSQ9.2 Lessons Learned



To provide effective and expert clinical management services, it is imperative to remain current with clinical pharmacy guidelines and relevant industry standards.



To meet expectations of the State and associated stakeholders, it is important to maintain open lines of communication with their representatives.



Communicating regularly with PBA and PDRS vendors is crucial in completing required tasks.



If data used for communications and analysis is inside the timely filing window, there is a risk that it will be changed and negatively impact the effectiveness of our analysis.



In order to ensure project deadlines are met, internal timelines must be developed and regular internal meetings conducted.



10. Bookmark Title: MSQ10 – Transition & Integration

Narrative description is limited to three (3) pages.

Describe how you will handle the transition activities from the incumbent Clinical Management vendor. Include the value-add of your approach and techniques in terms of cost savings, quality improvement, and/or savings to the project schedule for the State.

Describe your integration approach with the Pharmacy Benefit Administrator (PBA) vendor and its system.

As NorthStar HealthCare Consulting (NHC) is the incumbent Pharmacy Clinical Management Services (PCMS) Vendor for the Georgia Medicaid Fee-For-Service (FFS) program, transition of *service-related* activities from another PCMS vendor will not be necessary, resulting in significant time, resource, and cost savings for the State. However, NHC acknowledges the potential for transition and the need for integration should there be a change in other suppliers, including the Pharmacy Benefits Administrator (PBA) and/or Pharmacy Drug Rebate Services (PDRS) Vendors, the manner in which we access the State's data, or contract award from a participating state.

Throughout its history, NHC has extensive experience working with several claims processors particularly in the Medicaid FFS space. Regardless, any changes to the state of our integration with the current PBA and PDRS Vendors in the case of the lead state, or as an incoming supplier in a participating state, would largely occur during Design, Development, and Implementation (DDI). These factors assist in minimizing the cost impact not only to the lead state of Georgia, but also for any participating states.

Indeed, it has been our experience, most of the cost of standing up a clinical management engagement, including for Retrospective DUR (RetroDUR) services, is incurred in the first three months of implementation as these initiatives in particular are often conducted quarterly. Thus, the financial impact of implementation of a new vendor will largely be accounted for during the DDI phase.

Finally, NHC affirms "we will treat your money like it is ours" knowing that we are in the business of assisting states with assessing value for their clinical programs.

Transition

For states in which we are not the incumbent, the transition will initially focus on data receipt and ingestion. This may also be true for the lead state should there be a change in how NHC accesses the data from today. The initial transition will start by collaborating with identified stakeholders, including the PCMS Vendor and the State, to assume Clinical Management (CM) services, as well as the designated source of claims data



feed for integration into the *CompassDUR* system. To initiate transition efforts, NHC will ingest historical clinical services data as needed from the outgoing PCMS Vendor, either directly or indirectly, via a conduit authorized by the State. NHC takes data security very seriously and is positioned to receive this data in a secure manner. Any data received by NHC will be cleansed to identify and address inconsistencies. After cleansing, the data will undergo a thorough quality assurance process and then be mapped for ingestion into our database.

While data integration is being conducted, review of prior efforts on behalf of the State will commence. As such, previous State Advisory Board (SAB) meeting minutes will be reviewed, as well as prior RetroDUR interventions and Centers for Medicare and Medicaid Services (CMS) annual reports. Current policy manuals, Utilization Management (UM) criteria, Step Edits, Quantity Level Limits (QLLs), Provider Administered Drug List (PADL), and Preferred Drug List (PDL) placement will also be examined. This information, coupled with our current knowledge of the State and its programs, will be incorporated into our approach and commitment to delivery of a comprehensive PCMS program. Once this has been completed, NHC will propose an individualized PCMS program tailored to and reflective of the needs of the State. The culmination of NHC's experienced approach to CM services is minimal disruption, limited effort and cost to the State and its stakeholders.

Integration

NHC acknowledges and understands the necessity of integrating with the PBA Vendor and other vendors when implementing a successful PCMS program. Such integration is crucial for data access surrounding CM services, provider relations, member communications, and other PCMS functions. Indeed, open communication will be paramount as the PBA Vendor will be partly reliant upon the PCMS supplier to provide final UM decisions and NHC will be reliant upon metrics provided by the PBA Vendor for completion of the CMS Annual DUR Report. To ensure this integration is completed in a timely manner, NHC will leverage a detailed Integration Plan, outlining the coalescence of multiple factors into a cohesive, functional program. Scope, cost, time, quality, and communications must all be expertly assessed, addressed, and monitored for a successful integration.

Scope

NHC works with the State and any other assigned vendors to define and refine the functions and features of the PCMS Program as well as program objectives. A clearly defined scope of work that satisfies the needs of the State is key to successful integration. Any changes to the scope will be identified and implemented in accordance with NHC's Change Management Plan, ensuring stakeholder satisfaction.

Open communication and documentation of policy and processes will be paramount as the PCMS Vendor will be the supplier of final UM decisions including PDL status, Step



Edits, QLLs, and Prior Authorization (PA) criteria, critical information for the PBA Vendor. Further, the PBA Vendor will serve as the source of several metrics such as call center statistics and reporting on DUR edits required for the completion of the CMS Annual DUR Report.

NHC anticipates collaboration with the PDRS Vendor to make the most appropriate recommendations for the state particularly with designation of PDL status and development of PA criteria as these efforts can have downstream effects on supplemental rebates and value-based contracting. Additionally, the PBA Vendor should be aware of potential RetroDUR interventions as these initiatives may result in provider contact to the call center.

Value Added Services

Finally, should NHC also be retained as the Pharmacy Fraud, Waste, and Abuse (PFWA) Vendor, the State will benefit from the collaborative efforts for further program refinement and enhancement. As a value add, recommendations and referrals are often exchanged between the CM and FWA departments at NHC. Past exchanges have resulted in the creation of QLLs for products that were identified as routinely misbilled by the FWA department. Because clinical pharmacists are involved in profile review as part of our RetroDUR process, aberrant billing practices have often been referred to the FWA department. An additional value-added service for consideration could include a quality improvement (QI) program to review the accuracy and timeliness of completion of prior authorization requests by the PBA Vendor. These types of QI programs assist with refinement of PA criteria and call center processes and provides the State with an opportunity to view their prior authorization program through the lens of an independent auditor.

Cost

Because a Medicaid FFS program has a significant economic impact on the State, the cost of a project of such importance must be carefully managed to avoid wasting resources. As a consulting company, NHC acknowledges that the bulk of our costs, and our value, are in our people. As such, our personnel and their efforts are fixed costs. Nevertheless, NHC has a Cost Management Plan in place to keep misallocation or waste of funds to a minimum during the process of integration with the PBA Vendor and throughout the life of the contract.

Time

Confusion and delay in the implementation of the program only serves to decrease the confidence of providers and stakeholders in the PCMS program. Time goes hand-in-hand with cost on a task with high-level consequence. In accordance with our Communications Management Plan, NHC will coordinate with the PBA and Pharmacy



Drug Rebate Services (PDRS) Vendors, along with the State, to link functionality and provide efficient PCMS services, ensuring integration is completed in a timely manner.

Quality

NHC has had the privilege of providing quality PCMS and PFWA services to the Georgia Medicaid program for 18 years. We are committed to maintaining the highest standards not only in our services but also in our professionalism when interacting with providers, stakeholders, and clients. To ensure quality of integration with the PBA Vendor, any integrated data will undergo a thorough quality assurance process prior to ingestion into our database.

With respect to quality improvement in our processes and by extension the State's programs, NHC meets weekly with all team members assigned to an account to review operations and assess any opportunities for improvements. Mentioned previously, interdepartmental recommendations and referrals typically arise through these meetings. These recommendations and referrals have improved the quality of our UM program. For example, potential opportunities for medication-specific billing errors and by extension waste and misuse of program resources are brought to light. Whenever possible, NHC will make UM recommendations such as QLLs or claim lookbacks to systematically address potential claim errors.

Communications

Good communication is the foundation of any successful endeavor. It is crucial to ensure that all involved share the same understanding of the PCMS program's form and functions and that any proposed changes are accepted, integrated, and are prepared for implementation. NHC leverages a detailed Communications Management Plan to make certain that all project stakeholders have the information they need to perform their roles throughout the project. The finalized communication plan will include an outline for a kick-off meeting to facilitate a successful integration process and progresses to project end and contract run out.

Finally, NHC pledges to have its team members available to the State and their suppliers, for both standing and as needed meetings to ensure program success.

11. Bookmark Title: MSQ11 – Project Management

Bookmark title for supporting material:

- [MSQ11.1 - Project Schedule/Project Work Plan \(Sample\)](#)
- [MSQ11.2 - WBS tasks and Project Outputs \(Sample\)](#)
- [MSQ11.3 - Implementation Plan \(Sample\)](#)
- [MSQ11.4 - Quality Management Plan \(Sample\)](#)
- [MSQ11.5 - Requirements Management Plan \(Sample\)](#)
- [MSQ11.6 - Change Management Plan \(Sample\)](#)
- [MSQ11.7 - Risk Management Plan \(Sample\)](#)
- [MSQ11.8 - Communications Management Plan \(Sample\)](#)
- [MSQ11.9 - Integration Plan \(Sample\)](#)
- [MSQ11.10 - Operations & Maintenance Plan \(Sample\)](#)
- [MSQ11.11 - Training Plan \(Sample\)](#)
- [MSQ11.12 - Cost Management Plan \(Sample\)](#)
- [MSQ11.13 - Stakeholder Management Plan \(Sample\)](#)

Narrative description is limited to five (5) Pages, not including the required supporting material.

Provide a description of the project management approach, including, but not limited to, the methodology and implementation of the system to be used for monitoring and control of scope, schedule, and cost. Additionally, describe any previous experience managing similar projects using the Project Management Lifecycle (PMLC) and Project Management Book of Knowledge (PMBOK) throughout the life of the contract.

Refer to Attachment C - Common Scope Requirements and Security Standards, Section 2 Project Organization and Management.

In the Supporting Material, include a draft or sample project management plan representative of this project. In your narrative response, explicitly identify any differences between the State's project management approach from your proposed approach, including all responsibilities.

NorthStar HealthCare Consulting (NHC) is the incumbent vendor for Pharmacy Management Clinical Services (PCMS) for the State of Georgia's Medicaid Fee-For-Service (FFS) program. Even so, the principles of project management have value and as such are incorporated throughout the initiatives we provide to our clients. NHC takes a flexible project management approach that emphasizes feedback from, and collaboration with, the Client. In this way, NHC crafts a bespoke solution for the State or Client's particular needs. Using an adaptive methodology for project management allows the State to determine the course of action best suited to achieve the desired

outcomes of maximizing the therapeutic outcomes for the program's enrollees while minimizing the financial repercussions to state resources.

NHC undertakes the development of a PCMS Program by first collaborating with the State in a comprehensive planning effort to assess the Scope of Work (SOW) and institute, initialize, and anticipate the administration and management of the project. NHC will assess and make proposals for a successful program that complies with all state and federal laws and regulations. Regardless of the individuality between states, the linchpins of a winning PCMS Program are support of the State Advisory Board (SAB), an approach to Drug Utilization Review (DUR), and Utilization Management (UM).

NHC acknowledges that for service-only scopes of work, not all of the two project phases and six project stages may apply. Nevertheless, to the extent that the project phases and stages do apply, NHC is committed to following the project management path as outlined in Attachment C for both the design, development, and implementation stages as well as the operations and maintenance stages.

The Project Management Book of Knowledge (PMBOK) is, at its basic level, an approach to effective project management. Contained therein is a standardized collection of best policies, project management processes, and guidelines. Having a standardized approach to project management facilitates successful implementation. The PMBOK's standardized approach is useful on most projects, and to the extent the approach provides value to individual state Medicaid programs, NHC incorporates these processes.

At a high level, the pathway of a successful implementation can be divided into five distinct domains. The first step involves defining the project, project goals, identifying stakeholders, and aligning expectations early. This is known as Initiation. The Planning stage maps out activities required for project completion and identifies requisite resources, including people. The following two stages, Execution and Monitoring/Controlling can, and often do, run concurrently. Finally, the Closure stage is an opportunity to discern Best Practices and Lessons Learned for future implementation.



Previous Experience

The principals at NHC have been a party to many implementations; both large and small across several Medicaid clients. Large projects such as the implementation of a Retrospective Drug Utilization Review (RetroDUR) system would follow project management best practices for design, development, and implementation. Continuing into the operations and maintenance phase, many of the core processes of project management are found in our daily client initiatives including State Advisory Board (SAB) presentations and drug utilization review projects. By way of example, RetroDUR interventions follow a project management approach.

RetroDUR System Implementation

For much larger projects, NHC still generally follows the PMBOK approach to project management. Consider the implementation of a RetroDUR program.

Phase 1 – Project Initiation: Details of the project goal are gleaned from the request for proposal, our experience, and during the kickoff meeting. For an implementation with the size and scale of a RetroDUR program, a project charter would be created which details:

- Project Constraints
- Goals including high level scope of work
- Budget
- Expected Timeline
- Stakeholder Identification.

Phase 2 – Project Planning: The scope of work is defined through a requirements analysis document involving comprehensive planning efforts between the client and vendor. Primary tasks are then defined via a work breakdown schedule and would likely include the source, frequency, method of transfer, file layout, and ingestion of claims data feeds utilized in interventions. Technical requirements would include the standardization of file formats and methods and systems used to access the data transfers. A detailed project schedule will then be formulated with incremental steps and milestones identified. The completion of the project schedule assists in developing the communication plan and identifying stakeholders so that project status information can be communicated.

Phase 3 – Execution: The project will commence implementation of the provision of services. Claims data files will be created and provided to the receiving vendor for data ingestions. The RetroDUR system will be queried for test interventions once the data has been scrubbed and ingested. Letter generation often serves as one of the final milestones in the implementation. While the work is being done, project progress will be monitored and communication with stakeholders becomes critical. Weekly, if not daily, meetings occur as go-live approaches. User Acceptance Testing, if applicable, should

occur as the implementation reaches selected milestones and deliverables. Phase 3 often occurs simultaneously with Phase 4, Project Monitoring and Controlling.

Phase 4 – Monitoring and Controlling: Previously identified critical success factors and key performance indicators are consistently monitored (and controlled) as they can serve as early signals of potential issues. The identified indices should be tied to a successful project implementation to provide value towards the attainment of goal completion. Falling short on any of these indices may be an early signal of project delay and derailment. For instance, timely file transfer via the appropriate medium is a critical success factor for all data driven programs. The ability to scrub and ingest the data serves as a key performance indicator of a successful implementation. Internally, efforts and expenditures will also be tracked in a nod to any budgetary concerns.

Phase 5 – Project Closure: Lessons learned, and best practices are documented for future implementations. The project monitoring and controlling that occurred in Phase 4 are reviewed and documented in the project closure report which may serve as a historical record of how the implementation was guided. Finally, participating staff are thanked for their efforts and any records with potential historical value are archived.

PMBOK Application to Smaller Projects – RetroDUR Intervention

The use of PMBOK principles also has value in smaller projects such as a RetroDUR intervention.

Phase 1 – Project Initiation: Initiation of RetroDUR begins with the identification of a clear goal of the intervention while detailed initiative information will be found in Phase 2. For instance, the client may wish to address the number of patients who are seen for asthma exacerbations in the emergency room. This is the goal of the project. The scope of work would include the number of providers and patients (stakeholder identification) targeted and the method of contact. Any project constraints, such as lag in medical data, will be identified. Finally, a timeline for intervention and outcomes will be determined.

Phase 2 – Project Planning: In Phase 2, we drill down to define the scope of work. While the goal of the project is to improve outcomes in patients with asthma exacerbations; the scope of work provides further details of the initiative. The population for intervention is defined as providers of patients with asthma who have had a recent emergency room visit for exacerbation, but who lack a controller medication for asthma. The primary tasks are outlined in this phase. In this case, they would include initiation and selection from claims data, identification of cohort for intervention, collateral development, and client approval. A detailed project schedule is formulated which facilitates the development of a communication plan for identified stakeholders.

Phase 3 – Project Execution: This is where we get the work done. Upon receiving client approval, NHC commences work towards project completion. Since the stepwise



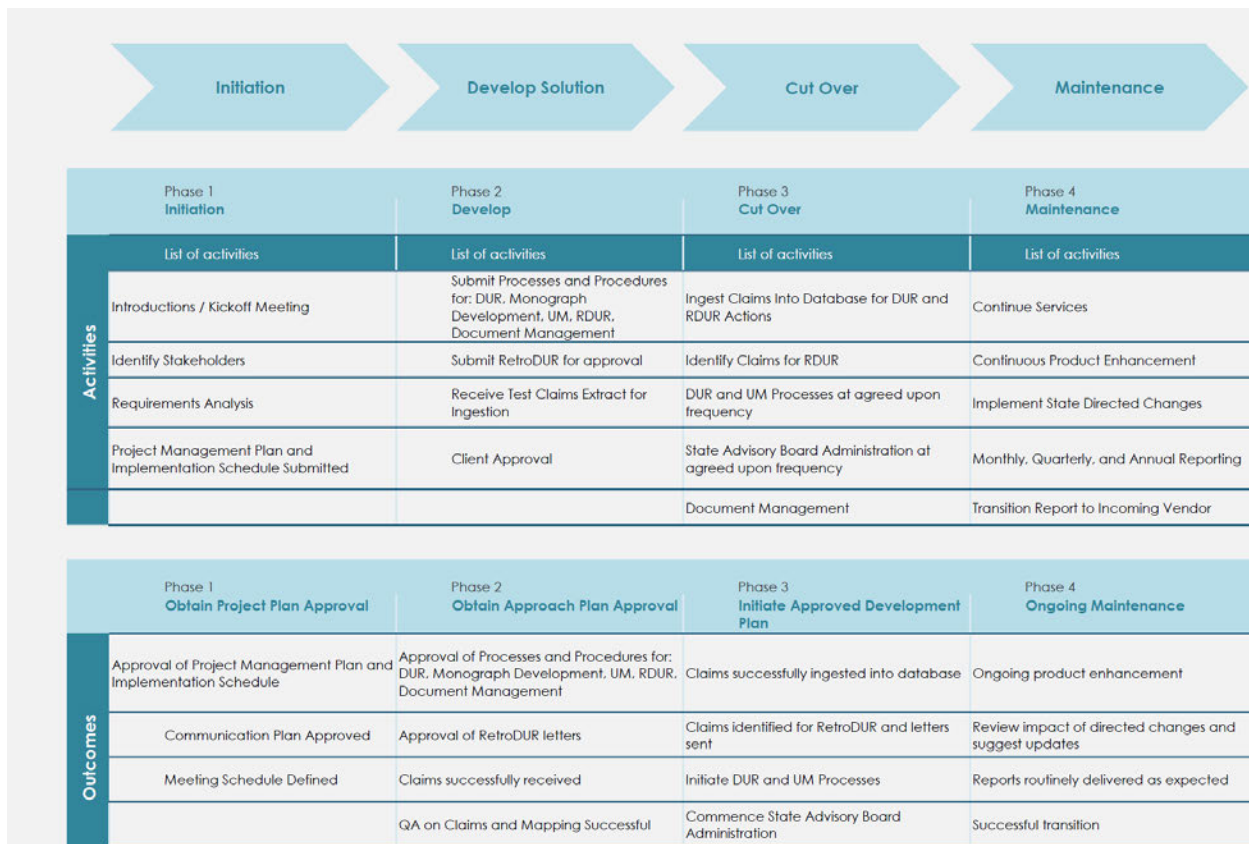
process has been previously defined, NHC will monitor project progress and maintain collaboration and communication with stakeholders.

Phase 4 – Project Monitoring and Control: Phase 4 runs concurrently with Phase 3 and involves identification of critical success factors (e.g., client approval of intervention collateral) and key performance indicators (e.g., number of cases eligible for intervention) are identified and established to ensure the goal of the project is achieved. Because RetroDUR interventions are heavily dependent on timelines, deliverables, and milestones (e.g., mailings) will also be monitored. The goal of monitoring and controlling is to prevent small problems from developing into much larger problems that derail the project entirely.

Phase 5 – Project Closure: The team meets to discuss successes and failures. The intervention's final outcomes will be provided in a pre- and post-intervention report. If the results of the intervention are generally positive, future enhancements to the RetroDUR process will be captured. Interventions with less than expected outcomes will undergo further analyses to identify "soft spots" in the process. These "soft spots" may be examined to determine if there are alternative approaches or enhancements that can be made to improve outcomes.

MSQ11.1 – Project Schedule/Project Work Plan

NHC's Project Work Plan will be used to assure the project progression is meeting the established timeline. It has been designed to memorialize all projects initiatives required to meet the State's requirements and will include the schedule, staff effort, additional resources, and all associated costs.





MSQ11.2 WBS Task and Project Outputs – PCMS

MSQ11.2 includes all tasks and deliverables required pursuant to the eRFP and NHC's implementation and ongoing operational processes. Within the tasks and deliverables, certain dependencies do exist and have been considered. To interpret this deliverable, each task, and associated subtasks are numbered in a hierarchical fashion relative to the timeline.

This supporting item begins on the following page.



1. Pharmacy Clinical Management Services
 - 1.1. Initiation
 - 1.1.1. Project Kickoff Meeting
 - 1.1.2. Requirements Analysis
 - 1.1.3. Develop Project Plan
 - 1.1.4. Submit Project Plan
 - 1.1.5. *Milestone: Project Plan Approval*
 - 1.2. Planning
 - 1.2.1. Create Approach Plan
 - 1.2.1.1. Policy and Procedures
 - 1.2.1.1.1. ProDUR and RetroDUR Management
 - 1.2.1.1.2. Utilization Management
 - 1.2.1.1.3. State Advisory Board Administration
 - 1.2.1.1.4. Document Management
 - 1.2.1.2. Communications
 - 1.2.1.2.1. Develop Provider Notification Letters
 - 1.2.1.2.2. Develop Member Notification Letters
 - 1.2.1.2.3. Educational Outreach
 - 1.2.1.2.4. External Stakeholder Introductions
 - 1.2.2. Submit Approach Document
 - 1.2.3. *Milestone: Approach Plan Approval*
 - 1.3. Execution
 - 1.3.1. Receive Test Claim File
 - 1.3.1.1. Scrub Data
 - 1.3.1.2. Data Mapping and Ingestion
 - 1.3.2. Testing Phase
 - 1.3.2.1. Analytics
 - 1.3.2.2. Letter Generation
 - 1.3.2.3. Document Repository
 - 1.3.3. Install Live System
 - 1.3.4. User Training
 - 1.3.5. Go Live
 - 1.4. Control
 - 1.4.1. Project Management
 - 1.4.2. Project Status Meetings
 - 1.4.3. Risk Management
 - 1.4.4. Update Project Management Plan
 - 1.5. Closeout
 - 1.5.1. Pharmacy Clinical Management Services Procurement
 - 1.5.2. Document Lessons Learned
 - 1.5.3. Update Files/Records
 - 1.5.4. Gain Formal Acceptance
 - 1.5.5. Transfer Archive Files/Documents



MSQ11.3 - Implementation Plan

On the following page, we are presenting a draft Implementation Plan that includes tasks, assignments, contingencies, and timelines for all phases of implementation. We look forward to collaborating with the State to expand upon this initial draft to assure that all aspects of implementation important to NHC and the State are thoroughly considered and that the plan fully meets expectations.



Implementation Plan - Clinical Management Services

NorthStar HealthCare Consulting

TASK	ASSIGNED TO	PROGRESS	START	END
Gather Requirements				
Identify Key Stakeholders	Emily B, Chad N, Mary-Beth P	0%	7/1/24	7/1/24
Kickoff Meeting with Stakeholders	Emily B, Chad N, Mary-Beth P, Matt R	0%	7/2/24	7/2/24
Requirements Analysis	Emily B, Chad N, Mary-Beth P	0%	7/3/24	7/18/24
Develop the Schedule				
List Tasks	Emily B, Chad N	0%	7/18/24	7/18/24
Set Task Priorities	Emily B, Chad N	0%	7/19/24	7/19/24
Determine Timeline	Emily B, Chad N	0%	7/19/24	7/19/24
Assign Resources	Emily B, Chad N	0%	7/23/24	7/23/24
Plan for Communication (DCH, PBA, PDRE)	Emily B, Chad N	0%	7/23/24	7/23/24
Identify Customer Security Requirements	Gaby R, Matt R, PTG	0%	7/24/24	7/25/24
Implement Identified Security Measures	Gaby R, Matt R, PTG	0%	7/26/24	8/9/24
Design the Solution				
Develop Approach Document	Emily B, Gaby R, Chad N	0%	8/9/24	8/12/24
Create Solution Design Document	Emily B, Gaby R, Kris B, Chad N, Mary-Beth P	0%	8/13/24	8/26/24
Define Product Specifications	Emily B, Gaby R, Kris B, Chad N, PTG	0%	8/27/24	9/5/24
Update the Schedule	Emily B, Chad N	0%	9/6/24	9/6/24
Build the Solution				
Configure Features	Gaby R, Kris B, Matt R, PTG, Chad N	0%	9/6/24	9/13/24
Customize RetroDUR System	Gaby R, Matt R, Chad N, Mary-Beth P	0%	9/16/24	9/20/24
Perform System Testing	Kris B, Matt R, Chad N, Mary-Beth P	0%	9/23/24	9/24/24
Document Issues Found	Gaby R, Kris B, Matt R, Chad N	0%	9/25/24	9/25/24
Correct Issues Found	Gaby R, Kris B, Matt R, Chad N	0%	9/26/24	10/14/24
Test Corrections	Gaby R, Kris B, Matt R, Chad N, Mary-Beth P	0%	10/15/24	10/15/24
Integrate the Solution				
Receive Claim File	Gaby R, Kris B, Matt R	0%	10/15/24	10/15/24
Set up the Customer Database	Gaby R, Kris B, Matt R	0%	10/16/24	10/17/24
Migrate Data	Gaby R, Matt R, PTG	0%	10/18/24	10/21/24
Integrate the Desktop (Internal)	Gaby R, Kris B, Matt R	0%	10/22/24	10/25/24
Monitor the Solution				
Define Success Metrics	Emily B, Matt R, Chad N	0%	10/28/24	10/28/24
Review Business Performance	Emily B, Matt R, Chad N	0%	10/29/24	10/31/24
Provide Training				
Schedule Training	Gaby R, Chad N, Mary-Beth P	0%	10/28/24	10/28/24
Train End Users	Gaby R, Chad N, Mary-Beth P	0%	10/29/24	10/31/24
Create User Documentation	Gaby R, Chad N, Mary-Beth P	0%	11/1/24	11/4/24



MSQ11.4 - Quality Management Plan

The pages that follow include a draft of NHC's quality management plan specifically for this engagement. It provides quality standards and protocols relative to clinical management services. We look forward to working with the State to further develop this plan to assure our full compliance with the State's requirements and expectations.

NorthStar Healthcare Consulting Quality Management Plan

Pharmacy Clinical Management Services (PCMS) Area	Tasks	Deliverables with Established Frequencies	Quality Assurance and Control Methods
Drug Utilization Review (DUR)	- Develop and maintain step edits, QLL's, PDL, PADL - Develop Recommendations for Enhancement	- Quarterly evaluations of ProDUR and RetroDUR criteria and interventions - Report findings from literature reviews on a frequency determined by the State - Monthly and quarterly DUR summary reports as required - Annual report of DUR activities	- Clinical pharmacists remain current with industry standards, therapeutic guidelines, expert consensus, regulatory changes, active in DUR societies - Conduct regular internal meetings to assess adherence to timelines
Utilization Management (UM)	- Develop and maintain criteria for covered products - Develop and maintain protocols for all products, including those involving State-specific requirements - Provide the State with an automated workflow tool	On annual basis: review, update, and provide the State with UM algorithm criteria for each therapeutic class and UM forms	Clinical pharmacists remain current with industry standards, therapeutic guidelines, expert consensus, regulatory changes, active in DUR societies

Pharmacy Clinical Management Services (PCMS) Area	Tasks	Deliverables with Established Frequencies	Quality Assurance and Control Methods
			- Clinical pharmacists conduct therapeutic class reviews, develop monographs on new drug entities - Conduct regular internal meetings to assess adherence to timelines - Perform user access maintenance on automated workflow tool
State Advisory Board (SAB)	- Oversee, implement, direct SAB meetings - Prepare, provide materials for presentation - Post agendas to State website - Make recommendations regarding UM services	- Schedule meetings at an interval determined by the State - Provide minutes of meetings to the State within 3 business days	- Conduct internal meetings to plan for SAB meetings - Coordinate with PBA and PDRS Vendors to prepare for SAB meetings



Pharmacy Clinical Management Services (PCMS) Area	Tasks	Deliverables with Established Frequencies	Quality Assurance and Control Methods
	- Record meeting minutes - Recruit SAB members as directed by the State		
RetroDUR	- Identify, monitor drug usage for potential abuse/misuse and fraud assessments - Notify providers via letter of potential drug therapy concerns	Within 10 business days of State approval, update RDUR files and criteria tables as recommended by SAB	- Clinical pharmacists remain current with industry standards, therapeutic guidelines, expert consensus, regulatory changes, active in DUR societies - Conduct regular internal meetings to assess adherence to timelines
Document Management	Maintain document repository supporting no less than 2GB per file	Must be accessible 24/7	Conduct periodic internal audits to confirm and maintain S.O.P.

QLL- quantity level limits; PDL- Preferred Drug List; PAD- Provider Administered Drug List; ProDUR- prospective DUR; RetroDUR- retrospective DUR; PBA- Pharmacy Benefits Administrator; PDRS- Pharmacy Drug Rebate Services; S.O.P.- Standard Operating Procedure



MSQ11.5 - Requirements Management Plan

We have designed the following Requirements Management Plan to easily chronical how NHC will receive, analyze, document, and manage the service we will provide, while meeting and delivering all associated requirements and tasks – throughout the life of the project. The plan specifically shows a prioritized flow of needs, responsible entities, timeframes, and processes for modifications – assuring that all needs have been met.



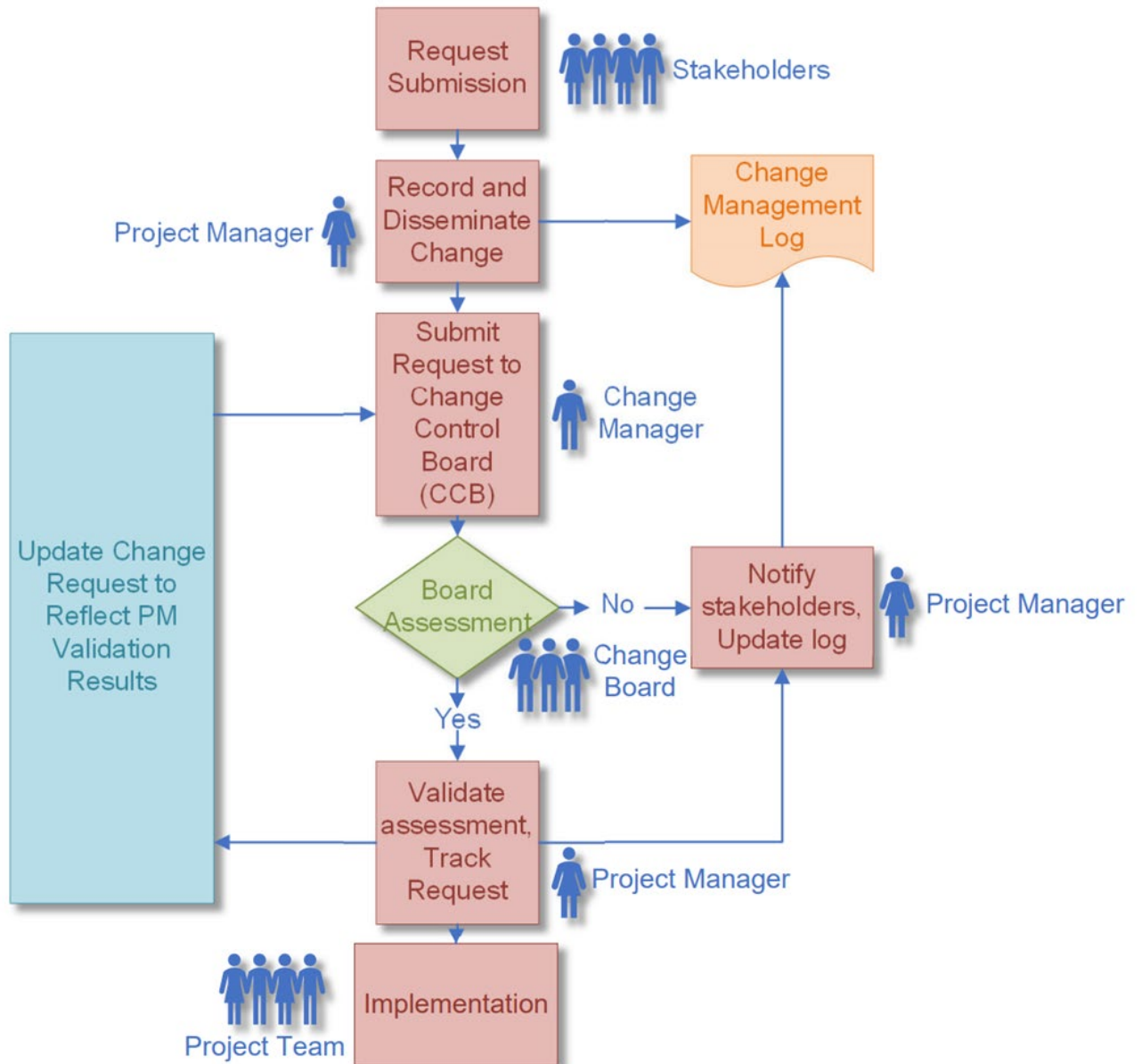
MSQ11.5 - Requirements Management Plan

Requirement	Stakeholders	Priority-based on Resource Intensity	Responsible Party(s)	Traceability	Changes		
					Reason for Changes	Who Authorizes Changes	How to Make Changes
State Advisory Board (SAB)	the State, NHC, SAB	1	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes; SAB-requested changes	the State, NHC, and SAB in collaboration	NHC system enhancements and process updates
Drug Utilization Review (DUR)	the State, NHC	3	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes	the State and NHC, in collaboration	NHC system enhancements and process updates
Utilization Management Plan	the State, NHC	2	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes	the State and NHC, in collaboration	NHC system enhancements and process updates
Retrospective DUR Services	the State, NHC	5	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes	the State and NHC, in collaboration	NHC system enhancements and process updates
Common Requirements	the State, NHC	4	Operations Manager	Assessments	The need to remain current with industry standards; State-requested changes	the State and NHC, in collaboration	Conduct annual risk assessments to identify opportunities for enhancement of security protocols and implement identified enhancements; Implement letter changes by obtaining approval of updated draft letters and replacing outgoing template in our central repository with updated and approved letters



MSQ11.6 – Change Management Plan

Our change management plan included below, has been designed as a simple roadmap for executing a project change in a controlled way. The plan sets the course by which a project change can be executed and how workflows and relationships might be affected. It shows the steps required from identification of need, to submitting a change request, to approval, and delivery. All approved project changes will be memorialized in the Project Plan - documenting the impact on resources (time, people, and budget).





MSQ11.7 - Risk Management Plan

Because NHC is currently working within the Pharmacy Clinical Management Services program, we have a keen understanding of the risks that are intrinsic to it. Should NHC continue in our role, we submit that such risks will be greatly minimized because of this knowledge. Nonetheless, our Risk Management Plan will help identify, evaluate, and plan for possible risks that may arise. It is a blueprint that guides us through the process of identifying, assessing, responding to, and monitoring risk within our purview of the program.

Our sample Risk Management Plan begins on the following page.



NorthStar HealthCare Consulting (NHC) Risk Management Plan

As the Pharmacy Clinical Management Services (PCMS) Vendor, NorthStar HealthCare Consulting (NHC) will assist the State by providing a program which includes Drug Utilization Review (DUR), Utilization Management (UM) services, and assistance in the administration of the State Advisory Board (SAB). NHC understands that risks are inherent in a project of this nature, both positive and negative. Project risks, defined as any uncertainty that may occur and have an impact on project objectives, must be addressed. With NHC as the incumbent vendor, these uncertainties will be minimized because of our extensive experience servicing the contract. Even still, NHC understands the importance of guarding against risks. As such, the following Risk Management Plan entails how NHC will identify, assess, and respond to risks throughout the life of the project.

Define Risks

To ensure risk management remains relevant, NHC will conduct internal weekly status meetings to identify new risks and changes to existing risks. During these meetings, we will work to define identified risks through illustrating their impact on the cost, time, quality, and scope of the project. This includes reviewing constraints, assumptions, critical success factors, and SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis.

Identify Risks

- Highlight and document all predictable risks to project objectives
 - Cause
 - Risk
 - Impact
 - Cost
 - Time
 - Quality
 - Scope
- Maintain a Risk Register

Assess Risks

- Qualitative
 - Risk Occurrence Probability
 - Impact
 - Cost
 - Time
 - Quality

- Scope
- Quantitative
 - Statistical analysis used to identify impact
 - Probability-Impact Matrix
 - SWOT analysis

Risk Response Identification

- Completed during internal weekly status meetings
- Address Risks
 - Avoid / Exploit
 - Eliminate risk cause via process change
 - Exploit risk by eliminating barriers and facilitating the opportunity
 - Mitigate / Enhance
 - Preventative measures to minimize probability
 - Refine processes to optimize outcomes
 - Acceptance
 - Passive
 - Account for impact in projected outcomes
 - Active
 - Create contingency plans for projected outcomes

Monitor and Review Risks

- Determine changes to project risks if any
- Analyze impact of risk response measures
- Communicate outcomes of risk management process to stakeholders



MSQ11.8 - Communications Management

Effective collaboration with the State, program stakeholders, and the project team can only occur with clearly defined communication conventions. Following, we have included a draft Communications Management Plan that will be the framework for communicating the right information to the right project stakeholders at the right time. As a living document, it can be modified – and improved – repeatedly throughout the contract term.



NorthStar HealthCare Consulting

Communications Management Plan

Clinical Management Services

Date : 3/14/2024
Doc. Version : 1.0



Document Control Information

Settings	Value
Document Title:	Communications Management Plan
Project Title:	Clinical Management Services
Document Author:	Emily Baker, MBA. MHA
Project Owner (PO):	Chad Nicholson, PharmD
Project Manager (PM):	DCH TBA
Project Manager (PM):	NHC TBA
Doc. Version:	1.0
Sensitivity:	High
Date:	3/14/2024

Document Approver(s) and Reviewer(s):

Name	Role	Action	Date
State (PM)	Authoritative Approval	Approve/Review	
PI Designee	Authoritative Approval	Approve/Review	
NHC (PM)	Oversight and Implementation	Approve	

Document History:

The Document Author is authorized to make the following types of changes to the document without requiring that the document be re-approved:

- Editorial, formatting, and spelling
- Clarification

To request a change to this document, contact the Document Author or Owner.

Changes to this document are summarized in the following table in reverse chronological order (latest version first).

Revision	Date	Created by	Short Description of Changes

Configuration Management: Document Location

The latest version of this controlled document is stored in MS SharePoint™.



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Communications Management Plan

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1. INTRODUCTION

The following Communications Management Plan ensures all stakeholders involved in the project remain informed of their responsibilities and of project progress throughout the lifecycle of the project. Thorough communication between all interested parties is critical to the success of any project.

The Communications Management Plan outlines the proposed methods of communication that will occur as the project progresses. It lists the meetings that will occur, their frequency, attendees, agendas, and associated documentation. It also gives each stakeholder clear guidance on their involvement and responsibilities regarding communication.

2. COMMUNICATIONS OBJECTIVES

All projects benefit from proactive communication. Communication needs to be:

- **Appropriate:** in the correct form with correct content.
- **Individualized:** for the intended audience.
- **Thorough:** providing all the pertinent information.
- **Succinct:** brief, avoiding redundancies and non-critical information.
- **Prompt:** addressing issues at the proper time.

Communication is an important step in managing stakeholder expectations:

- Follows progress and execution. Reports on the quality of the project.
- Assigns responsibilities.

2.1. Inputs

A significant input of communication planning is the *Stakeholder Matrix*, to identify stakeholders' groupings. To identify the information that should be provided to each specific group, the following list should be utilized:

- *Request For Proposal*
- *Request For Proposal Response*
- *Contract Scope of Work*
- *Project Work Plan*

2.2. Media

Various media forms can be used in the execution of a communication plan. The following are examples of the types of media that will be used in the execution of this plan:

- Email(s)
- Document(s) Word, Excel, PDF, PowerPoint
- Phone call(s)
- Meeting(s)
- Teams Chat
- Banner Messages

The media listed above include, or will be reinforced by:



Clinical Management Services

Communications Management Plan

- Minutes of Meeting (MoM)
- Project Work Plan
- Project Logs
- Project Repository
- Provider Notifications

3. PROJECT MEETINGS

MEETING	Planning Kick-off Meeting
Purpose	NorthStar HealthCare Consulting (NHC) will work closely with the State Pharmacy team members to design, develop, and implement a comprehensive communication plan based upon the RFP response and contractual requirements. Post go-live, all involved parties will work to create an effective communication plan for operations and maintenance.
Location	Defined by the Project Manager (PM) in time.
Frequency	Done once at project level. Date of the meeting to be defined.
Chairperson	Project Manager (PM)
Minutes by	To be defined by the Project Manager (PM).
Attendees	Project Owner (PO) Chad Nicholson Solution Provider (SP) NorthStar HealthCare Consulting Business Manager (BM)(s) Project Manager (PM) (State) Project Manager (PM) (NHC) Pharmacy Benefit Administrator Representative (if applicable) Pharmacy Drug Rebate Services Representative (if applicable) Project Manager Assistant (PMA)(s) (if applicable) Project Support Officer (if applicable) Project Quality Assurance (if applicable - optional) (Functional) Team Leader (optional) Local Information Security Officer (optional) Data Protection Coordinator (optional)
Agenda Items	• Introduce the agenda. • Introduce participants. • Outline the goals, expectations, and activities of the Planning Phase, and discuss the planning timeline. • Introduce the project scope statement. • Invite the Project Owner (PO) to explain the importance of the project for the organization and other beneficiaries. • Discuss the overall project timeline. • Discuss the overall approach of the project. • Discuss the project plans needed for the project. • Discuss risks, constraints, and assumptions. • Discuss or present any project supporting tools. • Allow time for any other business (questions and answers). • Summarize the discussion (decisions, actions, risk). • Communicate next steps.
Distribution list	All participants involved
Media	Meeting minutes written in MS Word or by email.



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Communications Management Plan

MEETING	Executing Kick-off Meeting
Purpose	Official kick-off of the executing phase of the project. After this meeting, the Project Core Team (PCT) is aware of the scope of the project, the project governance structure, the roles, and responsibilities of the team members as well as the project rules.
Location	Defined by the Project Manager (PM) during onboarding.
Frequency	Done once at project level or for each major project phase. Date of the meeting to be defined.
Chairperson	Project Manager (PM)
Minutes by	To be defined by the Project Manager (PM).
Attendees	Project Owner (PO) Chad Nicholson Solution Provider (SP) NorthStar HealthCare Consulting Business Manager (BM)(s) Project Manager (PM) (State) Project Manager (PM) (NHC) Pharmacy Benefit Administrator Representative (if applicable) Pharmacy Drug Rebate Services Representative (if applicable) Project Core Team (PCT) Project Manager Assistant (PMA) (if applicable) Project Support Office (PSO) (if applicable) Other project roles or stakeholders (optional).
Agenda Items	• Introduce the agenda. • Introduce participants. • Present the Project Schedule/Project Work Plan. • Present the Communications Management Plan. • Agree on the conflict resolution process and present the escalation procedure. • Present the Risk Management, Issue Management, Project Change Management processes, and the Quality Assurance and Control activities. • Clarify the expectations for the Project Core Team (PCT). • Agree on the team's ground rules (communication via email, meetings, phone, meeting minutes to be produced, availability, etc.). • Allow time for any other business (questions and answers). • Summarize the discussion (decisions, actions, and risk).
Distribution list	All participants invited.
Media	Meeting minutes written in MS Word or by email.



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Communications Management Plan

MEETING	Project Status Meeting
Purpose	- Discuss project status. - Discuss open actions and check progress. - Discuss new risks or/and issues and define action points. - Discuss and resolve conflicts. - Discuss and review change requests and possibly approve/reject.
Location	Office of Project Manager (PM) (or meeting room to be defined in time).
Frequency	Done once at project level or for each major project phase. Date of the meeting to be defined.
Chairperson	Project Manager (PM) (or delegated person if Project Manager (PM) cannot attend) or Project Manager Assistant (PMA)(s).
Minutes by	Project Manager
Attendees	Project Owner (PO) Chad Nicholson Solution Provider (SP) NorthStar HealthCare Consulting Business Manager (BM)(s) Project Manager (PM) (State) Project Manager (PM) (NHC) Pharmacy Benefit Administrator Representative (if applicable) Pharmacy Drug Rebate Services Representative (if applicable) Project Core Team (PCT) (Functional) Team Leader (optional) Project Manager Assistant (PMA)(s) (If applicable - optional) Project Support Officer (optional) Project Quality Assurance (optional) Business Implementation Group (BIG) (If applicable - optional)
Agenda Items	Progress status review (presentation of periodic Project Status report). - Accomplishments (Current and Planned actions). - Work Completed vs Work Planned. - Milestones status. - Current deliverables status: - Indicators. - Existing change requests (current progress). - New change requests - Next deliverables status: - Existing change requests (Current progress). - New change requests - Risks and Issues: - Major risks, issues and actions monitoring.
Distribution list	All participants invited.
Media	- Project Status Report will be written in MS Word document, and sent by e-mail; and/or - Meeting minutes written in e-mail.



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Communications Management Plan

MEETING	Project Core Team (PCT) Meeting
Purpose	- Obtain commitment on the execution tasks. - Review the accomplished work and estimate time to complete + schedule. - Review risk and issues. - Assess new change requests.
Location	State Offices
Frequency	To be Determined
Chairperson	(Functional) Team Leader
Minutes by	Minutes will be made by the (Functional) Team Leader (or delegated person). Include: Estimated Time to Completion / Schedule updated in Project Work Plan. Other plans / outputs will be updated when needed
Attendees	All Project Core Team (PCT) members working on the project under concern.
Agenda Items	Project status: - Current and next milestones. - Done. - To do. - Estimate Time to Completion review. - Plan reviews. - Indicators review. Process status: - Debriefing on quality assurance aspects. Risk and Issues: - Risks, issues, and actions monitoring. Change management: - Assess new change requests.
Distribution list	(Functional) Team Leader Project Manager (PM) State Project Manager (PM) NHC Project Core Team (PCT) members working on the project under concern
Media	- Updated project plans. - Estimate Time to Complete updated for every task in Project Work Plan. - Updated Change Log with assessment results. - Meeting minutes (if used): written in an email or MS Word document.



Clinical Management Services

Communications Management Plan

MEETING	Project Review Meeting
Purpose	• Management Review meeting. • Meeting discussing about project progress. • Topics to be discussed: major scope changes, major re-baselining of the Project Work Plan (PWP), confirming alignment to portfolio goals and objectives, and business strategies.
Location	NorthStar HealthCare Consulting Offices
Frequency	Weekly (or more frequently, depending on project duration)
Chairperson	Project Manager (PM)
Minutes by	Project Support Officer (or delegated person)
Attendees	Project Manager (PM) NHC Solution Provider (SP) (Functional) Team Leader Project Support Officer Project Manager Assistant (PMA)(s) (if applicable) Project Quality Assurance (optional)
Agenda Items	• Follow-up of mandatory documents. • Major milestones review. • Testing progress. • Risks (budget, resources, others), issues, and actions monitoring. • Project Manager (PM) feedback. • Others: people / resources / contracts.
Distribution list	All participants invited
Media	• Project Progress Report • Meeting minutes in MS Word and sent by e-mail.



Clinical Management Services

Communications Management Plan

MEETING	Stakeholder Meetings
Purpose	- Meeting with Stakeholder(s) about the implementation of the project. - This meeting must also be held when there are: - Approval of RetroDUR Letters. - Program Launch Imminent
Location	No specific location. Defined by Project Owner (PO) in time.
Frequency	At the moment there is an important project milestone reached (collateral approved), that needs approval(s) from the State.
Chairperson	Project Owner (PO) Project Owner (PO) may delegate their responsibility to Project Manager
Minutes by	Business Manager (BM) or to delegated person.
Attendees	Stakeholder Meeting Attendees - NorthStar HealthCare Consulting - State Representative - Pharmacy Department - Pharmacy Benefits Administrator Representative (if applicable) - Pharmacy Drug Rebate Services Representative (if applicable) - Project Manager (PM) - State Pharmacy Association Representative - Medical Association Representative - MMIS Vendor (optional) Project Support Officer (PSO) (optional) Contractor's Project Manager (CPM) (optional)
Agenda Items	Project debriefing: - Implementation of Pharmacy Clinical Management Services Program - DUR Services - Utilization Management - State Advisory Board Administration
Distribution list	All participants invited
Media	- Meeting minutes written in MS Word and sent by e-mail. - Project Progress Report updated



Clinical Management Services

Communications Management Plan

MEETING	Change Control Meeting
Purpose	- Discuss and prioritize change requests or client's inquiries. - Discuss and prioritize maintenance requests. - Prepare for decisions to be made by the Project Steering Committee (PSC) or the Change Control Board (CCB) or Change Advisory Board (CAB).
Location	NorthStar HealthCare Consulting Offices
Frequency	Weekly
Chairperson	Project Manager (PM) NHC
Minutes by	PM
Attendees	Business Manager (BM)(s) Project Manager (PM)(s) Project Manager Assistant (PMA)(s) (If applicable - optional) Project Support Officer (PSO) (optional) Project Quality Manager (PQA) (optional) Business Implementation Group (BIG) (optional)
Agenda	<u>Change request status:</u> 1- Progress update on open changes <u>Current deliverables status:</u> 2- Existing change requests (current progress) 3- New change requests (commitment on prioritization, on budget, on milestones, ...) <u>Next deliverables status:</u> 4- Existing change requests (current progress) 5- New change requests (commitment on prioritization, on budget, on milestones, ...)
Distribution list	All participants invited
Media	- Meeting minutes written in MS Word and sent by e-mail(s). - Change log to be updated.



Clinical Management Services

Communications Management Plan

MEETING	Project-End Review Meeting
Purpose	The objectives for the Project-End Review meeting are: • Review the main project performance and achievements. • Discuss the overall project experience. • Discuss if the objectives have been reached and if not, why. • Discuss problems and challenges faced during project and the way they were addressed. • Discuss Lessons Learned and Best Practices that might be useful for future project.
Location	No specific location. Defined by the Project Manager (PM) in time.
Frequency	No frequency. The meeting is realized once.
Chairperson	Project Manager (PM)
Minutes by	To be defined by Project Manager (PM) in time.
Attendees	Solution Provider (SP) Project Owner (PO) Chad Nicholson Business Manager (BM)(s) Project Manager (PM) User Representatives (Functional) Team Leader Project Core Team (PCT) Project Support Officer (PSO) (if applicable) Project Quality Assurance (PQA) (if applicable) Project Manager Assistant (PMA)(s)
Agenda Items	• Remind the project performance and achievements. • Enumerate project relevant facts (budget and work history, milestones and timing history, technical and methodological approaches used). • Indicate the Lessons learned. • Business continuity plan (operational organization, budgets, and procedures)
Distribution list	All participants invited
Media	Project-End Review MoM, Project-End Report MS Word Document; sent by e-mail.



4. SUMMARY TABLE

Item Name	Audience (summary)	Responsible person	Frequency	Media of Communication
Planning Kick-off Meeting	Project Owner (PO) Business Manager (BM) Solution Provider (SP) Project Manager (PM) Project Core Team (PCT) Business Implementation Group (BIG) User Representatives (URs) Other project roles or stakeholders (optional)	Project Manager (PM)	Once at Project Level.	Meeting and Meeting Minutes
Executing Kick-off Meeting	Project Owner (PO) Business Manager (BM) Project Manager (PM) Project Core Team (PCT) Other project roles or stakeholders (optional).	Project Manager (PM)	Once at Project Level or for each major project phase.	Meeting and Meeting Minutes
Project Status Meeting	Project Owner (PO) Business Manager (BM) Project Manager (PM) (Functional) Team Leader (optional) Other project roles or stakeholders (optional).	Project Manager (PM) or Project Manager (PMA)(s)	Once at Project Level or for each major project phase.	Meeting Minutes and Project Status Report.
Project Core Team (PCT) Meeting	All Project Core Team (PCT) members working on the project.	(Functional) Team Leader	To be determined	Meeting Minutes Updated Change log Updated project plans with actuals Estimate Time to Complete updated.



Clinical Management Services

Communications Management Plan

Item Name	Audience (summary)	Responsible person	Frequency	Media of Communication
Project Review Meeting	Project Manager (PM) Solution Provider (SP) (optional) (Functional) Team Leader Project Support Officer Project Manager Assistant (PMA) (if applicable) Project Quality Assurance (optional)	Project Manager (PM)	Quarterly (or more frequently, depending on project duration).	Meeting Minutes Project Progress Report
Project Steering Committee (PSC) Meeting	Solution Provider (SP) Project Steering Committee (PSC) members	Project Owner (PO) Project Owner (PO)	Monthly or at the moment there is an important project milestone reached, that needs approval(s) from Sponsor(s).	Meeting Minutes Decision log updated
Change Control Meeting	Business Manager (BM) Project Manager (PM) Other project roles or stakeholders (optional).	Project Manager (PM)	Weekly	Meeting Meeting Minutes Change log (updated)
Project-End Review Meeting	Project Owner (PO) Business Manager (BM) Solution Provider (SP) Project Manager (PM) User Representatives (URs) (Functional) Team Leader Project Core Team (PCT) Other project roles or stakeholders (optional).	Project Manager (PM)	Once per project or major project phase.	Meeting Minutes Project-End Report

Date : 3/14/2024

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Doc. Version : 1.0



Item Name	Audience (summary)	Responsible person	Frequency	Media of Communication
Project Review Meeting	Project Manager (PM) Solution Provider (SP) (optional) (Functional) Team Leader Project Support Officer Project Manager Assistant (PMA) (if applicable) Project Quality Assurance (optional)	Project Manager (PM)	Quarterly (or more frequently, depending on project duration).	Meeting Minutes Project Progress Report
Project Steering Committee (PSC) Meeting	Solution Provider (SP) Project Steering Committee (PSC) members	Project Owner (PO) Project Owner (PO)	Monthly or at the moment there is an important project milestone reached, that needs approval(s) from Sponsor(s).	Meeting Minutes Decision log updated
Change Control Meeting	Business Manager (BM) Project Manager (PM) Other project roles or stakeholders (optional).	Project Manager (PM)	Weekly	Meeting Meeting Minutes Change log (updated)
Project-End Review Meeting	Project Owner (PO) Business Manager (BM) Solution Provider (SP) Project Manager (PM) User Representatives (URs) (Functional) Team Leader Project Core Team (PCT) Other project roles or stakeholders (optional).	Project Manager (PM)	Once per project or major project phase.	Meeting Minutes Project-End Report

MSQ11.9 - Integration Plan

Project complications can occur when working with many moving parts that must eventually align. Without proper alignment of these parts, the project can slow down, become less productive, and possibly cease to function. The following Integration Plan was developed to help with identifying, defining, combining, unifying, and coordinating the many processes and activities within the Pharmacy Clinical Management Services scope.

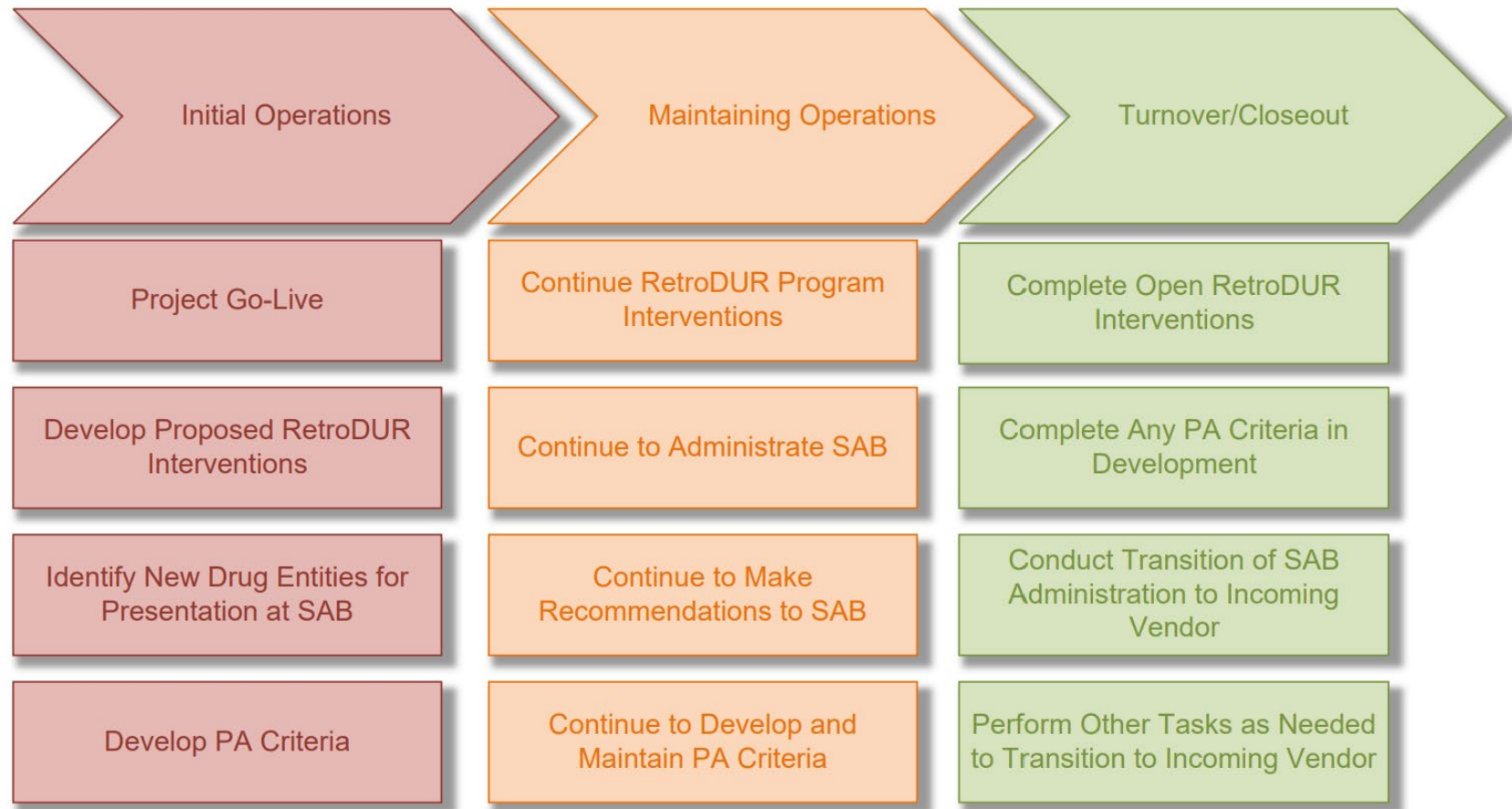




MSQ11.10 - Operations & Maintenance Plan

We have developed the following graphic to represent the composition of our Operations and Maintenance Plan. It is comprised of an interconnected ecosystem of activities that span initial operations, to operations maintenance, to the turnover/closeout period of the contract. Our final plan will include all day-to-day operational activities necessary for the program to function and for the professionals inside it to perform their tasks.

MSQ11.10 – Operations & Maintenance Plan



RetroDUR – Retro Drug Utilization Review
SAB – State Advisory Board
PA – Prior Authorization



MSQ11.11 - Training Plan

As the current Pharmacy Clinical Management vendor, with an experienced team currently serving the State, our professionals are well trained in their field(s) and State program specifics. However, we have developed a training plan to assure that new team members or key stakeholders who may not have the necessary knowledge to support the program will have a defined training path to follow.



MSQ11.11 NorthStar HealthCare Consulting Training Plan

TRAINING PLAN
PHARMACY CLINICAL MANAGEMENT SERVICES PROGRAM

NORTHSTAR HEALTHCARE CONSULTING
4080 MCGINNIS FERRY ROAD, SUITE 1001
ALPHARETTA, GA 30005

APRIL 23, 2024



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INTRODUCTION

This training plan, developed by NorthStar HealthCare Consulting (NHC), is designed to outline the objectives, methodology, and reporting of and for the Pharmacy Clinical Management Services (PCMS) program including State Advisory Board Support (SAB), Utilization Management (UM) Program, Retrospective Drug Utilization Review (RetroDUR) Program and the Document Repository System (DRS).

POINTS OF CONTACT

The point of contact for NHC is listed in the table below. For any questions concerning training development, coordination, or facilitation, please contact the point of contact below.

Role	Name	Contact Number
Training Developer	Matt Reed, CPhT	(678) 672-4200

NEEDS AND SKILLS ANALYSIS

The state has requested that NHC provide a comprehensive overview of the PCMS program including State Advisory Board Support, Utilization Management Program, Retrospective Drug Utilization Review Program and the Document Management System. In order to meet the State's needs, NHC has developed a training plan with the assistance of front-line employees who are involved in these processes each day.

The learning objective for this training are:

- Overview of the PCMS Program;
- Understanding of the RetroDUR letter generation process;
- Interpretation of RetroDUR reporting; and
- Utilization and Operation of the Document Repository System

REQUIREMENTS TRACEABILITY

NHC's Training Program is necessary to provide the state with the understanding of the PCMS program as the state may receive inquiries from stakeholders regarding UM and RetroDUR as well as frequently accessing and utilizing the Document Repository System.

TRAINING METHODOLOGY

In order to accomplish the learning objectives of the NHC Training Program, a thorough training methodology was developed for the appropriate target audience and skill sets. Training will consist of three modules conducted over an instruction time of two hours each and will include various training materials and scenarios focusing on initiation and selection; outcomes and reporting; and accessing and utilizing applications all applicable PCMS domains including State Advisory Board Support, and Utilization Management Program and with particular emphasis on the Retrospective Drug Utilization Review (RetroDUR) Program and the Document Management System



TRAINING ENVIRONMENT

Training will be conducted onsite at the State's office or virtually via Microsoft Teams.

TRAINING REFERENCES

There are several references which will be used throughout the three modules of training. All of these materials will be provided to the attendees on the day of training; however, these materials will also be available should attendees wish to reference them later. The table below provides a list of reference materials, the document and version numbers, formats, and location where the materials will be available.

Reference	Document/Version #	Format	Storage Location
Slide Presentation	State Advisory Board 1.0	PowerPoint Slides	Shared Drive "CM" Folder
Slide Presentation	Utilization Management Program 1.0	PowerPoint Slides	Shared Drive "CM" Folder
Slide Presentation	(RetroDUR) Program 1.0	PowerPoint Slides	Shared Drive "CM" Folder
Slide Presentation	Document Management System 1.0	PowerPoint Slides	Shared Drive "CM" Folder

TRAINING SCHEDULE

NHC's Training Program will span two hours for 3 modules with the following training schedule:

Module 1: SAB/UM

Time	Subject	Location	Materials Required
1:00-1:05	Introductions, distribute references	TBD	N/A
1:05-1:30	Overview	TBD	N/A
1:30-1:55	SAB Binder	TBD	N/A
1:55-2:05	Break	TBD	N/A
2:05-2:30	UM Outcomes	TBD	N/A
2:30-3:00	Reporting	TBD	N/A



Module 2: RetroDUR

Time	Subject	Location	Materials Required
1:00-1:05	Introductions, distribute references	TBD	N/A
1:05-2:00	Initiation and Case Selection	TBD	N/A
2:00-2:05	Break	TBD	N/A
2:05-2:30	Intervention	TBD	N/A
2:30-3:00	Outcome Reporting	TBD	N/A

Module 3: Document Repository System

Time	Subject	Location	Materials Required
1:00-1:05	Introductions, distribute references	TBD	DRS User Manual
1:05-1:35	Access	TBD	N/A
1:35-2:05	Functionality		
2:05-2:15	Break	TBD	N/A
2:15-3:00	Updates and Maintenance	TBD	N/A

CLIENT ACCEPTANCE

Approved by the Project Sponsor:

<Project Sponsor>

<Project Sponsor Title>

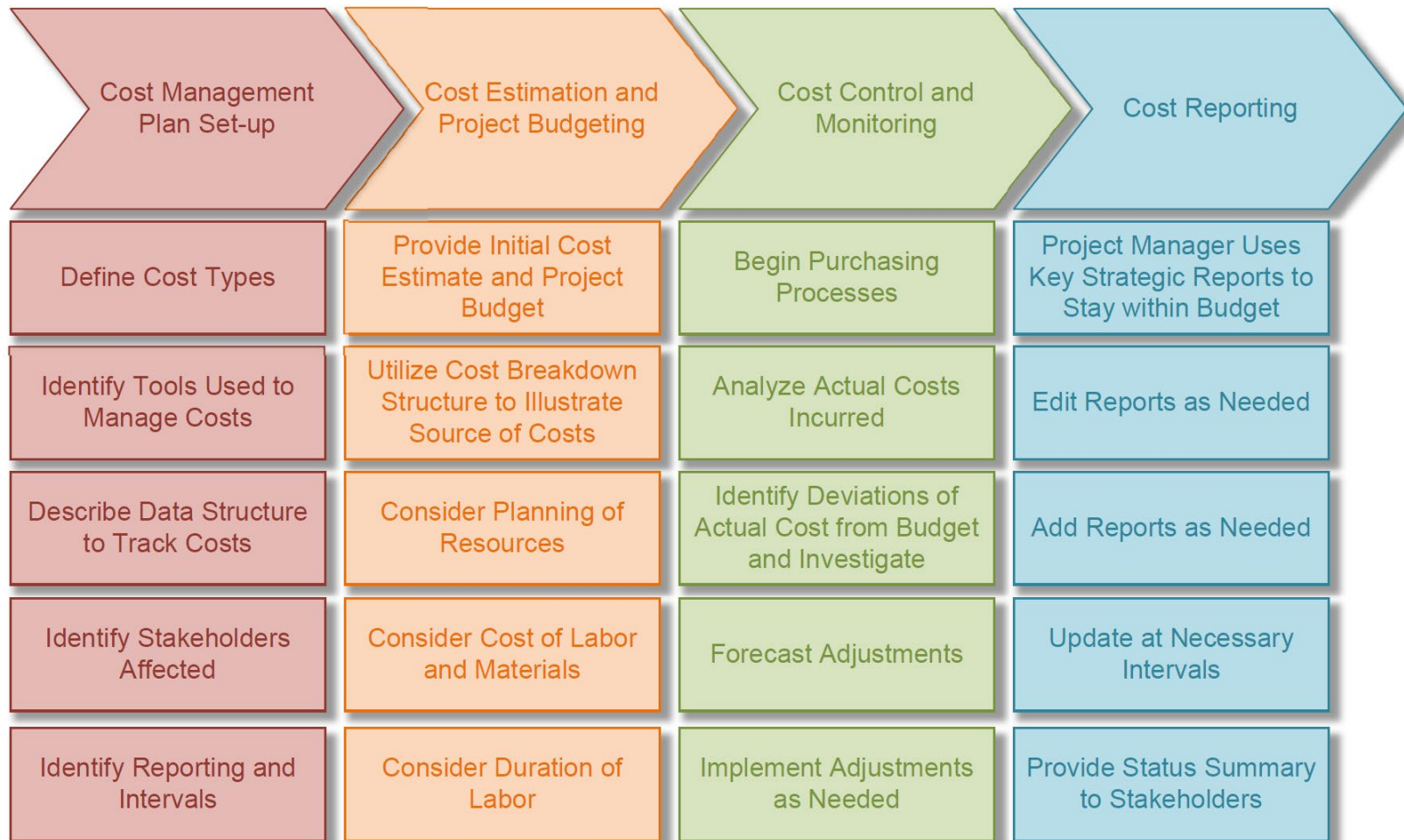
Date: _____



MSQ11.12 - Cost Management Plan

NHC takes our fiduciary responsibilities very seriously and has developed a framework for a program Cost Management Plan that encompasses cost management set-up, estimation and project budgeting, control, and monitoring, as well as reporting to the State. We hope to work with the State to develop a comprehensive plan that meets all state requirements for tracking, monitoring, and controlling costs.

MSQ11.12 - Cost Management Plan



MSQ11.13 – Stakeholder Management Plan

All projects have stakeholders and at the very least, they expect to receive the vendor's deliverables at a certain time, cost, and level of quality. As the current PFWA provider, NHC is intimately aware of who the program stakeholders are, as well as their expectations. We will work to document a comprehensive Stakeholder Management Plan, pursuant to the State's requirements, that specifically identifies all stakeholders, and plans for and manages stakeholder engagement.





12. Bookmark Title: MSQ12 – Role Understanding

Narrative description is limited to five (5) pages.

Describe your understanding of your role and responsibilities in the project, your relationship to the other resources and stakeholders involved, including the State's Project Management Office (PMO), or equivalent office, PBA vendor, and Fraud Waste and Abuse vendor. Describe how you will collaborate and provide leadership among the various resources and stakeholders and provide examples of past successes in a similar environment.

Refer to Attachment C: Common Scope Requirements and Security Standards.

NorthStar HealthCare Consulting (NHC) has successfully provided Pharmacy Clinical Management Services (PCMS) and Pharmacy Fraud, Waste, and Abuse Services (PFWA) to the State of Georgia for 18 years. Our staff has over 100 years of collective service to the State and by extension possesses significant historical and institutional knowledge of its program. As the incumbent for these services, we are intimately familiar with the roles and responsibilities associated with this scope of work. Over the course of providing these services, the departments at NHC have collaborated often with both internal and external stakeholders, providing support and robust solutions leveraging a broad range of experience. We recognize that successful programs require ongoing collaboration among interested parties while also recognizing that ultimately, we are here to serve the State's interests.

It should be highlighted that NHC's approach with our clients is based on a collaborative service model. We are not ones to stand on titles or rigid, narrow interpretations of scopes of work. Indeed, NHC very much enjoys assisting states in developing responsive, creative solutions quickly without the delay seen in larger organizations. NHC is here to execute with precision and effectiveness.

NHC's Internal Collaboration

Internal collaboration between NHC's PCMS and PFWA departments has laid the foundation for a unique perspective in supporting the State's goals and objectives. On a weekly basis, interdepartmental meetings are held at NHC wherein representatives from each department discuss the state of the State and provide feedback and suggested initiatives to address areas of need. Indeed, insights from one department can initiate an intervention in the other. For example, based on information elucidated during pharmacy audits, the PFWA department identified an area of potential exposure with respect to the prescriptions for hemophilia factor products. After an interdepartmental analysis, the PCMS department brought forth a recommendation to the client that would decrease the opportunity for waste resulting from a lack of visibility into the use and administration of hemophilia factor products for both prophylactic and breakthrough bleeding. The result was a policy change that afforded the PFWA department and the State visibility into the use case for the prescriptions, ensuring that the recipients of the



medications were given the proper dosages at the appropriate times, and improving the allocation of valuable resources.

State, Vendor, and Stakeholder Collaboration

While working together towards the realization of the State's goals, NHC has developed substantive relationships with the Georgia Department of Community Health (DCH). These working relationships have created a program that is tailored specifically to meet the needs of the State and its members. We pride ourselves on the partnership we have developed when DCH seeks creative solutions to complex problems. Given NHC's longevity in supporting the State, we serve as a reliable resource for program history and institutional knowledge, if needed. We understand it is our responsibility to support the State's best interests in serving Medicaid recipients and providers through the effective implementation and operation of a comprehensive PCMS program. Because we are privately held, NHC is not beholden to corporate oversight that may result in conflicting priorities with respect to the best interests of the State. While NHC has a rich history of positive working relationships with various stakeholders over numerous projects on behalf of our clients, NHC has no conflicts of interest that would impede our ability to provide outstanding services to the State. NHC maintains a professional and collaborative relationship with Georgia's current Pharmacy Benefits Administrator (PBA) Vendor and would continue endeavoring to foster such a relationship, regardless of the vendor. For instance, NHC frequently collaborates with the PBA Vendor on Utilization Management (UM) initiatives such as prior authorizations. Likewise, NHC maintains a supportive relationship with the current Pharmacy Drug Rebate Services (PDRS) Vendor and provides an additional perspective when requested by the State. Most recently, NHC has assisted the State with value-based contracting. In summation, NHC takes a highly collaborative approach when interacting with all vendors to provide excellent service, prioritizing the needs of the State and the program stakeholders.

As a privately held company, NHC is not beholden to corporate oversight that can create conflicting priorities. We have no conflicts to impede our ability to keep best of interest of the State and its members front and center.

With respect to collaboration with stakeholders, NHC pledges to work closely, as we have done in the past, with healthcare providers, payers, and the PBA Vendor for all things DCH. Additionally, NHC currently meets with the State's existing vendors and will continue these efforts to provide recommendations for improving processes and reducing vulnerabilities. As a result of this collaboration, we will coordinate efforts with other vendors to generate comprehensive reports on and responses to trends, anomalies, and potential issues. Further, NHC will serve in a leadership capacity leveraging our institutional knowledge resulting from the longevity of our relationship with the State.



Understanding the Engagement

An effective PCMS approach is the backbone of a Medicaid Pharmacy program and affects every aspect of it. NHC has worked extensively with Georgia to provide high quality products for their implementation. We have thoroughly reviewed the requirements of this engagement and stand ready to continue to provide the same level of service to the State. We affirm it is our responsibility to not only provide clinical consultative services, but to also provide the associated *deliverables*. Additionally, we understand we are to serve as the primary point of contact at the direction of the State for many of the requirements under this engagement.

Under this engagement, NHC will provide UM criteria in two formats: as a decision tree and a bulleted summary for posting to the State's website. NHC also provides guidance and recommendations for Step Edits (SE), Quantity Level Limits (QLL), Provider Administered Drug List (PADL), and Preferred Drug List (PDL) status. All these efforts function to provide not only appropriate clinical care but also cost management. NHC will continue to provide administrative management of the State Advisory Board (SAB) in the furtherance of the State's goals for its pharmacy benefits program. Inclusive in this service is the provision and maintenance of meeting minutes, facilitation of SAB membership and attendance, disclosure of conflicts of interest, plus preparation of materials for presentation.

"I've been working with DCH for more than two decades now and served as Chair of the DURB for 7 years. NorthStar has always worked incredibly hard to enhance the Board's ability to make sound PDL recommendations to DCH. I don't know how the Medicaid pharmacy program, including the DURB, could manage without [NHC]. While the healthcare landscape and DCH has evolved during these past 22 years, NorthStar has been a constant force ensuring objectivity, compassion, quality, consistency, and efficiency. Thank you for all you do to support providing excellent pharmacy care to the citizens of GA."

Matthew Perri III, BS Pharm, PhD, RPh

A robust Retrospective Drug Utilization Review (RetroDUR) program is another component to the Medicaid pharmacy benefits program that NHC will administer for the State. This program is customized to meet the unique needs of the member population and can be tailored to adhere to state-specific concerns. Further, an integral component of RetroDUR is the performance of data analytics as well as the implementation of the actual intervention and post-outcome reporting.

NHC supports our clients in the preparation of annual reports to CMS. Additionally, NHC works closely with the State providing data analysis and reporting, as well as collaboration with program stakeholders. To this end, NHC conducts in-depth analysis of pharmacy claims data to generate comprehensive reports on trends, anomalies, and



potential issues. This allows NHC to offer actionable insights to healthcare organizations and agencies for decision-making. NHC interfaces with healthcare providers, payers, and pharmacy benefit administrators to share findings and collaborate on preventive measures. NHC is always available to provide recommendations for improving processes and reducing vulnerabilities in the Pharmacy program.

Finally, although NHC enjoys incumbency status, we will avail ourselves to the State's Project Management Office (PMO), or equivalent, as needed for successful implementation of the PCMS program.